

# CPA Comments on Section 232 National Security Investigation of Pharmaceutical Imports

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## I. National Security Risks

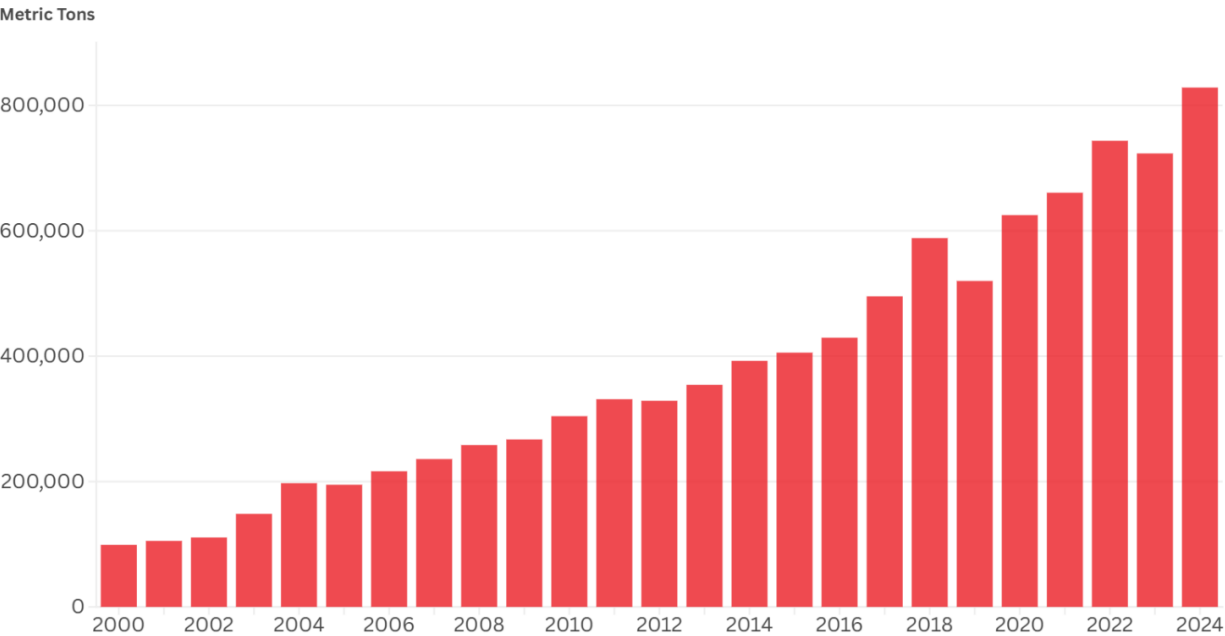
Overreliance on foreign pharmaceutical supplies—especially active pharmaceutical ingredients (APIs) and critical injectable drugs from China and India—poses a clear threat to U.S. national security. The U.S. Department of Defense (DoD) and healthcare system rely on 60 core medicines, yet an *alarming proportion* of these are made in highly concentrated global supply chains dominated by China and India. In fact, roughly 20% of these critical drugs have APIs [exclusively](#) from China, creating single points of failure. This overdependence is a strategic vulnerability: any geopolitical tension, export restriction, or factory disruption in those countries could [cripple](#) the availability of essential medicines in the United States.

### Dependence on Imports and Geopolitical Adversaries:

The U.S. is heavily import-dependent for most critical drugs. Total 2024 U.S. pharmaceutical imports reached over 828 thousand metric tons. This colossal import reliance is over 7 times higher than the import volume from 2000 and has resulted in a total \$118.3 billion pharmaceutical trade deficit for 2024.

### U.S. Pharmaceutical Imports Surging

Total 2024 Pharma Import Volume 7 Times Larger than 2000 Level



Source: U.S. Census Bureau

This massive import surge has left the country over-reliant on imports and given adversarial nations extensive leverage over our medicine supply. The U.S. currently imports [75%](#) of its essential medicines, with China and India playing outsized roles.

China is the dominant global source of APIs, from basic pain relievers to last-line antibiotics. China supplies an [estimated](#) 80–90% of the world's antibiotic APIs. This dominance is the result of decades of industrial strategy: China's government has specifically [targeted](#) and subsidized pharmaceutical chemical production, undercutting U.S. and European manufacturers and leading to offshoring. The risk is clear – if China halts exports, the U.S. would immediately face shortages in many vital medicines.

China [controls](#) 80% of the global supply of porcine-based heparin crude ingredient and [most](#) of the world's penicillin base. Any disruption—whether accidental or deliberate—such as COVID-era supply interruptions or export threats, would be devastating. This makes production reshoring and API source diversification essential. For example, developing a U.S. supply of bovine-based heparin is critical as a strategic redundancy to offset China's dominance in porcine-derived heparin.

Other countries (particularly India) also play significant roles in finished drug supply to the U.S. market. India supplies about [half](#) of the U.S.'s generic finished drugs. Indian pharmaceutical companies are key manufacturers of finished dosage forms for antibiotics, analgesics, and many of the drugs listed (amoxicillin, ciprofloxacin, labetalol, etc.). However, India [relies](#) on China for about 70–80% of its API and raw material [needs](#). For instance, Indian firms lead in formulating antibiotics, but China [provides](#) 80–90% of the bulk drug powder. This creates a cascading dependency: even “Indian-made” medicines often have extensive Chinese ingredients. The recent U.S. cisplatin shortage underscored this – an Indian company made the drug, but when it had issues, there were few alternative sources because upstream ingredients were limited and global capacity was constrained.

This concentration of production in a small number of countries enables hostile actors to “weaponize” exports and also makes the U.S. supply extremely volatile to global crises. During COVID-19, India [banned](#) exports of certain medicines to safeguard its own supply, and Chinese lockdowns [disrupted](#) shipping, both contributing to U.S. drug shortages. In a future crisis, China or any other supplier country could withhold critical drug components as an economic weapon. The House Select Committee on China has [warned](#) that this leverage is “a distinct national security risk.” The U.S. should not be in a position where an adversary can dictate our military and healthcare readiness by turning off the supply.

## Quality and Safety Concerns from Low-Quality Imports

Heavy dependence on foreign generics (particularly from India and China) has led to unsafe or substandard drugs reaching American patients, with little safer alternatives. [Results](#) from a 2025 medical study show that the risk of severe adverse events for generic drugs made in India was [54%](#) higher than for equivalent matched generic drugs made in the United States. Poor or falsified quality controls as well as operations and supply chain cost reduction efforts in foreign pharmaceutical facilities have compromised the drug quality and safety for all Americans.

The FDA has documented [criminal violations](#) of Good Manufacturing Practice (cGMP) regulations for pharmaceuticals in India, including falsifying safety data and test results.

These quality breaches are beyond just being a potential risk: one FDA [investigation](#) linked poor practices at Indian facilities to at least eight patient deaths in the U.S. and an outsized share of drug recalls. Similarly, China has a history of safety scandals (for example, the 2008 [heparin contamination](#) from China that killed dozens of Americans). Relying on foreign suppliers with spotty safety records heightens the risk that U.S. patients could use ineffective or dangerous medications and cedes extensive U.S. regulatory oversight. This is a security issue as much as a public health issue.

The national security and public health implications require a priority on stable and safe pharmaceutical supply. U.S. hospitals and consumers are more than willing to pay more for higher-quality, safer pharmaceuticals. A [2019 American Society of Health-System Pharmacists \(ASHP\) study](#) found:

- 87% of respondents who are involved with purchasing decisions rated manufacturer and product quality as very important.

- 59% would preferably buy products from manufacturers that meet a predefined quality standard – potentially addressing one of the major root causes of drug shortages.
- 85% would be willing to spend 5% or more above their annual generic injectable drug budget to buy from manufacturers that achieve quality recognition.

A 2023 Brookings [study](#) highlights the core incentive issue at the heart of the import quality issue: “Hospitals primarily consider the price of competing GSI products because they can neither observe drug quality directly nor do they carry the full burden of patient harm resulting from shortages. Price pressures, coupled with FDA’s inability to enforce strictly manufacturing quality standards, reduce a manufacturer’s commitment to good manufacturing practices. When manufacturing quality problems are uncovered, often after FDA inspections, recalls and production stoppages can lead to shortages.”

The misaligned incentive in the industry makes the need for import control and domestic production essential. The U.S. has better oversight, quality control, and sustainable supply with stronger domestic production capacity.

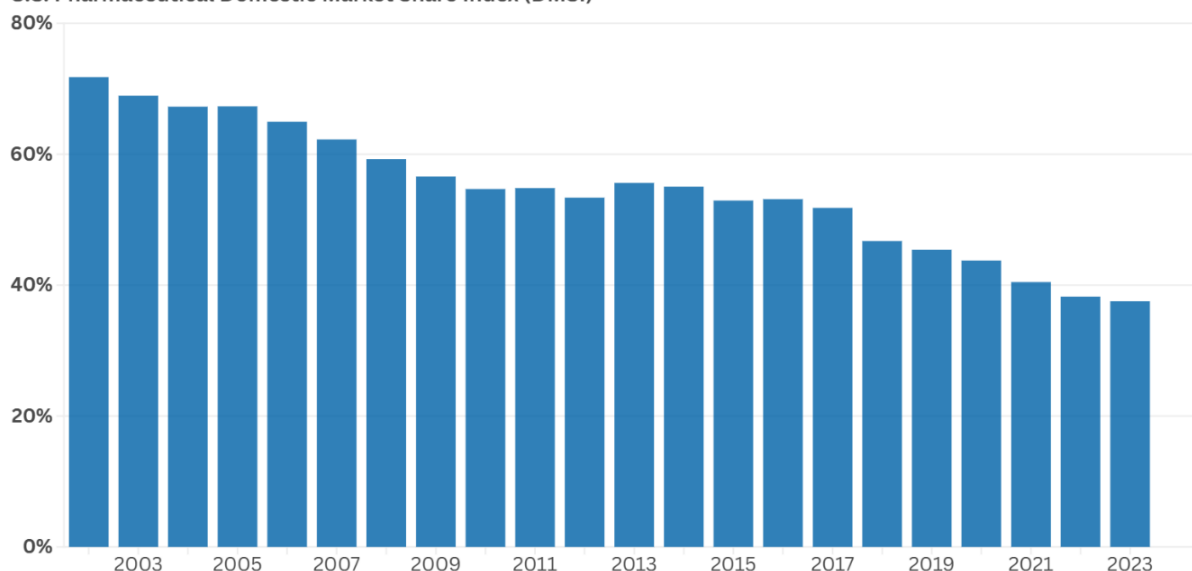
## Lack of Domestic Manufacturing Capacity

Over the past two decades, American pharmaceutical production has been hollowed out by imports, leaving the country unable to produce many vital drugs or ingredients. U.S. domestic manufacturing accounted for about 72% of our total pharmaceutical market in 2002, but only 37.5% by 2023 – a staggering 34 percentage point loss in market share. This fall is equivalent to an estimated \$113.9 billion loss in domestic production value in today’s value.

### Domestic U.S. Pharmaceutical Market Share Plummeting

U.S. Production Only Accounts for 37.5% of Total Pharma Demand (Even Less for Generics)

U.S. Pharmaceutical Domestic Market Share Index (DMSI)



Source: U.S. Bureau of Labor Statistics, U.S. Census Bureau

\*DMSI =  $1 - (\text{imports} / (\text{gross output} + \text{imports} - \text{exports}))$

*\*This DMSI calculation is based on U.S. Bureau of Labor Statistics [production data](#) and U.S. Census Bureau [import/export data](#).*

This means that the foreign producers control 62.5% of the U.S. pharmaceutical market by total value. The situation is even worse for generics and critical drugs and active ingredients. Currently no manufacturing source exists for more than 80% of the active ingredients in medicines the US Food and Drug Administration deems essential for public health, according to a new study from the [Center for Analytics and Business Insights \(CABI\) at Olin Business School](#). In practical terms, that means if foreign supplies were cut off, four out of five essential medicines have no U.S.-based source for patients in critical need. This includes basic generic antibiotics, critical care injectables, and even legacy drugs.

For example, the U.S. has not produced basic penicillin domestically [since 2004](#) when the last plant closed. This [last facility](#) in East Syracuse, NY produced nearly 70% of the world's penicillin supply until the 2000s.

Now that our production has been hollowed out, any foreign supply disruption would force the U.S. to scramble for less effective substitutes or simply go without crucial treatments altogether. The COVID pandemic offered a small preview of this vulnerability, when global supply chain disruptions led to shortages of sedatives, analgesics, and antibiotics needed for ventilated patients. A nation that cannot supply its own medicines is not fully sovereign or secure.

## Chronic Drug Shortages and Healthcare Impact

Because of the U.S.'s overreliance on vulnerable global supply chains and the consequential loss of domestic production capacity, U.S. hospitals have faced persistent drug shortages at increasingly unprecedented levels. According to an [American Hospital Association \(AHA\)](#) study, as of 2023, drug shortages reached a decade-high, with an average of 301 drugs in shortage per quarter (a 13% increase from 2022). Over 99% of hospital pharmacists reported shortages, and 85% called the shortages critically or moderately impactful. "Critically impactful" means shortages force rationing, delaying, or even canceling treatments, directly endangering patients. Recent shortages in critical drugs like the cancer drug [methotrexate](#) highlight this growing crisis.

Moreover, a 2019 [American Society of Health-System Pharmacists \(ASHP\) study](#) found more than half of respondents (57%) said shortages of antineoplastic (chemotherapy) drugs were critically impactful. The same study found extensive additional costs caused by widespread drug shortages in U.S. hospitals.

- Respondents who are involved in annual budgeting process estimated that drug shortages add between 5% and 20% to the budgets. Because of shortages:
  - 79% of respondents estimated a 6% or more increase in their drug budget.
  - 71% of respondents estimated between a 6% or more increase in their labor budget.

Managing drug shortages is a labor-intensive process. Operational and clinical drug shortage management strategies can divert time and resources away from clinical care in addition to the direct drug cost increase. In total, the [study](#) estimates the annual labor costs of drug shortages to U.S. hospitals is \$359 million. Worse yet, drug shortages cause 1% to 5% error rates in hospitals and 60% of the time drug shortages create unsafe conditions for patients.

In short, America's "cheap" import-reliant supply chains have resulted in higher costs, rationed care, and patient harm. This is a critical national security concern when our healthcare system cannot reliably provide lifesaving drugs.

## Economic and Strategic Costs

Beyond the direct health impact, losing our pharmaceutical industrial base has strategic economic ramifications. The domestic jobs and expertise in drug manufacturing have eroded, which in the long run weakens our innovation and workforce. Meanwhile, other countries (often through state subsidies) have built up massive overcapacity that drives drug prices to artificially low levels, undercutting U.S. producers. While low prices may seem beneficial, they conceal a hidden cost: fragile supply chains and sudden

price spikes when disruptions occur. Hospitals report paying [300-500% markups](#) for medicines on shortage, meaning the short-term “cheapness” of imports evaporates in a crisis. Furthermore, anticompetitive practices have been observed in the generics market, including foreign generic drug firms illegally [conspiring](#) to raise prices once they dominate supply. Relying on adversaries for cheap drugs has hollowed out our capacity, enriched foreign competitors, and left us paying dearly when things go wrong. Ensuring a stable domestic supply is thus not only a health imperative but also an economic security priority.

The United States’ overreliance on imported pharmaceuticals has created pervasive national security risks: life-saving treatments subject to shortage and rationing, exposure to substandard products, loss of control over critical medical supply lines, and vulnerability to hostile leverage. To protect American lives and military readiness, we must treat pharmaceutical supply reliance as the national security threat that it is.

## II. Supply Chain Mapping of 60 Critical Drugs

To illustrate the above risks, the table below presents 60 critical medicines (identified as essential to U.S. healthcare and DoD readiness) along with their primary API source countries, main manufacturing locations, and key supply chain vulnerabilities. This mapping reveals the concentrated and fragile nature of our medicine supply chains: for many of these drugs, a single country (often China) provides the bulk of the world’s API, with little to no backup. Many finished drugs are produced offshore as well, or by only one U.S. manufacturer, leaving no viable short-term fallback if any link in the chain fails.

### Table: Critical Drug Supply Chains and Risks

This table identifies 60 critical pharmaceutical products essential to U.S. military and civilian health security. Each entry includes the product class, generic drug name, API source and manufacturing location, and key supply chain risks.

Product Class	Drug (Generic)	API Origin and Manufacturing Location	Supply Chain Risk(s)
Catecholamine (vasopressor)	Epinephrine (IV)	API: Largely synthesized in India/China; Finished in U.S./EU	Relies on foreign API for emergency injectables; few suppliers and high demand. An estimated 90–95% of U.S. acute injectables depend on inputs from China/India, so any disruption threatens emergency care.



Catecholamine (vasopressor)	Norepinephrine (IV)	API: China/India (major producers); Finished in U.S. (hospitals)	Short shelf-life and few API suppliers. Often only 1-2 U.S. manufacturers, making supply highly vulnerable to outages.
Peptide hormone (vasopressor)	Vasopressin (IV)	API: China/India for peptide synthesis; Finished in U.S./EU	Complex peptide synthesis with limited GMP producers. Past shortages occurred after manufacturer consolidation in this niche field.
Anticholinergic (antidote)	Atropine (IV)	API: Historically plant-derived (belladonna); now synthetic mainly in China; Finished in U.S./Europe	2023 shortage due to manufacturing delays. API base is narrow; dependency on China increases risk.
Antiarrhythmic (Class III)	Amiodarone (IV)	API: Primarily India and China; Finished in U.S./India	Contains iodine – reliant on global iodine supply.  Sole API sources; any disruption can halt production.
Antiarrhythmic (Class IV)	Diltiazem (IV)	API: India/China; Finished in U.S.	Older generic; low-profit → few manufacturers. A single plant issue can create shortages.
Antiarrhythmic (Class V)	Adenosine (IV)	API: Synthetic (complex) – mainly in China; Finished in U.S./EU	Short half-life; high purity required.  API production is specialized; potential single-source risk.
Vasodilator (anti-anginal)	Nitroglycerin (IV)	API: China/India for chemical precursors; Finished in U.S./EU	Hazardous manufacturing process limits global facilities. Prior shortages due to plant issues.

Inotrope (cardiac stimulant)	Dobutamine (IV)	API: Few producers (e.g. India); Finished in U.S./EU	Short shelf life; single U.S. supplier at times. Plant outages or delays create vulnerability.
Inotrope/Pressor	Dopamine (IV)	API: China/India; Finished in U.S./EU	Commodity API, but few FDA-approved suppliers. Potential quality issues if sole source.
Opioid analgesic	Morphine (IV)	API: India/Australia; Finished in U.S./EU	Relies on opium crop harvests (geopolitical risk). Strict regulation limits number of suppliers. Past shortages when plants failed inspections.
Opioid analgesic	Fentanyl (IV)	API: China/India; Finished in U.S./Belgium	Few legitimate API sources. Factory issues could halt hospital supply. Potent opioid requires high safety.
Dissociative anesthetic / analgesic	Ketamine (IV)	API: India/Belgium; Finished in U.S.	Military-critical. Few global API producers. Past shortages from supply chain gaps.
Benzodiazepine (sedative)	Midazolam (IV)	API: China/India; Finished in U.S./Europe	High usage in critical care. Over 80% API imported. Domestic capacity limited.
Benzodiazepine (sedative/anticonvulsant)	Diazepam (IV/IM)	API: India/China; Finished in U.S.	Few API sources. Past recalls due to poor overseas quality. Antidote for nerve agent seizures.



Sedative anesthetic	Propofol (IV)	API: Germany/India; Finished in Europe/U.S.	Limited API facilities. Sole supplier incidents caused U.S. shortages. Complex formulation.
Neuromuscular blocker (depolarizing)	Succinylcholine (IV)	API: India/China; Finished in U.S.	Few global producers. Shortages threaten emergency care. Critical for intubation.
Neuromuscular blocker (non-depolarizing)	Rocuronium (IV)	API: India/Netherlands; Finished in U.S./Europe	Specialized synthesis. Supply disruptions impact surgery and ICU care.
Antidote (opioid antagonist)	Naloxone (IV/IM)	API: China/India; Finished in U.S./global	Essential antidote. Single-plant failures limit overdose response. High demand.
Antihistamine (H1 blocker)	Diphenhydramine (IV)	API: China/India; Finished in U.S.	Low-cost drug with limited suppliers. Outages cause shortages despite ubiquity.
Antidote (nerve agent antidote)	Pralidoxime (2-PAM) (IV/IM)	API: India/France; Finished in U.S./UK	Niche military-use product. Very few global API manufacturers. Readiness risk.
Anticoagulant (injectable)	Heparin (IV/SubQ)	API: China/Brazil/Europe; Finished in U.S./EU	80% of crude heparin from China. Vulnerable to animal disease and contamination. No U.S. supply.
Anticoagulant (LMWH)	Enoxaparin (SubQ)	API: China/France; Finished in U.S./EU	Same porcine supply risk as heparin. Shortfalls upstream threaten supply.

Antifibrinolytic (hemostatic)	Tranexamic Acid (IV)	API: China/India; Finished in U.S./EU	Few API producers. Mass casualty scenarios could exhaust limited supply.
Antidiabetic (hormone)	Insulin (injection)	API: U.S./Denmark/France; Finished in U.S./EU	Market concentration among 3 Western firms. Any plant issue poses national risk.
Corticosteroid (systemic)	Dexamethasone (IV)	API: India/China; Finished in U.S./India	Demand spikes (e.g. COVID) cause global shortfalls. Few API producers.
Corticosteroid (systemic)	Hydrocortisone (IV)	API: China/India; Finished in U.S./EU	Older drug. Low-profit margins reduce manufacturer incentive.
Diuretic (loop)	Furosemide (IV)	API: China/India; Finished in U.S.	Prone to shortages due to razor-thin margins. Few API producers.
H2-blocker (antacid)	Famotidine (IV)	API: China; Finished in U.S.	Concentrated API production. Demand spikes strain supply.
Proton-pump inhibitor	Pantoprazole (IV)	API: India/China; Finished in U.S./EU	Highly consolidated market. Few alternate therapies. Shortage-prone.
Antiemetic (5-HT3 blocker)	Ondansetron (IV)	API: India/China; Finished in U.S./UK	API quality recalls abroad. Disruption threatens chemo/post-op support.
Thyroid hormone replacement	Levothyroxine (oral)	API: China/Europe; Finished in U.S./India/China	Minimal U.S. API production. Single Chinese supplier dependence.

Analgesic/antipyretic	Acetaminophen (Paracetamol)	API: China (~70%); India (some); Finished in U.S./global	No U.S. API production. Highly reliant on China.  Any cutoff would empty shelves.
NSAID analgesic/ antipyretic	Ibuprofen (oral)	API: China/India; Finished in U.S./global	Pollution-heavy API production centralized in Asia. Prior shutdowns disrupted supply.
NSAID analgesic (injectable)	Ketorolac (IV)	API: India/China; Finished in U.S.	Low-profit injectable. Few suppliers.  Past shortages from plant lapses.
Antibiotic – Penicillin class	Amoxicillin (oral)	API: China/Austria; Finished in India/U.S.	China dominates API production. Recent pediatric shortages underscore fragility.
Antibiotic – Penicillin class	Ampicillin (IV)	API: China; Finished in U.S./India	Shared API source with amoxicillin. Risk cascades across related drugs.
Antibiotic – Penicillin/Beta- lactam + $\beta$ -lactamase inhibitor	Piperacillin-Tazobactam (IV)	API: China; Finished in U.S./India	2016 explosion at Chinese API plant caused global crisis. Supply still concentrated.
Antibiotic – Cephalosporin	Ceftriaxone (IV)	API: China/India; Finished in U.S./India	Complex semi-synthesis. No U.S. API production.  Past quality failures abroad.
Antibiotic – Glycopeptide	Vancomycin (IV)	API: China/India; Finished in U.S.	No U.S. fermentation capacity. China dominant. Critical MRSA treatment at risk.

Antibiotic – Tetracycline	Doxycycline (oral/IV)	API: China/India; Finished in India/U.S.	China controls tetracycline base. Past price spikes, shortages highlight risk.
Antibiotic – Macrolide	Azithromycin (oral/IV)	API: China/India; Finished in India/U.S.	Supply swings common. API complexity and Asia dependency raise risk.
Antibiotic – Fluoroquinolone	Ciprofloxacin (oral/IV)	API: India/China; Finished in India/EU	Indian API relies on Chinese precursors. Supply chain interruptions cascade.
Antibiotic – Carbapenem	Meropenem (IV)	API: China/India; Finished in U.S./India	Last-line drug. Few producers. Regulatory shutdowns have caused shortages.
Antibiotic – Sulfonamide combo	Trimethoprim-Sulfamethoxazole	API: China/India; Finished in U.S./India	Old generic. Few API sources. Export restrictions/quality lapses impact supply.
Antibiotic – Nitroimidazole	Metronidazole (IV/oral)	API: China/India; Finished in U.S./India	Supply sensitive to Chinese environmental regulation. Prone to chronic shortage.
Antibiotic – Aminoglycoside	Gentamicin (IV/IM)	API: China/India; Finished in U.S./Europe	Fermentation-based. Cold chain. China dominates. Global shortage risk.
Antibiotic – Lincosamide	Clindamycin (IV/oral)	API: China/Eastern Europe; Finished in U.S./India	Major 2022 shortage due to Indian plant shutdown. Few alternate sources.
Antibiotic – Penicillin (long-acting)	Penicillin G (Benzathine)	API: China; Finished in U.S.	Only one U.S. supplier. Single API source. Global shortage occurred in past.

Immunosuppressant (calcineurin inhibitor)	Tacrolimus (oral)	API: China/Japan; Finished in U.S./India	Organ transplant survival drug. Single-country API risk. No easy substitute.
Anticonvulsant	Levetiracetam (IV/oral)	API: India/China; Finished in U.S.	Indian API depends on Chinese precursors. Shortages force inferior alternatives.
Beta blocker (cardiovascular)	Metoprolol (IV/oral)	API: China/India; Finished in U.S./EU	>80% API imported. Low-margin generic. Past shortages.
ACE Inhibitor (cardiovascular)	Lisinopril (oral)	API: China/India; Finished in U.S./India	Offshore supply chain. No U.S. fallback. Alternate therapies not equivalent.
Antibiotic – Rifamycin	Rifampin (oral)	API: India/China; Finished in India	Indian API relies on China for precursors. TB therapy jeopardized by export bans.
Chemotherapy (oncology)	Cisplatin (IV)	API: India/China; Finished in India/U.S.	Oncology crisis in 2023. Limited producers. Supply relies on vulnerable mines.
Chemotherapy (oncology)	Carboplatin (IV)	API: India/China; Finished in India/U.S./EU	Sister to cisplatin. Few API sources. No U.S. API capacity.
Chemotherapy (oncology)	Vincristine (IV)	API: India/China (plant source); Finished in U.S.	2019 shortage from manufacturer exit. No redundancy. Pediatric cancer essential.
Tocolytic / Antiseizure (OB & cardiac)	Magnesium Sulfate (IV)	API: China/Russia; Finished in U.S.	Simple mineral salt. Dependent on imported raw materials. U.S. capacity limited.

Oxytocic (uterotonic)	Oxytocin (IV/IM)	API: China/India/EU; Finished globally	Cold chain required. 2021 API issue caused global shortage. Peptide synthesis bottleneck.
Bronchodilator (respiratory)	Albuterol (Salbutamol)	API: China/India; Finished in U.S.	2023 U.S. supplier bankruptcy. API delays from China. Millions depend on it.
Anticoagulant (alternative API)	Bovine-based Heparin	Potential U.S. production; formerly Brazil/U.S.	Not yet widely FDA-approved; domestic production limited but strong potential; needed for strategic redundancy against China-sourced porcine heparin.
Anticoagulant (oral)	Warfarin	India/China; Finished in U.S.	Low-margin generic with few manufacturers; limited global sources; narrow therapeutic index increases risk from disruptions.
Antimetabolite (oncology/immunosuppressant)	Methotrexate	India/China; Finished in U.S.	Injectable shortages have disrupted pediatric oncology care; imports have caused low profitability and limited producers.
Antidiabetic (oral)	Metformin	China/India; Finished in U.S.	High-volume drug with no U.S. API production; prior recalls for contamination; global shortages could affect millions.
Benzodiazepine (sedative/anticonvulsant)	Lorazepam	India/China; Finished in U.S.	Injectable form critical for ER use; few global producers; vulnerable to plant shutdowns.
Corticosteroid (systemic)	Betamethasone	China/India; Finished in U.S./EU	Essential for preterm labor; narrow supply base; no U.S. API production.

Antidote (gastrointestinal decontaminant)	Activated Charcoal	China/India; Finished in U.S.	Raw material and processing mostly offshore; emergency use drug with few approved suppliers.
Buffer/alkalinizing agent	Sodium Bicarbonate (IV)	India/China; Finished in U.S.	Low-profit injectable; vulnerable to shortages; essential in cardiac arrest and acidosis treatment.

**Key patterns:** This table underscores how China (and to a lesser extent India) dominate the supply of critical drug components, while the U.S. and allies play a much smaller role in API production. Many drugs listed have no U.S.-based API production at all, and often only one or two foreign sources. A single factory accident (e.g. the [piperacillin-tazobactam explosion](#)) or a disease outbreak in animals (e.g. swine fever affecting heparin raw material) can disrupt the entire global supply of a drug, with no quick fix for the U.S. Notably, [40%](#) of U.S. generic drugs have only one FDA-approved manufacturer, meaning even finished drug production is frequently a single-source vulnerability. The above examples of shortages (amoxicillin, vincristine, cisplatin, etc.) show that the lack of redundancy is not hypothetical – it has already led to crises in patient care. The United States' medicine supply is precariously concentrated in the hands of a few foreign actors, which is incompatible with the resiliency needed for national security.

### III. Policy Solutions to Mitigate Supply Risks

To address these vulnerabilities, the United States must pursue a multi-pronged strategy to rebuild a secure and resilient pharmaceutical supply chain. Section 232 trade measures must apply to both active pharmaceutical ingredients (APIs) and finished drug products to be effective in restoring national pharmaceutical security. Limiting only finished drug imports while allowing continued reliance on foreign APIs—particularly from China and India—would still leave the U.S. dangerously exposed to the same upstream chokepoints that currently fuel shortages, safety risks, and geopolitical vulnerability. Most finished drugs, even those labeled “Made in USA,” are assembled with foreign-made APIs; if those ingredients are disrupted, domestic fill-finish capacity becomes irrelevant. A comprehensive Section 232 action must therefore cover both API and finished formulations to address the full scope of supply chain fragility, reduce single-source dependency, and support the rebuilding of an integrated U.S. pharmaceutical manufacturing base.

#### Decoupling from High-Risk Suppliers

The U.S. should immediately reduce dependency on China and India for pharmaceuticals, especially for essential drugs and APIs. This means effective and comprehensive trade restrictions to divert short-term supply and actively incentivizing domestic manufacturing of critical drug ingredients – akin to how the CHIPS Act bolstered U.S. semiconductor fabs. Federal support (grants, tax credits, advanced purchase contracts) can help offset the cost advantages that Chinese and Indian producers currently enjoy and jumpstart U.S. domestic production, bringing supply of key antibiotics, analgesics, and other vital drugs back onshore. A stronger U.S. pharmaceutical base would ensure we can meet military and civilian needs even if foreign supplies are cut off. It also creates high-quality jobs and restores industrial capability. Fundamentally, strategic medicines should be treated akin to strategic materials – where domestic capacity is a matter of national security.



## Gradual Import Quotas and Controls

A finding that imports of pharmaceuticals and APIs are threatening national security would enable the deployment of strategic quota allocation to limit import sources from more reliable sources, while also boosting the incentive for domestic production. A quota system (phased and product-specific) could limit the import penetration of Chinese and Indian imports in particular, while also giving necessary certainty to existing and new U.S. manufacturers about total import volumes while domestic capacity scales up. These quotas can be tightened over several years as U.S. production comes online. Quotas send a clear market signal that overreliance will be curtailed, encouraging investment in U.S. and allied production. They also serve as a national security buffer—ensuring a minimum portion of supply is sourced domestically or even from allies vulnerable to supply disruptions.

This is not a novel concept in U.S. trade policy. For example, the United States Department of Agriculture has awarded sugar import quota to select countries based on forecasted estimates of U.S. sugar production. A “tariff rate quota” (TRQ) is used, with a lower in-quota rate that acts as a revenue tariff, and a higher over-quota rate that is protective against further commercial imports.

The quotas should be structured carefully to avoid immediate shortages, for example through “Ally-Shoring” and diversification of sources. The U.S. should pivot short-term pharmaceutical supply to coordination with foreign nations where both domestic oversight agencies, as well as U.S. law enforcement, have a history of close and successful collaboration and mutual recognition of quality standards, as U.S. domestic production capacity is scaled up. For example, if certain antibiotics can be procured from European manufacturers instead of China, quota should favor those sources. This would substantially de-risk U.S. pharmaceutical supply in the short-term as U.S. supply increases in the long-term. “Ally-shoring” builds resilient supply chains with nations that share our safety and security values, reducing the leverage of any single foreign player.

## Gradual Tightening of Quotas with Domestic Capacity Growth

The import quotas and other import restrictions should tighten and decrease in-quota volume over time in parallel with the expansion of U.S. production. Planned adjustments in import quota should be set far in advance to allow manufacturers to adjust accordingly. Initially, quotas might be set relatively high to avoid supply shocks (albeit shifting to trusted import sources), but with clear benchmarks to tighten them as new U.S.-based plants become operational. For instance, after 2–3 years of incentives, if a domestic factory for a key API comes online, the allowed import volume for that API could be reduced accordingly. This graduated approach ensures that we do not inadvertently cause shortages while still maintaining pressure to reshore production. With clear long-term guidance, it also gives industry a predictable timeline: companies know that by Year X, imports will be limited to Y%, so investing in U.S. capacity by that date is financially sensible. The end goal would be a substantial domestic share of production for essential drugs and diversified imports for the remainder, achieved over a defined period. Throughout this process, periodic reviews should assess market conditions to adjust quotas or provide emergency exemptions if needed to prevent any unintended harm to patients.

In addition to the above, the U.S. government can employ complementary measures such as establishing a Strategic Active Pharmaceutical Ingredient Reserve (stockpiling critical APIs and chemicals, similar to the petroleum reserve), using the Defense Production Act to address urgent shortfalls (as was done during COVID-19 for certain medical supplies), and expanding the FDA’s priority review and fast-track approvals for domestically made generics to speed their entry to market. Federal procurement (DoD, VA, HHS) should also adopt a “Buy American” preference for, to create guaranteed demand for U.S.-made products.

By gradually decoupling from adversarial sources, rebuilding domestic manufacturing capacity, and ally-shoring production with trusted partners, the U.S. can mitigate the serious national security risks posed by the current import reliance (particularly on China). These measures chart a path toward a resilient, sovereign pharmaceutical supply that puts American patients and service members first.

## IV. Responses to Section 232 Investigation Questions

The Department of Commerce has posed specific questions as part of the Section 232 National Security Investigation into pharmaceutical imports. Below are responses to each, incorporating data from the above analysis and relevant reports:

### (i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

The United States is the world's largest consumer of pharmaceuticals, with demand already at unprecedented levels—and still rising.

In 2024, the total U.S. pharmaceutical market was valued at [\\$634.32 billion](#) and is expected to grow at a compound annual growth rate (CAGR) of 5.72%, reaching an estimated \$883.97 billion by 2030. Generic drugs alone accounted for [90%](#) of total prescriptions filled and a total value of [\\$139.03 billion](#) in 2024, with forecasts predicting growth to \$231.69 billion by 2034 at a CAGR of 5.24%.

This growth is being driven by an aging population, an increase in chronic diseases, and the steady expansion of treatment options for conditions like cancer and diabetes. A key factor is the [47% increase](#) expected in the senior population over the next 25 years—an age group that consumes far more medication than younger cohorts. Increasing demand for and importance of pharmaceuticals and pharmaceutical ingredients in the United States is massive and structurally entrenched in long-term demographic and health trends. This surging need places a premium on securing a resilient, domestic pharmaceutical supply chain capable of supporting both public health and national security.

### (ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

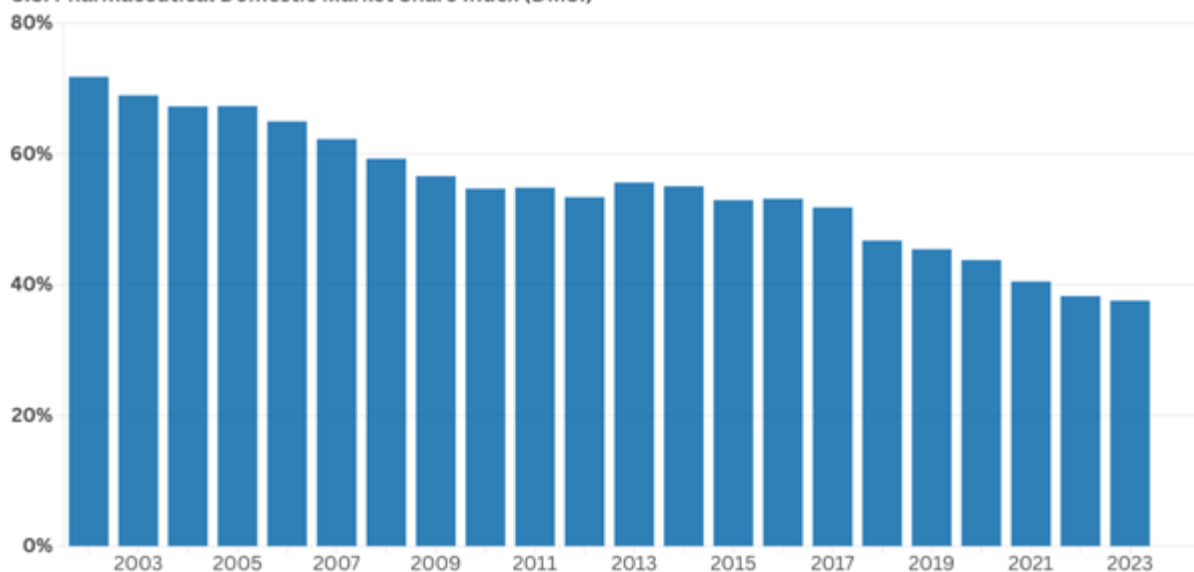
Domestic pharmaceutical manufacturing capacity currently meets only a fraction of U.S. demand, leaving the nation heavily reliant on imports. Decades of offshoring have eroded the U.S. industrial base in both finished drugs and Active Pharmaceutical Ingredients (APIs).

U.S. domestic manufacturing accounted for only 37.5% of our total pharmaceutical market in 2023. This represents an alarming 34 percentage point loss in market share (down from a 72% market share in 2002), equivalent to a \$113.9 billion loss in domestic production value in today's value.

## Domestic U.S. Pharmaceutical Market Share Plummeting

U.S. Production Only Accounts for 37.5% of Total Pharma Demand (Even Less for Generics)

U.S. Pharmaceutical Domestic Market Share Index (DMSI)



Source: U.S. Bureau of Labor Statistics, U.S. Census Bureau  
 \*DMSI =  $1 - (\text{imports} / (\text{gross output} + \text{imports} - \text{exports}))$

*\*This DMSI calculation is based on U.S. Bureau of Labor Statistics [production data](#) and U.S. Census Bureau [import/export data](#).*

Even for medicines formulated or finished in the U.S., the underlying ingredients are overwhelmingly imported, meaning domestic “production” often consists only of final tablet pressing or packaging. No U.S. manufacturer exists for [over 80%](#) of the active ingredients deemed essential by the FDA for public health. In practical terms, if foreign supplies were cut off, four out of five essential medicines would have no U.S.-made source – a perilous gap in capability.

Critical drug categories illustrate and underscore this downfall. For example, the U.S. has not produced basic penicillin domestically [since 2004](#) when the last plant closed. This [last facility](#) in East Syracuse, NY produced nearly 70% of the world's penicillin supply until the 2000s.

Current U.S. manufacturing cannot on its own supply the nation's pharmaceutical needs. Absent foreign inputs, hospitals and pharmacies would face immediate shortages. This reality underscores that domestic capacity must be significantly expanded to assure a self-sufficient supply; at present, the United States is far from able to meet its pharmaceutical demand with domestic production alone.

### **(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;**

The U.S. is extensively reliant on foreign supply chains in meeting domestic demand. Total 2024 U.S. pharmaceutical imports reached over 828 thousand metric tons. This colossal import reliance is over 7 times higher than the import volume from 2000. As

of 2023, total U.S. pharmaceutical market is dominated by imports at 62.5% of total value according to Domestic Market Share Index calculations.

This import reliance is even more concentrated with generic drugs, Active Pharmaceutical Ingredients (APIs), and other critical inputs. The vast majority of medicines used by Americans rely on foreign production at some stage. The U.S. currently imports [75%](#) of its essential medicines, with China and India playing outsized roles.

China is the dominant global source of APIs, from basic pain relievers to last-line antibiotics. China supplies an [estimated](#) 80–90% of the world's antibiotic APIs. Roughly 20% of critical drugs have APIs [exclusively](#) from China, creating single points of failure.

India produces about [50%](#) of the generic drugs the U.S. imports while relying heavily on China for 80% of its active pharmaceutical ingredients (APIs). For instance, Indian firms lead in formulating antibiotics, but China [provides](#) 80–90% of the bulk drug powder. In effect, “even ‘Indian-made’ medicines often have extensive Chinese ingredients, creating a cascading dependency that compromises U.S. supply chain security.

#### **(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;**

U.S. pharmaceutical imports are highly concentrated in a small number of source countries and even single suppliers, which poses serious national security risks. China and India together dominate many supply lines, meaning a disruption in either country can have an immediate and sweeping impact on U.S. medicine availability.

China alone controls about [80%](#) of the world's supply of heparin's raw ingredient (porcine intestinal mucosa) and essentially all global production of certain penicillin precursors. This level of concentration means that any event in China – from a factory accident to a geopolitical conflict – could choke off the lifeline for critical drugs worldwide.

Likewise, India has become a sole or primary source for numerous finished generic drugs that Americans rely on daily. The dangers of such dependence became clear in 2023, when a single Indian pharmaceutical plant's [shutdown](#) caused a U.S. cancer drug crisis. An FDA inspection uncovered egregious quality failures at an Intas Pharmaceuticals factory in Gujarat – a facility that made around 50% of the U.S. supply of the chemotherapy drug cisplatin.

When production halted, cisplatin and related oncology drugs fell into shortage across the United States, as other manufacturers could not quickly compensate for the lost capacity. Hundreds of thousands of cancer patients were forced to delay or switch treatments because one overseas plant had been a lone source.

This example underscores how fragile and centralized the supply chain can be, even for lifesaving medicines. Beyond cisplatin, numerous drugs have only one or two qualified producers globally, many of them abroad. The U.S. has faced recurring [shortages](#) of saline IV fluids, anesthetics, and antibiotics after single foreign factories encountered problems. Heavy import concentration amplifies every risk – whether it be a natural disaster, a pandemic, or deliberate export bans. When 80–90% of a drug's supply comes from one country or one facility, any disruption can leave the U.S. with no quick alternative. Thus, the current concentration of imports in a few foreign sources creates a brittle supply chain, lacking the redundancy and resilience that national security demands.

## **(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;**

Foreign government subsidies and predatory trade practices by China and India have severely undermined the competitiveness of the U.S. pharmaceutical industry, particularly in generics and active pharmaceutical ingredients (APIs).

China's pharmaceutical sector has benefited from a wide array of state subsidies. These include export-contingent grants, tax rebates, subsidized infrastructure, and support through industrial policy initiatives like "Made in China 2025," which prioritizes biopharmaceuticals. The U.S. successfully challenged China's Demonstration Bases-Common Service Platform program at the WTO in 2015 for offering [prohibited export subsidies](#) to pharma and chemical exporters. Yet China [continues](#) to offer indirect subsidies, especially via Made in China 2025 initiatives, encouraging pharmaceutical overcapacity through low-cost land, power, and tax incentives.

India similarly offers [production subsidies](#) through its Production Linked Incentive (PLI) scheme, which provides 10–20% of incremental sales value to domestic API and formulation producers. India also launched a Bulk Drug Parks program that pays up to [90%](#) of infrastructure costs to reduce input prices for key pharmaceutical manufacturing regions.

These subsidies have empowered Chinese and Indian firms to dominate the U.S. market. The U.S. currently imports [75%](#) of its essential medicines, with China and India leading the import surge. The foreign subsidies led to a long-term decline in the U.S. pharmaceutical domestic market share. U.S. domestic manufacturing accounted for about 72% of our total pharmaceutical market in 2002, but only 37.5% by 2023 – a staggering 34 percentage point loss (equivalent to \$113.9 billion in today's value).

The influx of subsidized imports directly contributed to the shutdown of numerous U.S. pharmaceutical facilities, including the [Akorn](#) plant in Decatur, Illinois. In February 2023, Akorn abruptly ceased operations across all four of its manufacturing sites, resulting in the loss of 400 jobs at the Decatur facility alone. Similarly, China cornered the global penicillin market by the early 2000s by selling inputs far below cost, causing the last U.S. plant to [close](#) in 2004.

Combined, these foreign subsidy practices have decimated U.S. production capacity, eroded supply chain security, and eliminated thousands of middle-class jobs. Without relief, the U.S. pharmaceutical sector risks becoming permanently dependent on foreign adversaries.

## **(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;**

Artificially suppressed prices driven by unfair foreign trade practices and state-sponsored overproduction by China and India have economically destabilized the U.S. pharmaceutical manufacturing base.

In China, massive state investment and export incentives have led to overcapacity in APIs like penicillin, cephalosporin, and vitamin C. Chinese producers, often operating with local government support and reduced input costs, flooded global markets with ultra-cheap products—sometimes below cost—to force out competitors. The U.S.–China Commission (USCC) [found](#) that “the United States is losing its ability to produce generic drugs because Chinese drug companies dumped low-price products into the global market.” China's unfair trade practices have already consolidated substantial control. China supplies an [estimated](#) 80–90% of the world's antibiotic APIs, [controls](#) 80% of global heparin's crude ingredient, and now produces [most](#) of the world's penicillin base ingredients.

India, meanwhile, built massive generic drug and API production capacity aimed at exports. The Indian government [subsidizes](#) production through the PLI and Bulk Drug Parks schemes, encouraging output growth even in the absence of market demand. This

allows Indian manufacturers often bid below sustainable pricing levels to secure U.S. supply contracts and push out domestic U.S. producers.

These dynamics result in globally suppressed prices. Generic drug prices in the U.S. have fallen so low that production has become [unsustainable](#) for many manufacturers, leading to widespread shortages. This artificially low pricing has also created systemic fragility. U.S. hospitals face frequent [shortages](#) of cheap, off-patent generics because foreign suppliers, having displaced U.S. producers, often lack the reliability or surge capacity in times of crisis.

These suppressed prices also misalign incentives in the healthcare system and often lead to quality issues. A 2023 Brookings [study](#) highlights how the current import dependent pharmaceutical market “does not reward quality and reliability”. Instead, “Hospitals primarily consider the price of competing GSI products because they can neither observe drug quality directly nor do they carry the full burden of patient harm resulting from shortages. Price pressures, coupled with FDA’s inability to enforce strictly manufacturing quality standards, reduce a manufacturer’s commitment to good manufacturing practices.”

Without trade remedies, these artificially suppressed prices will continue to hollow out the domestic pharmaceutical sector, making future resilience, independence, and quality control impossible.

### **(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;**

America’s heavy dependence on foreign pharmaceutical sources exposes it to the risk that a foreign nation could restrict exports of medicines as a geopolitical weapon. This scenario is not theoretical – U.S. officials and experts have been warning about it openly. In 2019, as U.S.-China trade tensions grew, Chinese state media [suggested](#) that Beijing could halt exports of antibiotics and other drugs to the U.S. to “squeeze” America if hostilities worsened. This is a risk that medical industry experts are already [warning](#) about.

Such threats echo China’s increasing use of export restrictions (such as with [rare earth minerals](#)) as leverage against the United States, and they underscore that pharmaceuticals could similarly be “weaponized” in a conflict or trade war. The U.S. reliance on China for key medicines is so extensive that this leverage is real and poses a substantial long-term risk. For example, China supplies an [estimated](#) 80–90% of the world’s antibiotic APIs, and China is a leading (often sole) supplier of many vitamins, pain relievers, and chemotherapy ingredients. Roughly 20% of critical drugs have APIs [exclusively](#) sourced from China, creating single points of control.

If those supplies were suddenly cut off, American hospitals could run out of critical drugs within months or even weeks. The potential for export bans is also not limited to China. In early 2020, India – another major U.S. supplier – [imposed export restrictions](#) on 26 essential drugs and ingredients (including acetaminophen, several antibiotics, and hormones) amid the COVID-19 outbreak. India’s temporary ban sent shockwaves through the U.S. market and foreshadowed what a broader embargo might look like. This incident revealed how quickly a country the U.S. overly relies on can halt medicine shipments in any kind of crisis.

The national security implications of these risks are severe. In a geopolitical confrontation or global crisis, the U.S. could find its medical supply at the mercy of a strategic rival. A foreign power could deliberately withhold pharmaceuticals to cripple the U.S. healthcare system and military operations, knowing that alternatives are limited and slow to scale up. The U.S. House Armed Services Committee has already [warned](#) that “overreliance on China in critical supply chains, particularly in the defense sector, creates significant strategic and competitive risk for the United States.” Likewise, the [Defense Department](#) has “identified that 54% of the DoD pharmaceutical supply chain is considered either high or very high risk” and that “DoD has a high dependence on foreign material and trade agreements to maintain current pharmaceutical capabilities.”

The ability of foreign nations to cut off pharmaceutical exports – whether for economic advantage or strategic coercion – represents a grave risk to U.S. national security. This risk is magnified by the lack of domestic stockpiles or fallback production for many drugs. Any serious disruption could jeopardize care for civilians and incapacitate the military's medical logistics. Reducing import dependence is thus critical to neutralize this potential weapon.

### **(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;**

Rebuilding America's pharmaceutical manufacturing capacity is entirely feasible with sustained trade policy commitment and subsequent investment. The U.S. retains significant strengths, including advanced technology, an innovation-driven private sector, and a skilled workforce. These advantages can be marshaled to expand domestic drug production when paired with an appropriate trade policy.

Strong trade policy can substantially boost domestic capacity by signaling long-term support and incentive for domestic investments. Looming tariffs have already had this effect for pharmaceutical manufacturing in 2025, with many major companies announcing large investments and production expansions.

- [Merck](#) initiated construction on a \$1 billion, 470,000-square-foot biologics facility in Wilmington, Delaware, designed to produce its leading cancer drug, Keytruda, and other biologic therapies.
- [Eli Lilly](#) announced a \$27 billion investment to build four new U.S. mega-sites for active pharmaceutical ingredients and injectables, creating 3,000 permanent jobs.
- [Johnson & Johnson](#) broke ground on a \$55 billion U.S. expansion including a major biologics facility in North Carolina, expected to generate 500 jobs and a \$3 billion local economic impact.
- [Novartis](#) committed \$23 billion over five years to build six new U.S. manufacturing plants and a San Diego research hub, aiming to produce all key medicines domestically.
- [Roche](#) committed \$50 billion to expand U.S. manufacturing and R&D across multiple states, targeting gene therapy and cardiometabolic treatments while creating over 12,000 jobs.
- [AbbVie](#) pledged over \$10 billion to grow its U.S. manufacturing footprint, focusing on scaling production of complex biologics and advanced therapies.
- [Novo Nordisk](#) announced a \$4.1 billion investment to build a North Carolina facility for expanding production of its diabetes drugs.

These examples show that with the right incentives, domestic manufacturing can grow substantially with major private sector support and investment.

The feasibility is further reinforced by policy proposals currently on the table. The Department of Health and Human Services, in a 2024 [report](#) on drug shortages, recommended incentivizing domestic production of key drugs and ingredients as a core solution. Congress is actively considering measures such as tax credits for API and final drug production and grants for building or modernizing plants. These supports could offset the cost disadvantages that have historically driven production offshore and accelerate the expansion of domestic production.

The COVID-19 pandemic response proved U.S. companies can rapidly stand up vaccine production when incentivized; the same can be true for generic drugs and APIs. In fact, the Defense Production Act has already been invoked to [boost production](#) for critical drug components domestically. With strategic investment and coordination, the U.S. can begin to markedly increase domestic production, reducing import reliance and enhancing supply chain resilience.



**(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and**

Current U.S. trade policies have been the primary cause of the surge in pharmaceutical imports and the steady decline of domestic pharmaceutical manufacturing. For decades, the U.S. has maintained essentially zero barriers on imported drugs and active pharmaceutical ingredients (APIs), even for essential and life-saving medicines. Meanwhile, key foreign suppliers—most notably China and India—have aggressively subsidized their pharmaceutical sectors, allowing them to flood the U.S. market with low-cost, often lower-quality products that undercut American manufacturers. This combination of unilateral trade openness and foreign industrial policy has driven the offshoring of U.S. production capacity, degraded supply chain resilience, and exposed American patients to quality risks and geopolitical vulnerabilities.

Today, the U.S. pharmaceutical trade deficit has reached a staggering \$118.3 billion (as of 2024), and domestic producers now supply only 37.5% of the U.S. market, compared to 72% in 2002. This collapse is not the result of inefficiency or lack of innovation, but the consequence of deliberate policy choices that have favored global supply chains over domestic production. Even critical drugs—such as antibiotics, cancer treatments, and insulin—face no meaningful trade protections or domestic sourcing requirements.

The COVID-19 pandemic and subsequent supply chain disruptions revealed the dangerous fragility of this system, yet policy has failed to change course. Continuing this approach is not only economically unsustainable but a direct threat to national security. The United States cannot afford to rely on adversarial or unstable foreign regimes for core components of its public health system.

To reverse this strategic decline, the U.S. must implement robust trade measures, including targeted tariffs, quotas, and local content requirements for essential medicines and ingredients. These actions can be paired with federal procurement reforms, domestic production incentives, and stricter import standards to ensure quality and safety. Only by restoring a competitive domestic pharmaceutical base can the U.S. guarantee secure access to life-saving treatments, reduce its trade deficit and import dependence, and effectively protect the health of its citizens in times of crisis.

**(x) any other relevant factors.**

Beyond the core economic and trade aspects, quality assurance, transparency, strategic stockpiling, workforce readiness, and military requirements are all crucial pieces of the national security pillars as it relates to pharmaceuticals. Addressing these factors will enhance the effectiveness of any measures taken under Section 232.

- **Drug Quality and Safety:** Outsourcing production abroad can introduce serious quality control issues, which become a national security concern if substandard medicines reach troops or the public. The FDA has documented frequent [violations](#) of Good Manufacturing Practices at foreign plants, including data fraud and contamination problems, especially in parts of India and China. Another notorious example occurred in 2008 when [contaminated heparin](#) sourced from China led to dozens of American patient deaths. When the U.S. must depend on overseas manufacturers, it effectively cedes a degree of oversight. This raises the risk that in a critical moment, medicines might be ineffective or harmful. Ensuring quality is thus a security issue; a domestically controlled supply would allow far stricter oversight and confidence in the medicines given to military personnel and civilians.
- **Supply Chain Transparency:** The pharmaceutical supply chain suffers from poor transparency. Manufacturers are not currently required to disclose API source countries on drug labels, and in many cases even U.S. regulators and

purchasers have limited visibility into upstream supply. The Department of Defense recently found that for about [22%](#) of essential drugs, the country-of-origin of their ingredients could not be determined. This opacity is a risk factor – if you don't know where your critical inputs come from, you cannot fully assess or mitigate vulnerabilities. Improving data on supply chain provenance (through reporting requirements or tracking systems) is an important supporting measure to manage national security risks.

- **Stockpiles and Surge Capacity:** Mitigating import risks also involves having buffer stocks and surge manufacturing capacity for essential medicines. Currently, the Strategic National Stockpile holds only a [limited](#) selection of drugs, and stockpile levels for many crucial medications are insufficient for a prolonged disruption. Expanding strategic stockpiles of antibiotics, antivirals, and other mission-critical drugs is a relevant factor to cushion short-term shocks. In parallel, maintaining robust potential capacity that can be ramped up in an emergency is a strategy used for other strategic materials that could be applied to pharmaceuticals.
- **Workforce and Know-How:** The decline of U.S. drug manufacturing has not only shuttered factories but also eroded a vital base of specialized skills. Highly trained chemical engineers, pharmaceutical technicians, and quality control experts are just as essential to national security as the physical infrastructure itself. As domestic production and employment continue to shrink, the country risks permanently losing this critical expertise. The longer this trend continues, the harder it becomes to reshore pharmaceutical manufacturing—making timely trade action essential to halt the surge of imports and begin rebuilding the industry.
- **Military Readiness and Healthcare Independence:** It bears emphasizing that medicine availability is directly tied to military readiness. A [Defense Department report](#) in 2023 highlighted that more than one in four essential medicines for the military are at “very high risk” of supply disruption due to foreign reliance. Ensuring that U.S. forces have assured access to medications – from antibiotics for wound infections to nerve agent antidotes – in conflict or crisis is paramount. This may necessitate DoD-specific arrangements, such as onshore production facilities dedicated to military medical logistics or contractual agreements that priority-fill military orders. Additionally, reducing civilian import dependence would free up capacity for the military in a crisis, since in a severe shortage scenario civilian and defense needs would compete.