Scalare Advisors

Supply Chain Security Research

Critical Dose

America's Pharmaceutical Reckoning

A drug-by-drug analysis of eleven widely used generic medicines — from precursor chemicals through active ingredients to finished dose — and of the federal policy framework that has not kept pace with the risk.

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ABOUT THE RESEARCH

This report's supply chain mapping, source aggregation, and dependency tracing were conducted using Integrity™, a geopolitical intelligence platform developed by R.A. Levinson & Associates.

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CONTENTS

FIGURES

TABLES

I Executive Summary

This report examines the supply chains of 11 widely-used, low margin generic drugs, chosen to span the range of American pharmaceutical exposure: the most prescribed antibiotic, the most common pain reliever, the first-line treatment for diabetes, the anticoagulant used in nearly every cardiac surgery and dialysis session, the chemotherapy agents used to treat lung and ovarian cancer, and the antibiotic the federal government reached for when anthrax-laced letters arrived at Senate offices in the fall of 2001.

These are not exotic compounds; they are the workhorses of American medicine. And across every one of them — including several high-volume drugs that are used daily by millions of Americans — the upstream chemistry runs through China. This report finds that Chinese dominance of U.S. pharmaceutical supply chains is not a problem concentrated in one drug or one therapeutic category. It is a structural vulnerability, spanning antibiotics, analgesics, anticoagulants, diabetes medications, oncology drugs, and biodefense stockpiles. There are no readily available substitutes, and disruptions in supply chains would impact hundreds of thousands of Americans' health care.

China represents the single largest source of active ingredients in the antibiotics the United States imports, supplying more than 70 percent as of 2024, and the three most widely prescribed outpatient antibiotic classes are all China-dependent. If access were to be simultaneously disrupted, the United States would lose the active ingredients and production capacity needed for its most commonly prescribed outpatient antibiotics.

> *China represents the single largest source of active ingredients in the antibiotics the United States imports, supplying more than 70 percent as of 2024. The three most widely prescribed outpatient antibiotic classes are all China-dependent.*

One striking example of this vulnerability, from the 11 that we analyzed below: Metformin – one of the most widely prescribed medications in the United States and the first-line treatment for the large majority of the 40 million Americans living with diabetes[1] – has no domestic active pharmaceutical ingredients (API) producer at scale,[2] and falls entirely outside every federal resilience program.

This dependence is the product of decades of Chinese state subsidies, lax environmental enforcement, and state-supported pricing that made offshoring progressively more attractive to U.S. firms, and progressively harder to reverse.[3] American pharmaceutical manufacturers made economic-driven decisions to close domestic plants, consolidate upstream chemistry in China, and optimize for cost over resilience. No individual company had a rational incentive to pay the premium for domestic or allied-nation sourcing while competitors sourced from China at lower prices, and the U.S. Federal regulatory framework generally did not require them to do so. Despite recent federal initiatives to encourage domestic manufacturing, improve supply-chain visibility and establish a strategic reserve of selected active pharmaceutical ingredients, federal law still does not require manufacturers of essential medicines to maintain minimum domestic capacity or a geographically independent backup source. Manufacturers must notify the FDA of certain discontinuances and manufacturing interruptions, and publicly traded companies must disclose material business risks to investors. But manufacturers are not generally required to report merely because a critical drug has become dependent on a single foreign source, and the identity and concentration of those sources are not systematically disclosed to the public.[4] In a market environment that places little or no premium on supply security, manufacturers continue to face powerful incentives to source from the lowest-cost supplier while the concentration risk remains invisible to the public.

As this report documents, correcting this market failure is increasingly important because of the sheer breadth of Americans' exposure to China for vital and widely-used medicines for which there are no available substitutes at scale. Doing so will require a coordinated response from Congress, the Executive Branch, allied nations, and the pharmaceutical industry itself to alter the underlying incentive structures.

In particular, both Congress and the Executive Branch would do well to pay more attention to the supply chain vulnerabilities of widely-used outpatient drugs, not simply the acute-care hospital drugs that have been the focus of resiliency programs. There is a compelling economic logic to making the investments necessary to shift the incentive structures that have driven rational but risky outsourcing of pharmaceutical supply chains; and there is an equally compelling political logic to ensuring that Americans do not face a possible catastrophic disruption of drugs that are commonplace and essential, but that today depend on shockingly fragile networks of supply that are largely controlled by China.

Jurisdiction over the problem of resiliency is currently fragmented across the Food and Drug Administration (FDA), Department of Defense (DOD), Health and Human Services (HHS), Commerce, and the United States Trade Representative (USTR). The result is a patchwork of underfunded programs and unimplemented authorities.[5] There are critical medicines that fall entirely outside every federal pharmaceutical resilience program, and shortages across drug categories are already occurring – suggesting an underlying vulnerability even without any effort by an adversarial power or competitor such as China.[6] Considering China's history of leveraging supply chain dominance, most notably in rare earth minerals, America's government should be motivated to protect the security of the US' drug manufacturing pipeline.

There is a growing body of research that is drawing attention to these pharmaceutical vulnerabilities. A June 2026 report by the Council on Foreign Relations (CFR), for example, provides a useful "archetypal" framework for understanding the nature of risks to U.S. pharmaceutical supply chains.[7] Focusing on the first of the archetypes described in the CFR study – the upstream supply chain concentration and fragility – this report offers a drug-by-drug analysis from precursor chemical suppliers to API producers to finished-dose manufacturers.

In addition to recommendations for U.S. government actors, this report proposes recommendations to the pharmaceutical industry itself. Getting the incentive structure right requires all three principal players to move: the government must set the rules, industry must be held accountable, and allied nations must be brought into a coordinated response that no single country can mount alone.

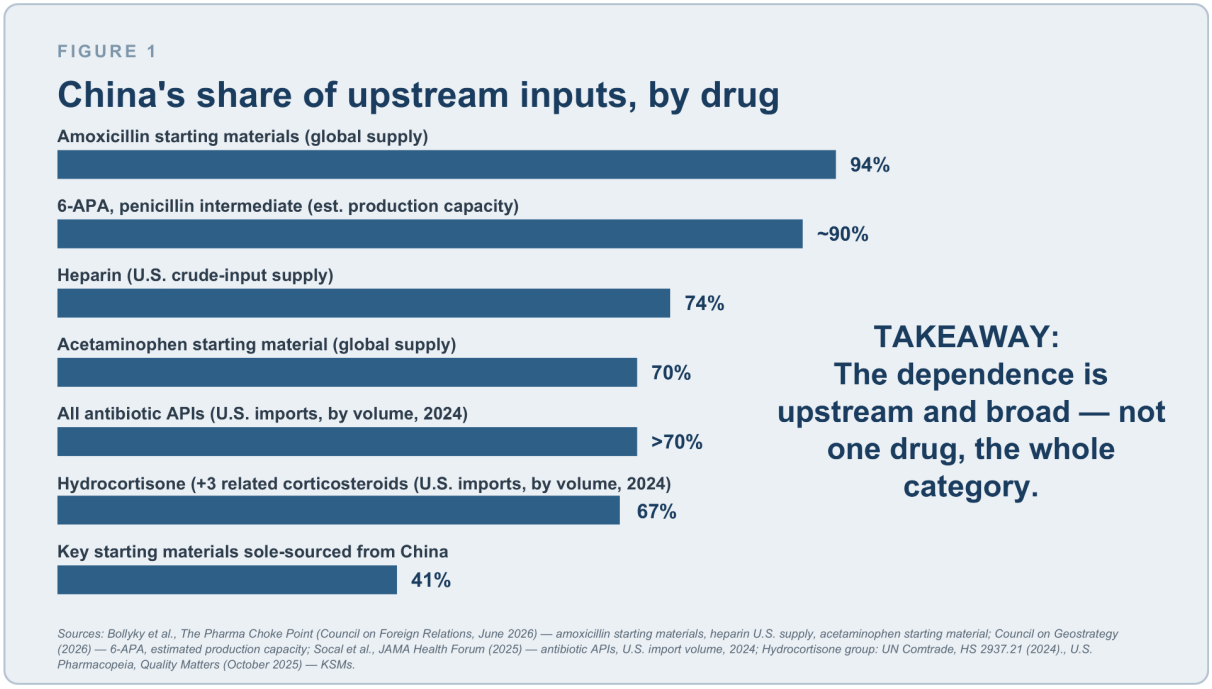


FIGURE 1 China's share of upstream inputs, by drug

Section II

II

Introduction: A Dangerous Dependence

A dependence that sits several tiers upstream of the finished medicine — opaque even to the firms inside the supply chain, and invisible to the patients at the end of it.

In 2007 and 2008, contaminated heparin from China was associated with at least 149 deaths in the United States.[8] The contaminant was traced to a single facility in China. Chinese officials denied the contamination originated in China and refused FDA access to conduct a criminal investigation.[9] In the end, no one was held accountable. Of the three U.S.-based plants that produce heparin, two – one in Wisconsin, one in Ohio – are now controlled by Chinese owners: the Wisconsin plant (Scientific Protein Laboratories, Waunakee) is wholly owned by Shenzhen Hepalink, and the Ohio plant (Smithfield Bioscience, Cincinnati) belongs to Smithfield Foods, whose majority shareholder is Hong Kong-listed WH Group.[10] The remaining U.S. suppliers predominantly rely on Chinese-sourced crude heparin for the active ingredient.[11] Heparin sodium injection has been listed on FDA's drug shortage database continuously since November, 2017; ASHP reports Pfizer heparin injection on shortage due to increased demand and manufacturing delays – with four vial presentations temporarily discontinued.[12] Not only is the supply base not diversifying, but it is contracting, leaving the roughly 550,000 Americans, many of whom depend on heparin for dialysis with no equivalent substitute.[13]

> *In 2007 and 2008, contaminated heparin from China was associated with at least 149 deaths in the United States.*

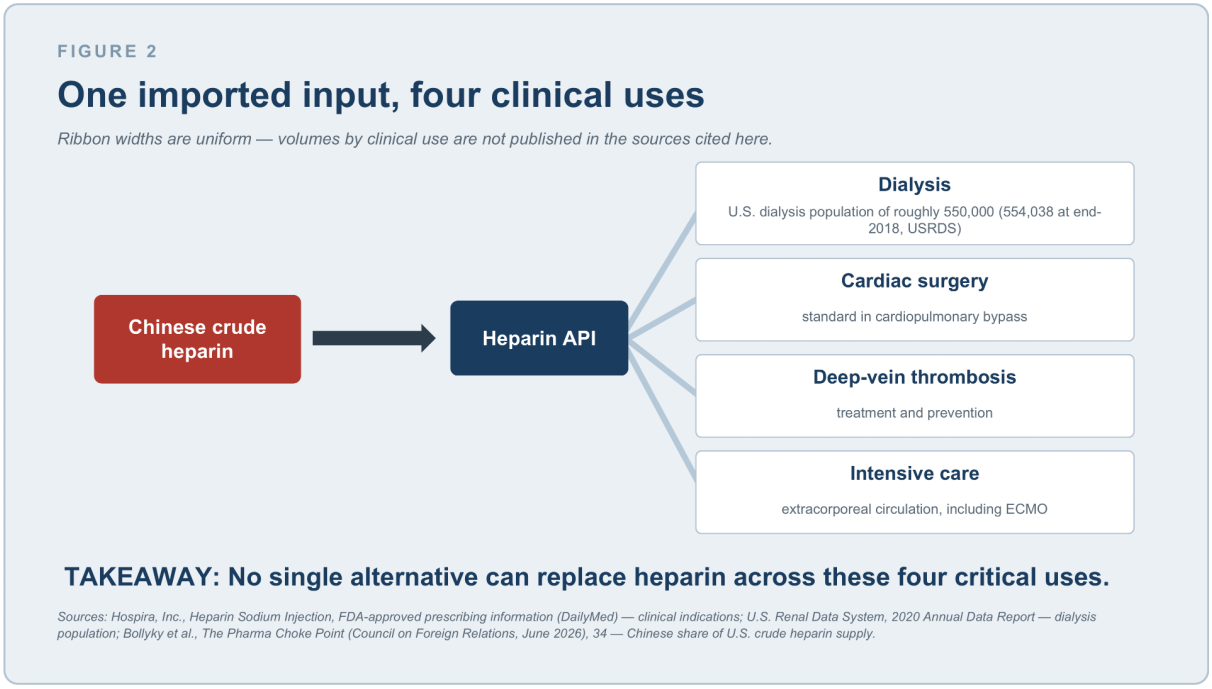


FIGURE 2 One imported input, four clinical uses

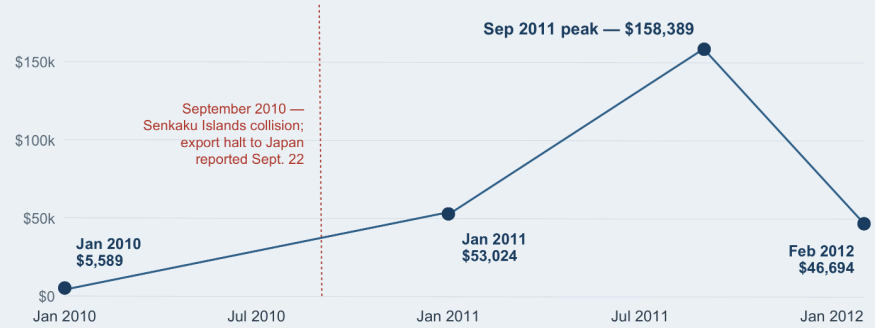
Heparin is one of the most visible symptoms of a structural problem that runs across the entire U.S. pharmaceutical supply chain. China dominates the production of APIs for dozens of medications that Americans depend on daily – from the most commonly prescribed antibiotics to drugs used in cancer treatment, cardiac surgery, and diabetes management. These are not exotic compounds. They are the workhorses of American medicine, and their upstream chemistry increasingly runs through China. If left unchecked, Chinese companies could keep advancing to the point of monopolistic control of key pharmaceutical supply chains. In some cases, they already have.

China's dominance of these upstream chemicals does not pose merely a passive risk. Beijing has demonstrated on multiple occasions that it is prepared to use supply chain leverage as a coercive instrument. It reportedly and temporarily restricted rare earth exports to Japan during a 2010 territorial dispute.[14] It imposed informal trade barriers on Australian barley, wine, and coal after Canberra called for a COVID-19 origins investigation.[15] It curtailed exports to Lithuania after Vilnius opened a Taiwanese representative office.[16] China's dominance of pharmaceutical inputs gives it similar leverage over the United States, and one that directly impacts the health and welfare of the American people.

FIGURE 3

What a quiet squeeze looks like

Average customs value per metric ton of U.S. rare earth imports from China, January 2010 – February 2012. Nothing was ever formally announced.



Line connects the four monthly benchmarks documented in CRS R42510; the full monthly series is CRS Figure 8 (USITC Dataweb). February 2012 prices remained roughly 11 times their February 2010 level.

TAKEAWAY: China's rare earths exports coercion show how easily and quickly Beijing can weaponize dependencies.

Sources: price series — Wayne M. Morrison and Rachel Tang, China's Rare Earth Industry and Export Regime, CRS Report R42510 (April 30, 2012), Figure 8, from USITC Dataweb customs data; episode and chronology — U.S.-China Economic and Security Review Commission, 2025 Annual Report to Congress, chap. 9, 477, and CRS R42510. China never officially stated that the 2010 halt was an export ban.

FIGURE 3 What a quiet squeeze looks like

The United States is dependent on China for APIs, key starting materials (KSMs), and precursor chemicals across a range of drugs central to American healthcare. These dependencies typically sit several tiers away from finished products, making the connections, and the dependencies, opaque even to organizations operating inside the pharmaceutical ecosystem – let alone to the policymakers who would need to act on them or the public whose well-being stands at risk.

Pharmaceutical supply chains have evolved over several decades to prioritize efficiency and cost optimization rather than transparency or resilience. As a result, upstream dependencies on APIs, precursors, and raw materials are often opaque, multi-layered, and, in recent years, increasingly geographically concentrated in China. While finished medicines may be formulated or packaged in the United States or allied countries, upstream inputs frequently originate from Chinese suppliers. Even when final manufacturing occurs elsewhere, Chinese firms often supply the chemical building blocks required by intermediate producers. Regulatory authorities themselves have acknowledged limited visibility into these upstream dependencies.[17]

Sources · [18], [19], [20], [21], [22], [23]

While these figures vary by methodology, the directional risk is clear: concentrated upstream dependencies create systemic vulnerability. Impacts to the supply chain for pharmaceuticals are directly tied to patient outcomes. Disruptions in upstream inputs can cascade rapidly into shortages, rationing, delayed procedures, and regulatory intervention. Export controls, regional instability, public health emergencies, or geopolitical conflict could translate into material risk within weeks.

This report analyzes that dependency in detail. It examines how China achieved dominance over these key aspects of the pharmaceutical supply chain, why alternatives – including shifting supply chains to India, reshoring, or relying on allied supply chains – are more constrained than they appear, and what the United States can do about it to shore up pharmaceutical supply chain security.

The analysis draws on a survey of 11 drugs spanning the range of American pharmaceutical exposure: from the most widely used generic analgesics and antibiotics to those that keep dialysis patients alive and cancer patients in treatment. The picture that emerges is of a severe structural vulnerability that is getting worse, and of a federal policy framework that has not kept pace with the risk and with the market failures that sustain it.

The report concludes by providing specific recommendations that Congress, the Executive branch, and industry can take to address these challenges and begin to alter the incentive structures of key players in this space.

Section III

III

How Did We Get Here?

Four decades of subsidies, lax environmental enforcement, and unbeatable prices that made offshoring rational for every individual firm and dangerous for the country.

The story of China's dominance over today's global pharmaceutical supply chain rose in tandem with the country's economic journey over the last 40 years. It began in the 1980s and 1990s, when Chinese leaders, guiding a nation that was emerging from decades of internal political upheavals, focused on rebuilding its economy by opening up to foreign investment. Beijing presided over a young and growing population that was eager to move to cities and willing to work. The government offered investors massive subsidies and incentives, little to no environmental regulations, and an authoritarian system that ensured a pliant workforce. Over 160 million migrant workers would enter the labor market, setting the basic conditions for China to emerge as a manufacturing powerhouse.[24]

Over the past two decades, China has moved from the lower end of the pharmaceutical value chain—focused largely on generic compounds and APIs—to a dominant position in generic API production and a rapidly expanding role in higher-value biopharmaceutical innovation.[25]

As China gradually scaled up the industrial and manufacturing value chain over the next two decades, Beijing became much more strategic in prioritizing areas that it felt were most important to both China's continued economic development and global influence. Chinese leaders had their eyes on the pharmaceutical industry. Until the mid-1990s, roughly 90 percent of APIs were produced in the West and Japan.[26] In 2008, Chinese officials designated "pharmaceutical production"a "high-value-added industry", supporting the industry through government subsidies, tax rebates, and export incentives for Chinese companies to produce more at lower prices and then selling them to the world.[27] By 2017, an estimated 40 percent of all APIs came from China.[28]

Beijing continued to press its ambitious agenda. In 2015, the Chinese government released "Made in China 2025" – essentially the Chinese leadership's public statement outlining how it would make the country more innovative, competitive, a bigger manufacturing powerhouse when it comes to the most strategic and advanced sectors and, most critically, more self-reliant and resilient from external pressure and challenges.[29] It focused on technology, drones, advanced rail, electric vehicles, and biopharma as well as next generation medical equipment. It was not a secret plan but one that was dissected, analyzed, and scrutinized by policymakers, industry watchers, and market analysts.[30]

As China pursued its industrial policies, it aimed to win by offering unbeatable prices. India, a global drug manufacturing powerhouse, sources roughly 70 percent of its imported APIs from China.[31] The raw materials needed to produce APIs – the key starting materials – make up roughly two-thirds of production costs, and they are cheaper to make in China. By one industry estimate, it is 20 percent cheaper to produce a drug in China than it is in India.[32] Lax environmental standards are also a form of subsidy. European manufacturers have noted that to produce locally a facility would need more expensive and sophisticated techniques and anti-pollution technology to meet regulatory requirements.[33]

And that rigged landscape led American and other Western companies, one-by-one, to make individual decisions that made sense for their business priorities to keep prices competitive and focus their advantages and efficiencies at the tail end of drug production. But in the long term these cost-saving measures have become detrimental to the national, economic, and health security of the United States and its partners around the world.

In some cases, companies simply closed facilities in the United States. Bristol-Myers Squibb operated the last U.S. plant making penicillin by fermentation, in East Syracuse, New York.[34] It announced the closure in July 2004, and production ceased by 2006.[35] China now makes roughly 90 percent of the world's 6-APA, the core penicillin building block; only seven plants make it worldwide, five of them are in China.[36] No U.S. plant makes it from scratch anymore.[37] In its SEC filings, the company described the closure only as ending "bulk manufacturing" – never as the end of American penicillin production.[38]

In other cases, companies stopped making additional investments at plants that no longer made economic sense, and simply let them fail. Pfizer bought a working American sterile-injectables factory in Kansas and conditions deteriorated; the company was cited by the FDA for mold in a Form 483[39] and received a warning letter for other repeat violations – all while shortages of those drugs hit American hospitals. Pfizer has filed FDA discontinuation notices for its injectable azithromycin products (September 2025 and January 2026) removing one of the few remaining suppliers from a market that has sat on the shortage list throughout.[40]

Pfizer is the sole supplier of Bicillin L-A, and FDA records identify no approved generic equivalent. Bicillin L-A contains benzathine penicillin G; according to CDC, penicillin G is the only known effective antimicrobial for treating fetal infection and preventing congenital syphilis. The U.S. market therefore depends on a single supplier for a medicine without a clinically equivalent substitute for treating syphilis during pregnancy.[41]

Indeed, in a May 2026 analysis of China's evolving industrial policy, the Rhodium Group concluded that Beijing "is actively reinforcing its control over value chains using regulations and economic coercion to pre-empt de-risking and lock in its dominance across critical supply chains."[42] The report found that the number of products for which China supplied for more than half of global exports by volume increased by roughly 64% between 2021 and 2024[43], from 192 to 315. The 15th Five-Year Plan, issued in March 2026, names biomanufacturing as one of the sectors targeted for "decisive breakthroughs" – meaning Beijing intends to move further up, not retreat from, the pharmaceutical value chain even as American supply diversification stalls.[44]

In short, the United States and its partners are in a vulnerable position today because China has, over decades, pursued policies designed to advantage its own industries, and create the infrastructure, regulatory framework, incentives, and political environment to attract foreign drug makers to produce in China. Beijing has forced the transfer of technology and pharmaceutical innovation (with the promise of access to the Chinese market) to make its homegrown champions more competitive globally, and then flooded the world market at a scale where the business case only favored Chinese supply chain and industry.[45] Most of all, the United States and our partners failed to respond with actions that could counter China's industrial strategy as it was being implemented.

FIGURE 4

How China built pharmaceutical dominance

1990s	Until the mid-1990s, roughly 90 percent of active pharmaceutical ingredients (APIs) were reportedly made in the West and Japan.
2004–06	Bristol-Myers Squibb closes the last U.S. plant making penicillin by fermentation, in East Syracuse, NY.
2008	Chinese officials declare pharmaceutical production a "high-value-added" industry, guaranteeing subsidies, tax rebates, and export incentives.
2015	Beijing releases "Made in China 2025," naming biopharma among the sectors targeted for self-reliance.
2017	China's share of global API production reaches an estimated 40 percent.
2026	Rhodium Group finds the number of products where China supplies more than half of global exports, by volume, nearly doubled since 2021 — from 192 to 315.

Sources: Nikkei Asia (April 5, 2022), reporting a 2017 U.K. MHRA estimate and pre-mid-1990s API shares; USCC, 2019 Annual Report to Congress, ch. 3 §3 (2008 designation); PRC State Council, "Made in China 2025" (May 19, 2015; CSET translation t0432); Bristol-Myers Squibb Form 10-Q (Q2 2004); Rhodium Group, "China's Next-Generation Industrial Policy" (May 11, 2026).

FIGURE 4 How China built pharmaceutical dominance

Section IV

IV

An Inventory of Exposure

Eleven drugs traced from precursor chemical to finished dose: acetaminophen, azithromycin, heparin, metformin, amoxicillin, ciprofloxacin, cisplatin and carboplatin, dexamethasone and hydrocortisone, losartan, ibuprofen.

This section examines several cases in depth, chosen to span the range of American pharmaceutical exposure: drugs that are prescribed to tens of millions of people every year; drugs with no clinical substitute for patients who need them; drugs with documented histories of Chinese contamination or supply failure; and drugs whose supply chain geography reveals systemic weaknesses in how the United States has designed its pharmaceutical safety net. Although each case is different, taken together these cases demonstrate the risks that permeate the supply chain, the limitations of what might seem to be "obvious" alternatives, and the policy gaps that leave commonly prescribed medications in America at risk.

Flu and Pain: Acetaminophen PARTIAL DOMESTIC API

If there is an ingredient that can be found in just about every American medicine cabinet in homes across the country, it would be acetaminophen. Whether for cold, flu, or alleviating pain, approximately 52 million Americans – just about a quarter of all U.S. adults – use an acetaminophen-containing medicine every week.[46] It is found in more than 600 over-the-counter and prescription products, including familiar brands such as Tylenol, NyQuil, Excedrin, Percocet, and Vicodin.[47] Acetaminophen is the most common drug ingredient in the United States, and the acetaminophen–hydrocodone combination alone accounts for roughly 19 million prescriptions annually.[48]

TABLE 1 At a glance: eleven drugs

DRUG	DOMESTIC API	KEY VULNERABILITY	FDA STATUS
Metformin	NO None identified	India 38-46% of global API; China ~81% of the DCD precursor	Not on FDA shortage list; not on the FDA Essential Medicines List
Heparin	PARTIAL Pfizer (Franklin, OH); SPL and Smithfield Chinese-controlled	~74% of U.S. crude supply from China (80% globally)	Active shortage (2017-)
Amoxicillin	NO None since 2006	China ~90% of global 6-APA input	2022 national shortage
Acetaminophen	PARTIAL Par Health/SpecGx (US)	~70% of U.S. imports from China	Not on FDA shortage list; on EO 13944 Essential Medicines List
Azithromycin	NO None identified	CSPC Ouyi holds US registrations for both the azithromycin ingredient and its erythromycin-derived intermediate	Not disclosed
Ciprofloxacin	NO None identified	India sources almost all of its ciprofloxacin API from China	No current shortage, on the EO 13944 list as a biological-threat countermeasure
Cisplatin / Carboplatin	NO None identified	Single Indian plant made >50% of U.S. supply	Cisplatin resolved Jun 2024; carboplatin listed continuously since Apr 2023
Dexamethasone	NO None identified	~80% of diosgenin precursor China-sourced	Continuous since 2019
Hydrocortisone	PARTIAL Pfizer (Kalamazoo, MI)	~67% of U.S. imports (tariff heading incl. related corticosteroids) China-sourced, 2024	Injection shortage Mar 2023 – Feb 2026, resolved
Ibuprofen	YES BASF (Bishop, TX)	Domestic plant since 1992, not federally supported	Resolved (2022-23)
Losartan	NO No US API manufacturer; EU output limited to vertically integrated generic makers	NDMA contamination undetected 2011-2018	Not FDA-listed

Full sourcing for each figure appears in the corresponding case study below.

Every acetaminophen tablet begins with para-aminophenol (PAP), a precursor chemical produced overwhelmingly in China.[49] Roughly 70 percent of America's acetaminophen imports originate in China, where, according to Chinese state media citing national regulatory data, 986 domestic companies hold production licenses for the ingredient.[50] FDA records show 28 companies registered to supply acetaminophen's active ingredient for the U.S. market; 11 of them are Chinese, including six held by a single company, Anqiu Lu'an Pharmaceutical, and the only U.S.-based company on that list is SpecGx.[51] In fact, by Chinese state-media accounts, one company – Anqiu Lu'an Pharmaceutical – can reportedly produce nearly 30,000 tons of acetaminophen a year, roughly twice China's domestic demand.[52] Notably, some acetaminophen granules are among products manufactured in China's Xinjiang Uyghur Autonomous Region – the area where the Chinese government has carried out systematic human rights abuses against the Muslim population, actions that Washington has labeled as genocide.[53] Under the Uyghur Forced Labor Prevention Act, goods produced in Xinjiang are presumed to be made with forced labor and are prohibited by CBP from import.[54]

70%

of America's acetaminophen imports originate in China, per its own case study above.

Currently, there are no alternative pathways to quickly derisk from China's dominance for this drug.[55] While India produces significant acetaminophen APIs through companies such as Granules India and Farmson Pharmaceutical, Indian manufacturers themselves are estimated to depend on China for roughly 65 percent of their bulk drug inputs.[56]

The Well-Known Antibiotic: Azithromycin NO DOMESTIC API

For most Americans, the Z-Pak is not just a familiar name but also a well-known expectation that its five-day course is the most efficient answer to cure infections of all kinds. Azithromycin is, in fact, the second most prescribed antibiotic in the United States, accounting for 10.6 percent of all antibiotics dispensed in 2024.[57] It is the dominant macrolide antibiotic and a cornerstone of outpatient therapy for pneumonia, bronchitis, sinusitis, and sexually transmitted infections.[58] Any disruption to this ingredient will invariably hamper Americans' access to critical supply of key antibiotics.

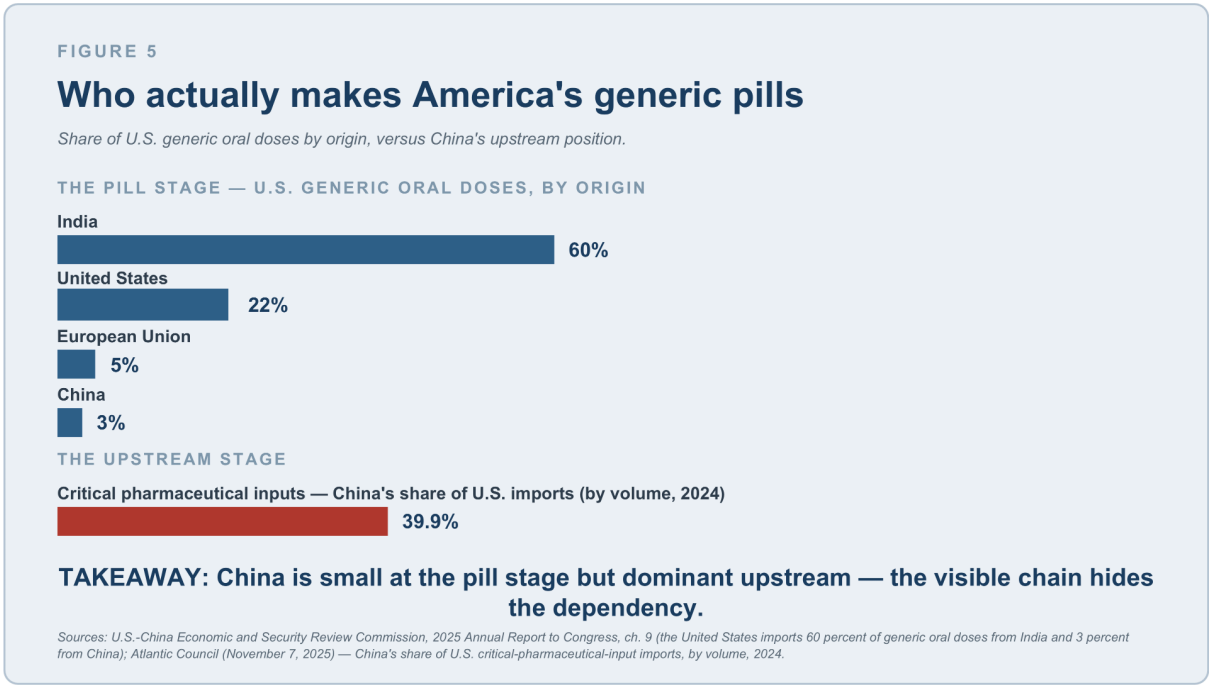


FIGURE 5 Who actually makes America's generic pills. Shares shown cover the four largest sources; the remaining ~10 percent is distributed across other producers.

Azithromycin cannot be made without erythromycin, an antibiotic produced by a soil bacterium.[59] China exported approximately $221 million of the roughly $423 million in global erythromycin-derivative trade in 2022, about 52 percent by value and roughly 64 percent by volume.[60] CSPC Pharmaceutical Group manufactures azithromycin tablets for the U.S. market through its CSPC Ouyi subsidiary.[61] CSPC's website advertises "our own API industry chain advantage" for azithromycin, indicating vertical integration from erythromycin starting material through finished dose.[62] In other words, a Chinese conglomerate straddles America's two most prescribed antibiotic classes: penicillin and macrolides.

A Chinese conglomerate straddles America's two most prescribed antibiotic classes: penicillin and macrolides.

The best current alternative for erythromycin production, India, is also heavily reliant on China. India is simultaneously the second-largest exporter (approximately $95 million) and the largest importer (approximately $121 million), processing Chinese-sourced erythromycin for re-export.[63] China supplied about 82% by value of India's erythromycin-derivative imports in 2022.[64] The economics also make it challenging: A generic Z-Pak costs around $6 with a discount card, and pharmacies acquire it for under $2.[65] With such a low-margin product, it would be an expensive proposition for American companies to invest in domestic API manufacturing, let alone domestic erythromycin fermentation.

As a result, Americans are deeply vulnerable to any potential Chinese supply chain shock. The three most important outpatient antibiotic classes in the United States – Amoxicillin, Azithromycin, and Ciprofloxacin – are all China dependent.[66] If all were simultaneously disrupted, Americans would lose their most commonly prescribed outpatient antibiotics.

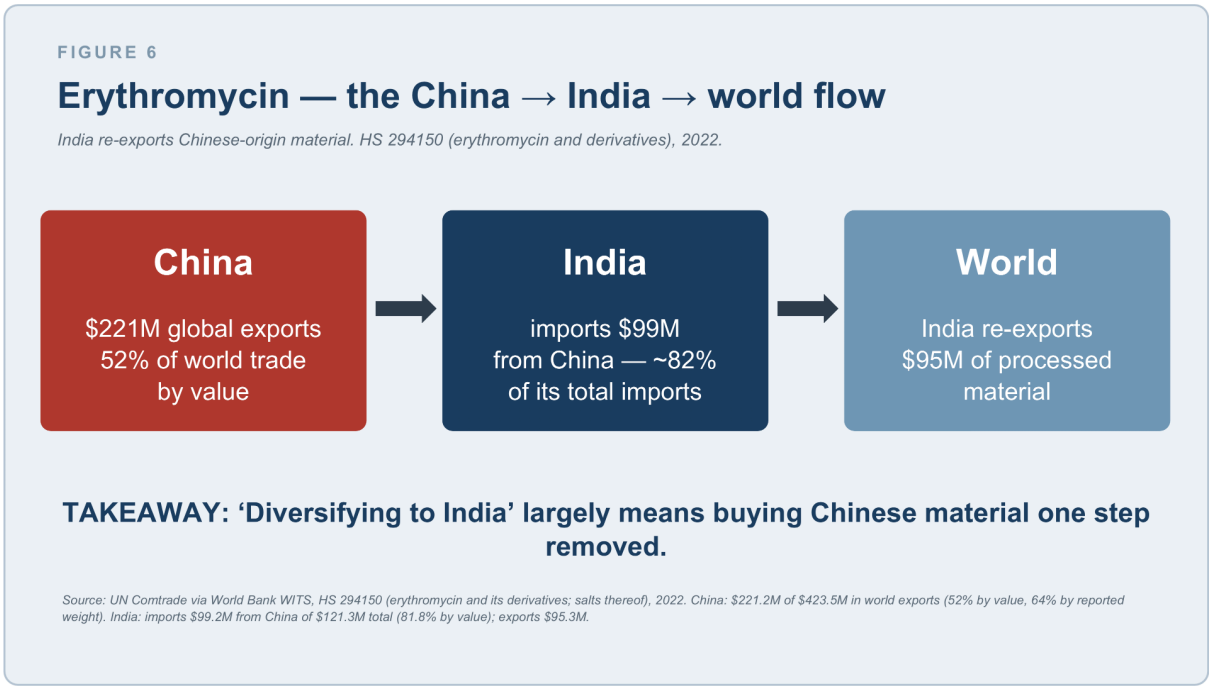


FIGURE 6 Erythromycin — the China → India → world flow

Blood Thinner for Surgery: Heparin PARTIAL DOMESTIC API

Heparin is a foundational anticoagulant in American medicine. It is the standard anticoagulant for most conventional hemodialysis session and cardiac procedures involving cardiopulmonary bypass and it is widely used in intensive care, vascular procedures, and for initial treatment of many patients with deep vein thrombosis.[67] For the roughly 550,000 Americans receiving dialysis, alternatives may exist, but they cannot replace heparin nationwide with comparable simplicity, availability and cost.[68] A sudden heparin shortage would therefore disrupt dialysis and cardiac care at a scale that existing alternatives could not readily absorb.

The raw material for heparin is extracted from porcine intestinal mucosa. In China, the traditional supply chain begins with pig intestines processed at thousands of small village facilities.[69] Consolidators collect and combine crude heparin lots before selling them to manufacturers that purify the material into heparin sodium API. By one market-research estimate, most of the U.S. supply originates this way.[70] Of the three U.S. plants that produce heparin API, two are Chinese-controlled: SPL in Wisconsin[71] and Smithfield BioScience in Ohio.[72] The third known heparin API producer in the United States is a Pfizer-operated API facility in Ohio.[73] That makes Pfizer the only known U.S. owned merchant heparin API producer with active production in the United States as of the publication of this report. [74]

This is not a hypothetical vulnerability: In 2007 and 2008, contaminated Chinese-origin heparin was associated with at least 149 deaths in the United States, and that contaminated supply reached at least 11 different countries.[75] The contaminant was traced to Changzhou in China's Jiangsu province.[76] Chinese officials denied that the contamination originated in China and refused FDA access to conduct a criminal investigation.[77] No one was held accountable.

The economic realities that produced this supply chain risk remain just as relevant today. Mucosa harvested across thousands of dispersed Chinese workshops remains cheaper than any alternative, and for at least two decades U.S. pharmaceutical companies and labelers treated that cost advantage as a fixed market feature rather than a structural risk. The 2008 fatalities did not alter the calculus for companies to reshore heparin production; neither has the current wave of supply shortages. Sources of production are thinning, not diversifying and that dependence raises the share of American patients whose treatment depends on a supply chain we do not control.

SIDEBAR Heparin — supply snapshot

First-Line for Type 2 Diabetes: Metformin NO DOMESTIC API

Metformin is the third most prescribed medication in the United States, with more than 82 million prescriptions dispensed in 2024, and the first-line pharmacotherapy for type 2 diabetes – a disease affecting an estimated 40 million Americans.[78] It is on the WHO Model List of Essential Medicines[79], has been FDA-approved since 1995, and costs less than $10 per month as a generic.[80] But the scale of its use and the absence of any federal protection are in sharp contrast. Metformin is not on the FDA Essential Medicines List (Executive Order 13944) as a structural matter since this list is focused on emergency response.[81] Similarly, it is not covered by Civica Rx[82] (which is focused on sterile injectables) and it is estimated that there are no at-scale domestic U.S. API manufacturers.[83] The third most prescribed medicine in the United States falls entirely outside every federal pharmaceutical resilience program. The government consciously designed its pharmaceutical safety net around acute-care hospital medications and excluded chronic outpatient drugs. The result: more than 82 million annual prescriptions in America have no protection whatsoever.

FIGURE 7

Heparin — a fully China-dependent lifeline

U.S. crude heparin supply from China	74%
Global crude heparin from China	80%
U.S. dialysis patients · no equivalent substitute	~550K
Americans hospitalized each year who receive heparin	12M+
U.S. deaths associated with 2007–08 contaminated Chinese heparin	149

TAKEAWAY: A drug with no equivalent substitute, for the most vulnerable patients, whose raw material comes overwhelmingly from one country.

Sources, by row. Crude-supply shares: CFR, The Pharma Choke Point (June 2026), 34. Dialysis population: U.S. Renal Data System, 2020 Annual Data Report (end-2018 data). Heparin exposure: CFR, 33, after Cuker et al., Blood Advances 2 (2018). Deaths: FDA adverse-event tally as reported in Pan et al., Nature Biotechnology 28 (2010): 203–7.

FIGURE 7 Heparin — a fully China-dependent lifeline

Metformin's supply chain is built on the precursor chemicals dicyandiamide (DCD) and dimethylamine.[84] The United States is the world's largest metformin importer, receiving an estimated 12,900 shipments annually.[85] By one market-research estimate, China produces roughly 81 percent of the world's dicyandiamide; one of the world's largest metformin API manufacturers is Keyuan Pharmaceutical of China, with an estimated 14 percent of global market share. Germany is the only significant non-Chinese source – the German producer AlzChem describes its plant as the only DCD facility outside China – producing roughly one-quarter of China's output. India holds an estimated 46 percent of the global metformin API market – by one market-research estimate, the largest country share – but India's production depends heavily on Chinese precursor inputs.[86] One of China's major DCD producers, Ningxia Jiafeng Chemicals, sells through a U.S. company registered in California. FDA records show 39 companies registered to supply metformin's active ingredient for the U.S. market, and none of them is a U.S.-based manufacturer producing the bulk ingredient at commercial scale.[87]

81%

of the world's dicyandiamide (DCD) precursor is produced in China.

38-46%

of global metformin API production share is held by India — itself dependent on Chinese precursor inputs.

FIGURE 8 Metformin's supply chain

The vulnerability of this supply chain is more than theoretical. In 2020, FDA testing prompted voluntary recalls of extended-release metformin by nine manufacturers – including Amneal Pharmaceuticals, Actavis/Teva, Apotex, Lupin Pharmaceuticals, and Marksans Pharma – after NDMA, a probable human carcinogen, was detected in their products; recalls continued through 2023.[88] The contamination pathway was identical to the sartan crisis: opaque upstream chemistry, no domestic API backstop, and no structural requirement to disclose manufacturing process changes that generate carcinogenic byproducts.

The Most Prescribed Antibiotic: Amoxicillin NO DOMESTIC API

Amoxicillin is the most prescribed antibiotic in the United States and the first-line treatment for a range of common infections – ear infections, strep throat, pneumonia, and Lyme disease. It belongs to the penicillin class, and its supply chain traces back to 6-aminopenicillanic acid (6-APA), the core penicillin building block. China now holds roughly 90 percent of global 6-APA production capacity[89], and there is no sign that any U.S. plant makes it from scratch.[90]

~90%

of the world's 6-APA production capacity — the core penicillin building block — is in China.

Bristol-Myers Squibb operated the last U.S. plant making penicillin by fermentation, in East Syracuse, New York.[91] Its board approved the closure in July 2004; production was phased out over the following two years and had ceased in 2006.[92] In its SEC filings, BMS described the action only as ending "bulk manufacturing" – language that obscured what had actually happened.[93] There was no disclosure that the United States was exiting domestic penicillin production entirely. The market, optimizing for cost, had produced an outcome with national security implications that neither the company, nor regulators, nor political leaders grappled with at the time.

The concentration of production that followed is now embedded in the structure of the Chinese pharmaceutical industry. CSPC Pharmaceutical Group, a Chinese conglomerate, manufactures amoxicillin while also producing azithromycin[94] – the second most prescribed antibiotic in the United States in 2024[95] – through its CSPC Ouyi subsidiary.[96] CSPC advertises its "own API industry chain advantage" for azithromycin. The registrations behind it are concrete: its CSPC Ouyi subsidiary holds active U.S. drug master files for both azaerythromycin, the erythromycin-derived intermediate, and the azithromycin active ingredient, and sells FDA-approved azithromycin tablets — with the effect being that a single Chinese firm spans the chain from key intermediate through finished dose for the second most prescribed antibiotic in America.[97] No U.S. producer of either active ingredient exists, and the 6-APA that both depend on is overwhelmingly sourced from China.

The Counter-Terrorism Drug: Ciprofloxacin NO DOMESTIC API

Ciprofloxacin is the first- or second-line treatment for every CDC Category A bioterrorism agent for which an antibiotic is indicated: anthrax, plague, and tularemia.[98] When the anthrax letters mailed to Senate offices in October 2001 exposed postal workers and congressional staff and Members, the federal government's immediate response was mass ciprofloxacin prophylaxis – a 60-day course for those at risk.[99] What that crisis also revealed, and what subsequent supply chain analysis has confirmed, is that the U.S. capacity to produce antimicrobials like ciprofloxacin at scale depends on Chinese-origin APIs.[100]

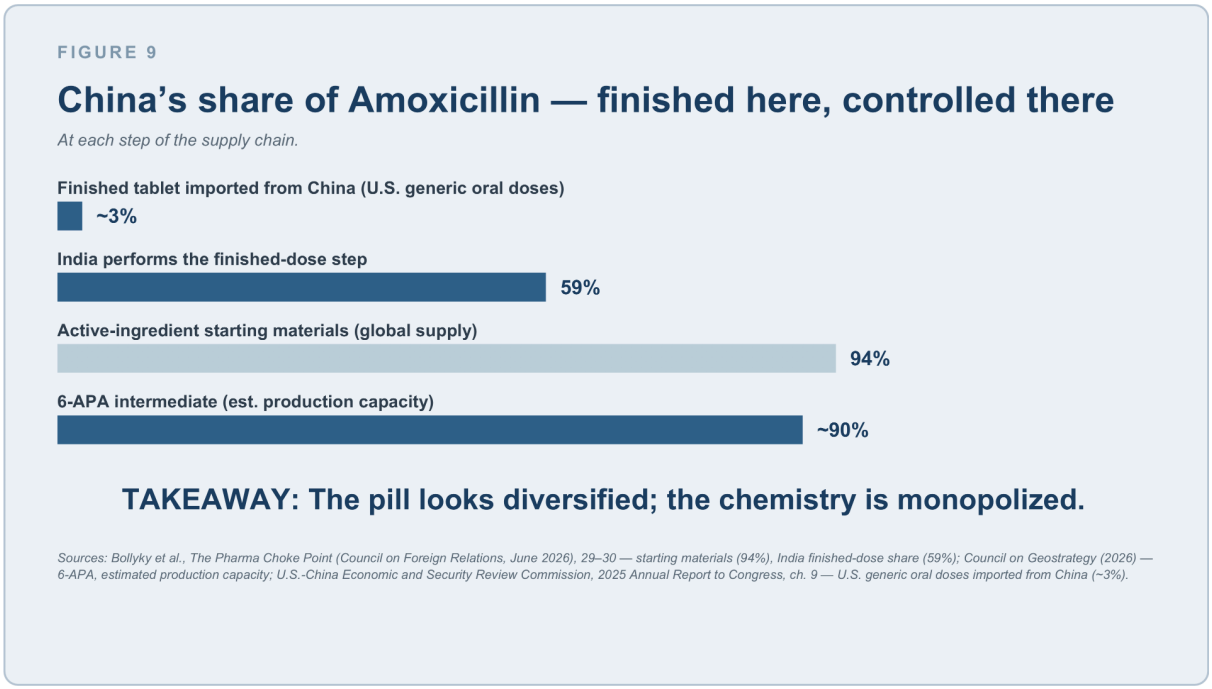


FIGURE 9 Amoxicillin — finished here, controlled there

China dominates the supply of the active ingredient for ciprofloxacin and other fluoroquinolones.[101] Indian generics manufacturers – the world's largest producers of finished ciprofloxacin – source almost all of their ciprofloxacin active ingredients from China, making India a secondary processor rather than an independent supply chain alternative. The SNS (Strategic National Stockpile) maintains reserves of finished ciprofloxacin,[102] but finished-dose reserves are only as durable as the ability to replenish them. A sustained Chinese supply disruption, which is unlikely but plausible given Beijing's demonstrated use of export restrictions in other sectors, would erode the stockpile without replacement capacity.

The Strategic National Stockpile maintains reserves of finished ciprofloxacin, but finished-dose reserves are only as durable as the ability to replenish them.

ALMOST ALL

of the ciprofloxacin API used by Indian generic manufacturers — the world's largest producers of finished ciprofloxacin — is sourced from China, making India a secondary processor rather than an independent alternative.

FIGURE 10 The last U.S. penicillin plant by fermentation

Generic Oncology Drugs: Cisplatin and Carboplatin NO DOMESTIC API

The 2023 shortages of cisplatin and carboplatin – two of the most widely used chemotherapy agents, present in treatment regimens for bile duct, lung, ovarian, testicular, bladder, and head and neck cancers – brought the oncology supply chain into congressional focus in a way that generic analgesics and antibiotics had not.[103] The Senate Finance and Homeland Security committees held hearings on the shortages[104] – at the Finance hearing, oncologists described rationing chemotherapy – and the FDA authorized temporary importation of unapproved Chinese cisplatin to extend supply.[105]

>50%

of U.S. cisplatin production came from a single Indian plant — halted in 2023 after an FDA inspection found egregious quality and data-integrity violations.

The immediate cause of those shortages was a quality failure at a single foreign supplier. Intas Pharmaceuticals, which produced more than half of U.S. cisplatin[106], halted its Ahmedabad, India plant in 2023 after an FDA inspection found egregious quality and data-integrity violations.[107] But the underlying structure – thin margins on generic oncology injectables, few suppliers, no mandatory redundancy requirements – is the same one that has led to Chinese API dependency in other drug classes. The manufacturing base for sterile oncology injectables has been consolidating for years, leaving an ever-smaller number of producers supplying an ever-larger share of the market. When a single plant has quality problems, there is no buffer. In this sense, the 2023 shortage was not a surprise to anyone tracking the supply geography. Several years after this high-profile supply shortage, it is notable that congressional attention has not yet translated into structural remediation of this underlying supply chain risk at a time when cancer diagnoses surpassed two million new cases annually since 2024.

Corticosteroids: Dexamethasone and Hydrocortisone PARTIAL DOMESTIC API

Dexamethasone and hydrocortisone sit at opposite ends of American medicine's therapeutic urgency spectrum, but they share the same upstream vulnerability. Dexamethasone is the standard of care for severe COVID-19 and a first-line treatment for allergic reactions and a range of inflammatory and autoimmune conditions[108]; hydrocortisone is the essential replacement therapy for Americans living with primary adrenal insufficiency, for whom supply disruption is not an inconvenience but a medical emergency.[109] Both are on the WHO Model List of Essential Medicines.[110] Both are on the FDA Essential Medicines List under Executive Order 13944.[111] Both are significantly sourced from China, with dependence growing.[112]

In this case, the chokepoint is not the finished tablet. It is the corticosteroid intermediate chemistry concentrated in two Chinese facilities. Tianjin Tianyao Pharmaceuticals (renamed Jinyao Pharmaceutical in 2022), is a leading Chinese producer of dexamethasone[113]; Zhejiang Xianju Pharmaceutical holds the corresponding active U.S. drug master file for hydrocortisone.[114] By Chinese industry estimates, approximately 80 percent of the world's diosgenin – the plant-derived feedstock from which dexamethasone is synthesized – is of Chinese origin.[115] China's share of U.S. imports under the tariff heading that covers hydrocortisone – together with cortisone, prednisone, and prednisolone – has run between roughly 50 and 77 percent since 2018, and was 67 percent in 2024.[116] A hydrocortisone-only figure cannot be computed because supply chain transparency at this level of the pharmaceutical value chain is not currently required by current U.S. law.

~80% (industry estimate)

of the diosgenin used globally to synthesize dexamethasone is of Chinese origin.

>67%

of U.S. imports under the tariff heading covering hydrocortisone and three related corticosteroids came from China in 2024

CORTICOSTEROID INTERMEDIATE CHEMISTRY — NAMED SUPPLIERS

DEXAMETHASONE SOURCE	HYDROCORTISONE SOURCE
Tianjin Tianyao Pharmaceuticals	Zhejiang Xianju Pharmaceutical

The vulnerability has already materialized. Dexamethasone has been on the FDA drug shortage list since February 2019 – nearly a year before COVID-19 reached the United States.[117] When the pandemic struck, the consequences were immediate: demand for dexamethasone spiked 183 percent in a single day, and 610 percent in a week; fill rates collapsed from 97 percent to 54 percent.[118] That crisis exposed what happens when a drug critical to emergency response has no domestic production buffer and no federal program capable of providing one. The shortage has continued for more than seven years without resolution.

The federal response has been notably limited. Dexamethasone and hydrocortisone are both on the FDA's Essential Medicines List, but no publicly disclosed federal production program has funded corticosteroid API capacity.[119] The BARDA BioMaP consortium – the federal government's primary domestic reshoring initiative – has prioritized to date antimicrobials and large-volume parenterals and has not targeted corticosteroid APIs.[120] The practical consequences of this gap are already visible in allied markets, where limited supply has encouraged corporate behavior that is harmful to consumers. For example, the UK's Competition and Markets Authority levied £266.5 million in fines in 2021 against companies that charged the NHS excessive and unfair prices for hydrocortisone tablets between 2008 and 2018 – raising the price of a pack by more than 10,000 percent.[121] Concentrated supply enables this kind of market exploitation. Washington has not acted to prevent the same dynamic from occurring here.

For High Blood Pressure: Losartan NO DOMESTIC API

Losartan was the seventh most prescribed drug in the United States in 2024, widely used to treat high blood pressure: 59.0 million prescriptions annually, 15.4 million patients, and nearly 70 percent of all single-ingredient angiotensin receptor blocker prescriptions.[122] It is on the WHO Model List of Essential Medicines.[123] It is not on the FDA Essential Medicines List, as no Angiotensin II Receptor Blockers (ARB) – prescription medications primarily used to treat high blood pressure, heart failure, and chronic kidney disease – are.[124] Further, there are no identified domestic API manufacturers in publicly accessible supplier databases reviewed in 2026.[125] FDA records show 32 active drug master files for losartan's active ingredient, held by 26 companies, and not one of them is U.S.-based.[126] Civica Rx does not cover it.[127] Phlow does not cover it.[128] In the hierarchy of federal pharmaceutical safety programs, losartan falls entirely outside the perimeter.

In 2011, Zhejiang Huahai Pharmaceutical – then among the world's dominant valsartan API suppliers – approved a change to its synthesis process.[129] The new route, using sodium azide in dimethylformamide, was cheaper. It also generated N-nitrosodimethylamine, or NDMA – a probable human carcinogen.[130] Zhejiang Huahai's quality control systems registered an unknown peak in residual solvent chromatograms and dismissed it as noise.[131] The company did not investigate. The contaminated process ran for more than six years before detection.[132]

In June 2018, laboratory testing first identified the contamination.[133] By then, approximately 15 million patients in the United States had active prescriptions for valsartan or losartan.[134] Recalls cascaded across more than 20 countries; in the United States alone 624 valsartan, 500 losartan, and 122 irbesartan products were recalled.[135] NDMA levels in some affected batches exceeded the acceptable daily intake limit by more than 200 times.[136] Three distinct nitrosamine carcinogens were ultimately identified across the sartan drug class: NDMA, NDEA, and NMBA.[137] A cohort study of 1.4 million French users found no increase in overall cancer risk for those exposed, but identified statistically significant elevations in liver cancer and melanoma.[138] Facing an acute supply crisis, the FDA temporarily authorized distribution of losartan containing NMBA at concentrations exceeding its own interim acceptable limit – 9.82 parts per million against a limit of 0.96 – because the alternative was no losartan at all.[139]

THREE NITROSAMINE CARCINOGENS IDENTIFIED ACROSS THE SARTAN CLASS

NDMA	NDEA	NMBA
Original 2011 contaminant	Found across the broader sartan class	FDA allowed distribution at 9.82 ppm vs. its own 0.96 ppm limit

The contamination did not remain confined to the sartan class. The same combination of opaque upstream supply chains and inadequate quality oversight that allowed NDMA to enter valsartan undetected for years was replicated across several additional drug categories in the years that followed: ranitidine in 2019, metformin in 2019 and 2020, varenicline in 2021, quinapril in 2022, and others.[140] The losartan recall was not a contained quality failure – it was a diagnostic, revealing what concentrated, opaque Chinese API supply chains produce when manufacturing shortcuts accumulate unseen.

The FDA placed Zhejiang Huahai's Chuannan facility on import alert in 2018.[141] The FDA closed out its 2018 warning letter in November 2021, and the import alert was lifted subsequently[142]. The company returned to the U.S. market through its Solco Healthcare subsidiary.[143] On June 6, 2025, FDA issued a new Warning Letter to Zhejiang Huahai's Xunqiao manufacturing site for current Good Manufacturing Practice violations.[144] The company that introduced a probable carcinogen into the U.S. drug supply and allowed it to persist for six years is back on the market – without any structural requirement that it demonstrate sustained compliance before returning to American patients.

Not All Bad News: Ibuprofen DOMESTIC CAPACITY

Ibuprofen is one of the few drugs in this review where domestic active-ingredient manufacturing is not a policy aspiration but an operating fact.

FIGURE 11

The losartan/valsartan NDMA timeline

2011	Zhejiang Huahai approves a cheaper synthesis route — generating NDMA, a probable human carcinogen — and does not investigate an anomalous quality-control reading.
Jun 2018	Laboratory testing first identifies the contamination; roughly 15 million U.S. patients hold active valsartan or losartan prescriptions.
Sep 2018	FDA places Zhejiang Huahai's Chuannan facility on import alert.
2018–19	Recalls cascade across more than 20 countries; in the U.S.: 624 valsartan, 500 losartan, and 122 irbesartan products.
Nov 2021	The import alert is lifted; the company returns to the U.S. market via its Solco Healthcare subsidiary.
Jun 2025	FDA issues a new Warning Letter to Zhejiang Huahai's Xunqiao site for cGMP violations.

Sources: FDA Warning Letters 320-19-04 (2018) and 320-25-78 (2025); FDA Close-Out Letter, November 4, 2021; FDA Import Alert 66-40; Eworuke et al., BMJ Open (2023); Georgescu et al., Scientific Reports (2024).

FIGURE 11 The losartan/valsartan NDMA timeline

BASF's predecessor, BHC Company, commercialized a three-step catalytic process for manufacturing ibuprofen active pharmaceutical ingredient at a Bishop, Texas facility in 1992 — replacing an older six-step method — and won EPA's Presidential Green Chemistry Challenge Award for the innovation in 1997; BASF still operates that plant today as one of the largest ibuprofen production sites in the world.[145] In 2017, BASF announced a roughly $228 million program to expand ibuprofen capacity – a new plant in Ludwigshafen, Germany, and an expansion of the Bishop site – to address a supply gap in the global market.[146] That domestic footprint stands in contrast to Shandong Xinhua Pharmaceutical, the first Chinese manufacturer to produce bulk ibuprofen, beginning in the 1970s, and now dual-listed on the Hong Kong and Shenzhen stock exchanges since 1996 and 1997, respectively.[147]

IBUPROFEN ACTIVE INGREDIENT — TWO PRODUCTION HISTORIES

DOMESTIC: BASF, BISHOP, TX

Operating since 1992; won EPA's Green Chemistry Challenge Award in 1997; expanded with a ~$228M investment in 2017.

OFFSHORE: SHANDONG XINHUA, CHINA

China's first bulk-ibuprofen producer, operating since the 1970s; dual-listed on the Hong Kong and Shenzhen exchanges since 1996-97.

The comparison should be read carefully. Neither BASF nor public records disclose what share of the U.S. ibuprofen market the Bishop, Texas facility actually supplies, and no publicly available FDA Establishment Inspection Report independently quantifies that share. Despite this domestic capacity, roughly 95 percent of U.S. ibuprofen imports are still estimated to originate in China — according to Commerce Department figures cited by Congress — meaning a viable domestic manufacturing alternative exists, but has not displaced the underlying dependence.[148]

Ibuprofen appears on the FDA's Executive Order 13944 Essential Medicines List, one of two drugs listed under the "Antipyretics" category alongside acetaminophen.[149] Yet BARDA's most recent domestic-manufacturing solicitation through the BioMaP Consortium — up to $200 million in funding, which closed on March 16, 2026 — was open to any Essential Medicines List input but stated a preference for antimicrobials and large-volume parenterals, and named no oral analgesics like ibuprofen.[150] That gap was not hypothetical: a 2022–2023 shortage of pediatric ibuprofen oral suspension, driven by a convergence of COVID-19, RSV, and influenza demand, forced FDA to issue emergency guidance authorizing outsourcing facilities to compound an already-approved product[151] — the kind of improvisation that becomes necessary when no standing federal program protects an Essential-Medicines-List drug's supply.

Ibuprofen's lesson is not that reshoring is easy. It is that reshoring is achievable, has already happened once, and has still gone unrecognized by the federal programs built to prevent exactly the kind of shortage that followed anyway.

Section V

V

Lack of Viable Structural Alternatives

Three courses of action are commonly proposed — sourcing from India, building allied supply chains, reshoring domestic production. All three are more constrained than they appear.

Close observers of America's growing dependencies on China for pharmaceutical products often highlight three possible courses of action to ameliorate these risks. The first involves sourcing from India; the second involves building allied supply chains; and the third emphasizes reshoring domestic production.

Unfortunately, all three approaches are more constrained than they appear. Understanding why that is the case is essential to designing policy responses that work.

TABLE 2 Three options often proposed — and why each is more constrained than it appears

OPTION	THE CONSTRAINT
1. Source from India	India's own API production is itself heavily dependent on Chinese precursors and key starting materials.
2. Build allied supply chains	Existing coordination mechanisms remain either consultative (the Biopharmaceutical Alliance) or not yet in force (the EU's Critical Medicines Act).
3. Reshore domestic production	Economically viable only for a subset of drugs, and typically requires 5-10 years from greenfield siting through FDA approval.

India is not an alternative supply source

The most dangerous misconception in U.S. pharmaceutical supply chain policy is that India provides a ready alternative to China. It does not – at least not for the upstream inputs that matter most. India is the world's largest exporter of generic medicines by volume and supplies approximately 47 percent of the generic prescriptions filled in the United States.[152] On its face, this looks like diversification. But a June 2026 study released by the Indian government cautioned that, while the country was no doubt a pharmaceutical manufacturing powerhouse, it nevertheless sources about 65 percent of the raw critical materials – KSMs, APIs – from China.[153]

47%

of the generic prescriptions filled in the United States are supplied by India.

65%

of India's own raw critical materials (KSMs, APIs) are sourced from China, per a June 2026 Indian government study.

Critically, India's pharmaceutical manufacturing sector is structurally dependent on China for the raw materials it needs to produce those APIs. A July 2025 Brookings Institution analysis found that U.S. upstream reliance on China – at the level of key starting materials and chemical precursors – significantly exceeds commonly cited API-level figures.[154] For amoxicillin, India's principal 6-APA precursor traces almost entirely to Chinese fermentation.[155] A 2025 peer-reviewed analysis in JAMA Health Forum found that India supplied 31.9 percent of the finished antibiotics the United States imported in 2020-24, but just 2.9 percent of the antibiotic active ingredients - against China's 62.6 percent - and cautioned that finished-dose diversification may understate U.S. dependence on China if those exporters themselves rely on Chinese ingredients.[156] The supply chains of the two countries are not parallel alternatives. They are a single, Chinese-anchored system with an Indian finishing layer on top.

This matters because U.S. policymakers have at times suggested that India might be a solution to Chinese pharmaceutical dominance. The logic is understandable: India has manufacturing scale, regulatory familiarity with FDA standards, and competitive labor costs. But redirecting U.S. procurement toward Indian suppliers without simultaneously addressing India's upstream dependence on China simply moves the chokepoint one step further from view. Any Chinese decision to restrict key starting material exports to India would collapse Indian production of drugs on which U.S. patients depend just as surely as a direct embargo.

Allied coordination remains underbuilt

The Biopharmaceutical Alliance – a partnership between the United States, European Union, India, Japan, and South Korea – was launched to reduce shared dependence on China for pharmaceutical inputs.[157] In practice it functions as a consultative forum: there are no shared inventories, no joint purchase commitments, and no mutual recognition of manufacturing inspections that would allow one country's approved supplier to fill another's shortage quickly. The alliance has the architecture of coordination without an infrastructure that actually creates resilience.

Europe faces the same structural problem. The European Union has made pharmaceutical resilience a formal priority through the Critical Medicines Act, provisionally agreed by the Council and Parliament in May 2026 but not yet in force,[158] and some European manufacturers have made meaningful investments that offer genuine proof of concept for what coordinated public investment can achieve. But European API capacity is nowhere near sufficient to serve as a U.S. backstop at scale, and most European producers remain dependent on Chinese and Indian active ingredients.[159]

The EU has launched Critical Medicines Alliance initiatives and the European Health Emergency Preparedness and Response Authority (HERA) has conducted supply chain mapping work.[160] These efforts are politically significant and worth engaging, but they have not yet changed the supply geography. European manufacturers face the same Chinese dependencies and similar margin constraints that have driven consolidation in the U.S. market.

Japan is a partial exception: it is rebuilding domestic API manufacturing capacity in specific drug classes, including by restarting penicillin ingredient production it halted in 1994 with policy incentives to sustain it.[161] Tokyo specified certain kinds of antibiotics as critical goods for economic and health security, thus setting a demand for producing them domestically. The government allocated funding for targeted investments, including for production facilities upgrades. Japan is a logical partner for bilateral supply chain coordination, particularly for the antibiotic and anticoagulant classes where Chinese dominance is most pronounced.

Allied coordination in its current form is therefore a hedge, but not a solution for the United States. And such mechanisms are likely to operate slowly, coordinating production across multiple non-Chinese supply nodes. In that context, an U.S.-EU-Japan-Australia coordination mechanism on essential medicines supply, modeled on emerging critical minerals cooperation frameworks, may be worth building now even though it will take years to matter.

TABLE 3 Allied coordination: status by partner

PARTNER	STATUS
Biopharmaceutical Alliance (US/EU/India/Japan/Korea)	Consultative forum only — no shared inventories, joint purchase commitments, or mutual inspection recognition.
European Union	Critical Medicines Act provisionally agreed (May 2026) not yet in force; genuine investment in some areas, but capacity remains far short of a U.S.-scale backstop.
Japan	Partial exception — rebuilding domestic API capacity in specific drug classes via targeted policy incentives.

This report focuses primarily on generic, off-patent drugs, where the evidence base is strongest and the supply chain geography is most clearly documented. A second-tier vulnerability is developing in biologics precursors and fermentation inputs for specialty drugs – areas where China's 15th Five-Year Plan targets "decisive breakthroughs" and where Chinese firms are moving further up, not retreating from, the pharmaceutical value chain.[162] The evidentiary base for that layer of the problem is still developing, and claims in that space are more contested than the generic API dependency documented here. It is a priority area for further research and for supply chain mapping that should not wait for a crisis to motivate it.

Domestic capacity is a long-term project, not a near-term fix

The generic drugs most vulnerable to Chinese supply disruption are also the ones where the economics of domestic manufacturing are most daunting. A generic Z-Pak sells for as little as $6 with a pharmacy discount card, and pharmacies acquire it for under $2. This price point leaves little margin to support domestic API manufacturing. Capital investment in low-margin generic drug manufacturing is not naturally attractive to private markets; the economics that drove production to China have not changed simply because policymakers have acknowledged the risk.

Brookings Institution senior fellow Marta Wosinska's testimony before the Senate Special Committee on Aging in October 2025 traced this invisibility to a structural regulatory gap: in a purchasing environment where price is the dominant procurement criterion and no law requires manufacturers to disclose upstream concentration to investors or the public, no manufacturer faces an incentive to invest in more expensive domestic or allied-nation sourcing – and none is required to reveal publicly the supply chain risks it has created.[163]

The BMS/penicillin case illustrates the point. The East Syracuse plant did not close because of policy failure; it closed because the economics made continued investment indefensible against Chinese pricing. Reopening equivalent capacity requires the government to make a market – through procurement preferences, restrictions, direct subsidy, or a combination thereof – not just clear regulatory obstacles.

There is a model that exists, but it is an expensive one: the Berry Amendment requires the Department of Defense to source certain textiles, clothing, and food domestically regardless of price premium.[164] Civica Rx has demonstrated that a nonprofit procurement vehicle can sustain domestic manufacturing of sterile injectables. Neither model has been extended systematically to the generic oral drugs that carry the broadest public health exposure.

The current administration has issued executive orders on pharmaceutical supply chain resilience and has applied tariffs to Chinese pharmaceutical inputs;[165] but the gap between those actions and operational domestic capacity remains years wide. An effective, comprehensive, and long-term strategy would need to include, among others, signals to the market on the types of drugs considered most important for U.S. national security through targeted government procurement; incentives and funding for drug makers to invest, build, and sustain manufacturing facilities domestically; government support for research and development work to induce continued innovation and development within the United States; and, close coordination with trusted, like-minded allies and partners to ensure that we can "shore up" together and gradually ease the dependence on China. In short, this cannot be treated simply as a trade issue.

A December 2025 analysis by Wosinska and Michael O'Hanlon of the Brookings Institution argued that the United States cannot address every supply-chain vulnerability at once, and that targeted domestic investment for the highest-risk drugs, combined with credible allied-nation partnerships, is both achievable and essential.[166] As described earlier in this paper, it is estimated that there is no commercial-scale U.S. manufacturer of amoxicillin API,[167] nor is there a U.S.-owned producer of heparin API that can fully cover our nation's anti-coagulant needs.[168] Building such capacity from greenfield siting through FDA approval typically takes an estimated five to ten years, according to an industry analysis, and requires sustained policy commitment that outlasts election cycles.[169] The 2023 Socal et al. analysis found that roughly one-third of all generic APIs it reviewed are made at a single facility worldwide:[170] this is a concentration vulnerability entirely invisible to current FDA oversight mechanisms.

5-10 yrs

is the typical time to build new API manufacturing capacity, from greenfield siting through FDA approval, according to industry analyses.

Section VI

VI

Conclusion and Policy Recommendations

What Congress, the Executive Branch, and industry can each do to change the incentive structures that produced this exposure.

The federal pharmaceutical safety net was consciously designed around acute-care hospital medications. It excludes chronic outpatient drugs of the kind that this report has explored in detail. The fact that the third most prescribed medication in America – metformin, the first-line drug for most of the 40 million Americans with diabetes – has no strategic reserve, no domestic API manufacturer, and falls entirely outside every federal resilience program illustrates the need to review and revise the way that the U.S. government assesses risk in this area.

01 Mandate supply chain mapping

Congress should require the FDA, in coordination with the Department of State, the Department of Homeland Security, and the Office of the Director of National Intelligence, to conduct and publish mandatory upstream supply chain mapping for a defined list of essential medicines – going beyond finished dose to APIs, key starting materials, and precursor chemicals. The existing Essential Medicines List under Executive Order 13944 is a starting point but was designed for acute-care hospital drugs and emergency response.[171] It should be extended to cover the chronic outpatient drugs that currently have no coverage, and its countermeasure-only listings for drugs like amoxicillin and ciprofloxacin should be broadened to cover routine outpatient use. The mapping should include a tiering methodology to establish priority drugs, including clinical substitutability, patient population size, and stockpile feasibility, so that the mapping reflects actual criticality rather than just the drugs that happen to have documented case studies already performed.

Mapping results should be reported to Congress annually and classified annexes should be provided to the intelligence, foreign relations, and armed services committees.

02 Establish and fund domestic production incentives modeled on existing frameworks

The market will not resupply domestic API manufacturing capacity for generic drugs at current price points. Government intervention is required. Congress should establish a pharmaceutical production incentive program modeled on the Berry Amendment (domestic sourcing preference for DoD procurement) and the Civica Rx nonprofit model (sustained procurement vehicle for sterile injectables). Federal purchase guarantees need to be predicated on meeting quality and redundancy standards – any such incentives have to build resiliency over the longer term.

For any federal effort to be impactful, Congress should prioritize the drug categories that are most critical to American national security – and ones with the best pathways for domestic production. The ones outlined in this report should offer some areas for initial focus, with attention extended to cover oral generic antibiotics, anticoagulants, and diabetes medications.

Congress should also determine what our closest allies and partners can do in conjunction with Washington's efforts – including outlining how pursuits to diversify supply chains and enhance resilience can complement each other within a trusted ecosystem. The program should include direct capital grants for new U.S. fermentation and chemical synthesis facilities, long-term off-take agreements that provide revenue certainty sufficient to justify capital investment, and regulatory fast-track procedures for essential-medicine producers. ASPR's announced investment in domestic pain management ingredient production is a start; it needs to be matched by equivalent commitments for antibiotics and anticoagulants, and funded at a scale commensurate with the strategic exposure documented here.

03 Enact mandatory country-of-origin disclosure for pharmaceutical ingredients

Without supply chain visibility, no other intervention can be effectively targeted. Legislation pending before Congress would extend country-of-origin labeling requirements to all U.S.-sold pharmaceuticals – finished dosage forms and APIs – across the full supply and distribution chain.[172] In addition, Congress could direct the FDA to systematize existing Investigational New Drug (IND), Abbreviated New Drug Application (ANDA), and Drug Master File data on API and KSM manufacturing sites into a searchable, interagency database. A 2023 Department of Defense report found that 54 percent of the DoD pharmaceutical supply chain was rated high or very high risk, driven by reliance on suppliers not compliant with the Trade Agreements Act and tracing back to China, India, or unknown origins through transshipment and repackaging.[173] Policymakers, hospitals, and federal purchasers cannot manage risks they cannot see.

04 Pass targeted pharmaceutical tariffs, but not blanket generic tariffs

A March 2025 Brookings analysis found that tariffs alone will not de-risk supply chains, because the exposure to China runs through upstream chemical inputs – KSMs and precursors – that tariffs on finished drugs and APIs do not address.[174] Congress should direct USTR to assess tariffs specifically targeting KSMs and APIs sourced from China, calibrated to narrow the cost advantage that Chinese producers hold through state subsidies, lax environmental enforcement, and strategic pricing. The Trump administration's April 2026 announcement of 100 percent Section 232 tariffs on patented pharmaceuticals is a partial step – but generics, the category of greatest strategic concern, currently remain exempt and under review.[175] Blanket tariffs on finished generics would raise costs on essential, low-margin medicines already in shortage and worsen the insecurity they are intended to address.

05 Take action to ensure corporate accountability

The companies that dismantled U.S. pharmaceutical manufacturing capacity made legal decisions based on economic realities. But Congress has the authority to shape the incentive structures for pharmaceutical manufacturing going forward.

Require pharmaceutical companies to disclose supply chain concentration to the SEC as a material risk. Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act established the precedent: companies that use certain minerals must conduct supply chain due diligence and report to the SEC on whether those minerals originate from conflict-affected regions.[176] Congress should apply a parallel framework to pharmaceutical APIs. Any publicly traded pharmaceutical company – or private company participating in federal healthcare programs above a defined revenue threshold – should be required to disclose annually: the country of origin of APIs used in drugs on FDA or WHO essential medicines lists; any single-source dependencies on suppliers in countries of concern; and known FDA compliance actions affecting their API or KSM supply chain. Supply chain concentration that creates a foreseeable risk of drug shortage is a material risk to both companies and patients.

Require annual supply chain vulnerability reports to Congress. Major pharmaceutical manufacturers should be required to submit annual supply chain vulnerability reports to the Senate HELP Committee and the House Energy and Commerce Committee, identifying: the five drugs in their portfolio most dependent on single-source or China-sourced inputs; steps taken or planned to diversify; and any anticipated shortage risks from upstream concentration. Large pharmaceutical companies already conduct this analysis internally for business continuity purposes. Congress is asking them to share it, and in doing so identify elements of the supply chain that could prove to be good candidates for expanding domestic production incentives.

Establish a pharmaceutical supply chain stress test mechanism. Congress should direct FDA and HHS, in coordination with DOD and ASPR, to conduct periodic pharmaceutical supply chain stress tests for the top 50 essential medicines – analogous to the Federal Reserve's annual Dodd-Frank stress tests for systemically important financial institutions.[177] These tests should model the patient-access impact of 30, 50, and 100 percent disruptions to Chinese API and KSM supply, identify companies most exposed, and require firms above a concentration threshold to submit remediation plans. Results should be reported to Congress in classified form with unclassified summaries published publicly. The goal is not to name and shame, but to create a feedback loop that gives companies, regulators, and Congress a shared factual basis for prioritizing intervention.

06 Strategic API reserves

The Strategic National Stockpile holds finished-dose medicines, but it is vulnerable to the same upstream disruption documented in this report: if Chinese API production is cut off, finished-dose reserves are consumed and cannot be replenished.[178] HHS and DoD should establish strategic reserves of APIs and key starting materials for the essential medicines categories identified through the mapping process above, with priority given to antibiotics, anticoagulants, and drugs used in biodefense response. Reserve requirements should be set in terms of months of supply and should include rotation protocols to prevent stockpile degradation.

07 UFLPA enforcement targeting pharmaceutical inputs

The Uyghur Forced Labor Prevention Act (UFLPA) establishes a rebuttable presumption that goods produced in whole or in part in the Xinjiang Uyghur Autonomous Region are made with forced labor and are prohibited from import.[179] Acetaminophen granules have been identified[180] among products manufactured in Xinjiang. Customs and Border Protection (CBP) and FDA should conduct a joint investigation of pharmaceutical inputs with potential Xinjiang-origin exposure, publish findings, and apply UFLPA enforcement to confirmed cases. This action is available under existing statutory authority and does not require new legislation. It would also create transparency incentives for companies to conduct the upstream due diligence that regulatory frameworks have not yet required.

08 Allied pharmaceutical supply chain coordination

The administration should negotiate supply chain coordination agreements with Japan, the EU, the UK, South Korea, Taiwan, India, and Australia covering essential medicines, with Japan as the priority given its renewed investment in API manufacturing capacity and aligned strategic interests. These agreements should include mutual disclosure of supply chain mapping results, coordinated strategic reserve standards, and joint investment in non-Chinese alternative sourcing and production nodes. The framework should be modeled on emerging critical minerals supply chain cooperation and should be explicitly linked to the Quad's health security agenda. No single allied country can substitute for Chinese supply across the full range of essential medicines; the goal is redundancy across multiple non-Chinese nodes, not a single-country alternative that recreates the dependency problem in a different geography.

09 Take action to ensure corporate accountability

Beyond direct supply chain management, the executive branch can use existing federal program participation as leverage for corporate accountability — without waiting for new legislation. Make participation in federal healthcare programs conditional on minimum supply chain transparency. Companies receiving federal revenue through Medicare, Medicaid, DOD, or VA purchasing should be required, as a condition of that participation, to meet minimum supply chain disclosure standards.This is consistent with how the federal government conditions defense procurement and technology funding – companies receiving federal semiconductor investment under the CHIPS Act[181] must disclose and limit certain technology transfers. There is no principled reason why pharmaceutical companies receiving tens of billions in federal reimbursement should face no analogous obligation. CMS, DOD, and VA should jointly develop a tiered compliance framework with real consequences – reduced reimbursement rates, exclusion from preferred formularies – for companies that fail minimum transparency thresholds within a defined timeframe.

The vulnerabilities documented in this report did not develop overnight and will not be resolved quickly. China's pharmaceutical dominance is the product of four decades of deliberate industrial policy, inadequate policy responses, and political inattention in Washington and other world capitals. The displacement of Western and Japanese production capacity that resulted from Beijing's deliberate efforts will not be reversed by tariff adjustments or executive orders alone.

In particular, both Congress and the Executive Branch would do well to pay more attention to the supply chain vulnerabilities of widely-used outpatient drugs, not simply the acute-care hospital drugs that have heretofore been the focus of resiliency programs. There is a compelling economic logic to making the investments necessary to shift the incentive structures that have driven rational but risky outsourcing of pharmaceutical supply chains; and there is an equally compelling political logic to ensuring that Americans do not face a catastrophic disruption of drugs that are commonplace and essential, but that today depend on shockingly fragile networks of supply.

What can be done now is to map the exposure accurately, stop pretending that India alone can substitute for China's production capacity, rebuild the domestic manufacturing base where the economics can be made to work with government support, and extend the federal pharmaceutical safety net to cover the chronic outpatient drugs that carry the broadest public health and national security exposure. The 149 U.S. deaths associated with contaminated Chinese heparin in 2007 and 2008 were a warning that went unheeded.[182]

APPENDIX A

Company Accountability

Eight manufacturers whose sourcing decisions, closures, or recalls appear in the case studies above, profiled individually.

Viatris

Heparin

EXITING (2025-26)

Discontinued every heparin injection product it sold in the U.S. between March and April 2025 — exiting a market serving a U.S. dialysis population of roughly 550,000 patients depends on uninterrupted supply. Separately, its Indore, India manufacturing site drew an FDA warning letter in December 2024 for quality-system deficiencies.

Pfizer

Heparin, Hydrocortisone, Azithromycin

PARTIAL DOMESTIC

Manufactures hydrocortisone (including API) at its Kalamazoo, Michigan site and heparin API at Franklin, Ohio; its Rocky Mount, NC plant, by contemporary press estimates, accounts for roughly 8% of all sterile injectables used in U.S. hospitals. Notified FDA of discontinuations across its azithromycin line between September 2025 and April 2026.

Bristol-Myers Squibb

Penicillin (6-APA feedstock)

EXITED 2006

Closed the last U.S. plant producing penicillin from raw materials — its East Syracuse, NY fermentation facility — in 2006. The site was sold to LOTTE Biologics for $160 million in a January 2023 deal; it now produces biologics, not antibiotics.

Merck

Contrast case (Cozaar/losartan predecessor)

DOMESTIC CAPACITY

The only manufacturer in the U.S. of MMRV and varicella vaccines and produces its major vaccines domestically at its U.S. sites (West Point, PA and Durham, NC) even as its top-selling product, Keytruda, relies substantially on overseas manufacturing. Losartan (Cozaar) moved to Organon when Merck spun that business off in 2021.

Teva

Losartan

RECALL / SHORTAGE

Its April 2019 losartan recall traced to Hetero Labs Limited, an Indian drug maker whose Unit V finished-dose plant had received a public FDA warning letter twenty months earlier, in August 2017. Teva was also the manufacturer FDA named when it posted the October 2022 Adderall shortage, citing "ongoing intermittent manufacturing delays."

Kenvue Acetaminophen

API GEOGRAPHY UNDISCLOSED

Granules India Limited, one of the world's largest acetaminophen API producers by its own account, received an FDA warning letter in February 2025 for its Hyderabad-area formulation plant. Kenvue's Shanghai subsidiary makes Tylenol only for the China market and holds no U.S. drug listings.

Par Health (formerly Mallinckrodt) Acetaminophen

DOMESTIC API

Its SpecGx unit - spun out of Mallinckrodt into the private company Par Health on November 10, 2025 - manufactures acetaminophen API at FDA-registered U.S. plants in North Carolina and Illinois — one of the few companies in this review with disclosed domestic API capacity.

Perrigo Acetaminophen and other generics

FINISHED DOSE + JV API (CHINA)

Perrigo's U.S. plants manufacture finished doses; API sourcing is not disclosed by country in SEC filings. Perrigo also runs a manufacturing joint venture in Zibo, China with a state-connected partner. FDA records show that joint venture, Zibo Xinhua-Perrigo Pharmaceutical Co. Ltd., is registered to supply ibuprofen's active pharmaceutical ingredient for the U.S. market.

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APPENDIX B

Federal Coverage Gaps

Across the eleven drugs examined in this report, federal supply-chain protection is measured against two verifiable programs: listing on the FDA's Essential Medicines List (Executive Order 13944) and coverage by a federal domestic-production initiative (Civica Rx, the Phlow Corporation/BARDA contract, or BARDA's BioMaP Consortium). A third potential column — the Strategic National Stockpile — is omitted because SNS composition is disclosed only in aggregate, never at the drug level.

No drug in this matrix receives full protection on both measures: heparin and dexamethasone are listed but covered only at finished-dose level through Civica; ciprofloxacin's coverage is partial on both measures. Listing on the Essential Medicines List, where it exists, resulted in a disclosed federal production program only for ciprofloxacin API.

TABLE B Federal coverage gaps: the stoplight matrix

DRUG	FDA ESSENTIAL MEDICINES LIST (EO 13944)	FEDERAL PRODUCTION INITIATIVE	RECOMMENDATION ADDRESSING THIS GAP
Metformin	**NOT LISTED** Excluded by design — EO 13944 covers only acute-care glycemic control (insulin, dextrose)	**NOT COVERED** Neither Civica Rx nor Phlow/BARDA includes metformin	Extend Essential Medicines List to chronic outpatient drugs; domestic production incentive program
Losartan	**NOT LISTED** No ARB class included in EO 13944	**NOT COVERED** Neither Civica Rx nor Phlow/BARDA includes losartan	Extend EML to chronic outpatient drugs; SEC material-risk / API-concentration disclosure
Acetaminophen	**LISTED** Oral antipyretic, API critical input — but PAP precursor dependency on China unaddressed	**NOT COVERED** Not on the Civica Rx list or in Phlow's pipeline; eligible under BioMaP but outside its stated antimicrobial/LVP preference, and no acetaminophen award has been announced.	Domestic production incentive program; targeted KSM/API tariffs
Amoxicillin	**LISTED** (countermeasure only) Listed under Biological Threat MCMs as "Amoxicillin/ liquid/oral / API only" - protected as an anthrax countermeasure only - not as a routine pediatric antibiotic.	**NOT COVERED** Not among the 53 presentations on Civica Rx's list; not named in Phlow/BARDA materials	Convert amoxicillin's countermeasure-only listing to routine-care status and add 6-APA as a critical input; domestic production incentive program (penicillin fermentation capacity)
Azithromycin	**LISTED** (injectable only) Listed as "Azithromycin / IV / API only"; the oral forms are not listed	**NOT COVERED** Not on Civica Rx list; eligible under BARDA BioMaP as a listed antimicrobial	Domestic production incentive program (fermentation infrastructure)
Ciprofloxacin	**LISTED** (countermeasure only) Listed under Biological Threat MCMs as "Ciprofloxacin HCl / liquid/oral / API only" - protected as a biodefense countermeasure, not as a routine-care antibiotic	**PARTIAL** (API ONLY) Not on Civica Rx list; but ciprofloxacin API is in Phlow's BARDA-funded pipeline - no finished-dose program	Convert countermeasure-only listings to routine-care status; fund and disclose the strategic API/KSM reserve

TABLE B Federal coverage gaps: the stoplight matrix (continued)

DRUG	FDA ESSENTIAL MEDICINES LIST (EO 13944)	FEDERAL PRODUCTION INITIATIVE	RECOMMENDATION ADDRESSING THIS GAP
Cisplatin & Carboplatin	**NOT LISTED** EO 13944's "Chemotherapeutic" category contains only cyclophosphamide	**NOT COVERED** Outside Phlow/BARDA scope; not in Civica Rx's oncology offerings	Extend EML to oncology; statutory FDA authority to require supply-chain diversification
Heparin	**LISTED** IV API + crude heparin listed — but two of the three U.S. API plants are Chinese-owned	**PARTIAL** (FINISHED DOSE ONLY) Civica RX lists heparin injection, made from the same foreign API base; no program addresses crude heparin or the API	Extend the strategic API reserve to animal-derived and extracted inputs, including crude heparin — which EO 13944 already names as a critical input; beneficial-ownership disclosure for U.S.-registered API sites.
Dexamethasone	**LISTED** On EML since 2020 — but zero confirmed API-level production programs	**PARTIAL** (FINISHED DOSE ONLY) Civica Rx lists dexamethasone injection; no program covers the API	Domestic production incentive program (shared corticosteroid intermediate)
Hydrocortisone	**LISTED** Same paper-protection pattern as dexamethasone	**NOT COVERED** Not on the Civica Rx list or in Phlow's pipeline; eligible under BioMaP, but no corticosteroid award has been announced.	Domestic production incentive program; corporate accountability (UK price-fixing precedent)
Ibuprofen	**LISTED** Oral antipyretic, API critical input	**NOT COVERED** Not on the Civica Rx list; not in Phlow's disclosed pipeline no BioMaP award announced	Domestic production incentive tied to sustaining existing U.S. API capacity (BASF, Bishop, TX)

184

APPENDIX C

Statutory Precedents for the Recommendations

Three of this report's recommendations don't require Congress to invent new regulatory authority — they extend frameworks Congress has already built, tested, and funded in other sectors. Each row below pairs an existing statute with the pharmaceutical-specific version of the same mechanism.

TABLE C No new machinery required: three existing statutory models

EXISTING FRAMEWORK	WHAT IS REQUIRED	PHARMACEUTICAL ANALOGUE	VEHICLE
Berry Amendment	10 U.S.C. § 4862 (recodified 2022; formerly § 2533a)	Bars DoD from using appropriated funds to buy covered items (textiles, food, other listed articles) unless grown, reprocessed, or produced in the U.S. Statutory exceptions and a DFARS 225.7002 waiver process already exist.	Domestic production incentive program for essential medicines, modeled on Civica Rx (the nonprofit generic manufacturer founded in 2018 by U.S. health systems) plus a Berry-style domestic-sourcing preference for federally procured drugs.
NDAA rider or standalone authorization; Armed Services precedent, Energy & Commerce / HELP implementation.	Dodd-Frank § 1502 / SEC Conflict Minerals Rule	17 C.F.R. § 240.13p-1; Form SD	Reasonable country-of-origin inquiry, supply-chain due diligence, and annual Form SD disclosure for conflict minerals sourced from the DRC/adjoining countries.
Mandatory country-of-origin disclosure for pharmaceutical APIs and key starting materials — due diligence plus disclosure, not a "certified clean" label (a labeling mandate was struck down as compelled speech in NAM v. SEC; the underlying disclosure obligation survived and remains in force).	SEC rulemaking under the Securities Exchange Act, or a standalone FDA-administered API-origin disclosure statute; Financial Services / Energy & Commerce jurisdiction.	Dodd-Frank Title I Stress Testing (DFAST)	12 U.S.C. § 5365; 12 C.F.R. Part 252 (Reg. YY)

Notes: The Berry Amendment was renumbered from 10 U.S.C. § 2533a to § 4862 effective January 1, 2022 (NDAA FY2021, Pub. L. 116-283). The Dodd-Frank conflict-minerals rule's due-diligence and disclosure requirements remain in force; only the compelled "conflict-free" labeling requirement was struck down (Nat'l Ass'n of Manufacturers v. SEC, D.C. Cir.). DFAST's statutory threshold and periodicity were narrowed by the Economic Growth, Regulatory Relief, and Consumer Protection Act of 2018.

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