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Chairman, Ranking Member, and Members of the Subcommittee: thank you for the opportunity to testify on behalf of the Coalition for a Prosperous America (CPA).

Executive Summary

The United States and the global market depend heavily on China for the upstream inputs of pharmaceutical production: the key starting materials (KSMs) and active pharmaceutical ingredients (APIs) from which medicines are made. That dependence is largely obscured in finished-drug trade data, because most Chinese inputs reach the U.S. market inside medicines finished in India and other third countries. Secure supply will require rebuilding domestic production and working with trusted partners to replace Chinese inputs at the source.

Key findings

- **U.S. dependence on China is concentrated upstream.** China manufactures a small share of the finished generic drugs Americans take, but China is the exclusive source of 41% of the KSMs used in U.S.-approved APIs and supplies 87% of U.S. antibiotic API imports.
- **Indian finished drugs do not provide an independent source of supply.** India finishes roughly 61% of the generic tablets and capsules dispensed in the United States, but depends on China for 65% of its critical APIs, KSMs, and intermediates, and about 90% of its antibiotic APIs.
- **The dependence is the product of policy.** Subsidized Chinese overcapacity pushed prices below the cost of reliable production, and a concentrated U.S. purchasing system rewarded the lowest bid. Since 2016, U.S. generic plant closures have eliminated more than 4,000 manufacturing jobs.
- **The exposure can be leveraged against the U.S. strategically.** An upstream disruption in China would reach the U.S. market through Indian and other third-country finished doses simultaneously. China already operates country-specific export licensing for chemicals, and U.S. drug shortages now last 5.3 years on average.
- **The cost of rebuilding capacity is modest.** Producing half of all U.S. generic prescriptions domestically would only add an estimated $0.82 per prescription and pays for itself with reduced supply disruption and shortage risks.

- **Secure supply requires domestic production supported by trusted partners.** CPA recommends specific tariffs on high-risk supply, production incentives, joint investment with partners whose regulators the FDA already recognizes, stronger oversight and origin reporting, and procurement that rewards reliability.

I. Upstream Concentration in the U.S. Pharmaceutical Supply Chain

Domestic production now supplies about one quarter of U.S. demand for finished pharmaceuticals. CPA's Pharmaceutical Domestic Market Share Index shows U.S. manufacturing's share of the market fell from 72% in 2002 to 27% in 2025, and imports reached a record $292 billion, showing a massive decline in U.S. self-sufficiency. [1]

However, finished-drug trade data understate China's role. China manufactures only about 3.5% of the generic tablets and capsules dispensed in the United States, and about 13% of U.S. generic drugs and their inputs are imported directly from China. [2] [3] The real exposure lies upstream, in the KSMs that are converted into APIs and then formulated into finished doses. The U.S. Pharmacopeia (USP) finds that 41% of the KSMs used in U.S.-approved APIs are sourced exclusively from China. [4] For individual products the share is far higher, reaching 90% or more for the building block of penicillin-class antibiotics.

Table 1. China's position in the upstream pharmaceutical supply chain

Indicator	China's share
KSMs for U.S.-approved APIs sourced exclusively from China	41% [4]
APIs for which China is the sole source of at least one KSM	679 APIs, or 37% of those analyzed by USP [4]
Key starting materials for amoxicillin, heparin, and acetaminophen	94%, 74%, and 70% [3]
U.S. antibiotic API imports, by volume (Jan. 2024–Dec. 2025)	87% [5]
U.S. ibuprofen and acetaminophen API imports (Jan. 2025–Apr. 2026)	99% and 68% [6]
Global supply of 6-APA, the building block of penicillin-class antibiotics	90–94%; 5 of the world's 8 plants [3] [5] [7]
Global antibiotic API exports (2020)	71% [7]
India's antibiotic API imports	91% [5]

One alarming example is antibiotics. Five of the eight plants in the world that produce 6-APA, the building block for amoxicillin and other penicillin-class antibiotics, are located in China. [7] Of the other three, one is in Mexico, another is a new, non-FDA approved, subsidized plant in India, and the third is the only high-

quality, reliable, FDA MRA-recognized supply, Sandoz's Kundl facility in Austria. The United States has not produced penicillin ingredients at industrial scale since 2004 and has no producer of 6-APA or penicillin-class API today. [8]

India's role. India supplies roughly 61% of the generic tablets and capsules dispensed in U.S. pharmacies. [2] However, India itself is also reliant on China. NITI Aayog, the Indian government's planning body, reported in June 2026 that India depends on China for 65% of its critical APIs, KSMs, and intermediates. [9] For antibiotic APIs, CPA's analysis of shipment records puts the figure at 91%. [5] The supply chain is sequential rather than diversified: China produces the chemical inputs, India largely formulates the finished dose, and the United States imports the product. India is therefore not an alternative to China in the way trusted MRA partners in Europe could be. It competes with U.S. producers on the same subsidized, lowest-cost terms while passing its own dependence on China through to the U.S. market.

II. Origins of the Dependence: Subsidized Overcapacity and Lowest-Bid Purchasing

China's position reflects sustained industrial policy rather than market outcomes alone. Chinese producers have benefited from tax preferences, subsidized credit, and state-financed infrastructure, and since the late 1990s have exported at prices below American and European production costs. [10] Since 1992, U.S. import prices have declined by more than 90% for finished antibiotics and by about 80% for antibiotic APIs. [5] India has followed the same model, using production-linked incentives and subsidized bulk drug parks to capture finished-dose manufacturing. [11] [12] China has undercut even India: when India used those incentives to rebuild its own ingredient base, Chinese producers exported APIs and KSMs below cost and undercut the new Indian suppliers. [3]

U.S. purchasing transmits that price pressure to domestic producers. Three group purchasing organizations control at least 80% of hospital purchasing, and three buying alliances account for nearly 80% of U.S. generic drug purchases. [13] These intermediaries award contracts primarily on price, with no measurable premium for reliability, redundancy, or the origin of inputs.

Since 2016, at least seven companies have closed or exited U.S. generic manufacturing plants in eight states, eliminating more than 4,000 manufacturing jobs. [1] The 2021 closure of the Viatris plant in Morgantown, West Virginia alone eliminated 1,500 to 2,000 jobs with a large economic impact to the community. [14] These closures followed price erosion, not a loss of technical capability or workforce skill.

III. Strategic and Foreign Policy Implications

Upstream concentration constrains U.S. options in any Indo-Pacific crisis, because confrontation with Beijing carries a risk to the supply of antibiotics and other essential medicines.

Correlated risk and export-control capacity. Disruption does not require intent: in 2016, an explosion at a single Chinese factory disrupted global supply of the hospital antibiotic piperacillin-tazobactam, because global supply was concentrated at this one facility. [15] A domestic source for one product mitigates that kind of failure: it adds redundancy and moves production to plants that receive more frequent FDA inspections. It does not, however, mitigate an upstream decision in China, which would affect every finished dose that relies on Chinese inputs, including those formulated in India, unless the U.S. enables increased domestic API capacity. China has used export controls on rare earths as leverage against the United States and its allies. [16] In 2019, the economist Li Daokui told a national advisory body that reducing China's exports of antibiotic raw materials could impair the medical systems of some developed countries. [3] China also now requires export permits for 18 drug-precursor chemicals shipped to North America. [17] These are presented as counter-narcotics controls, but they show that a country-specific licensing regime for chemical exports is already operating.

Current shortage conditions. There were 225 active drug shortages in the United States at the end of the third quarter of 2026. [18] The average active shortage has lasted 5.3 years, and 44% of drugs in shortage have at least one KSM produced in only one country, typically China or India. [19] Supply chain concentration, the lack of redundancy, and low-margin economics create and exacerbate these shortages. The link to price is measurable. USP found that generic sterile injectables in shortage were priced nearly 8.5 times lower than those not in shortage, and that 65% of the products discontinued in 2025 sold for less than $1 per unit. [20] [19] An HHS examination of 447 recently launched generic injectables found roughly 70% still unprofitable three years after launch. [21] HHS concluded in 2024 that generic prices are driven so low that they leave "insufficient incentives for redundancy or resilience-oriented manufacturing." [22] Manufacturers facing those margins consolidate production in the lowest-cost locations or exit the market, which is how low prices become concentration and concentration becomes shortage.

Quality and oversight. Moving production to China and India has also meant weaker oversight. In fiscal year 2023, roughly 90% of FDA's foreign inspections were announced in advance, and many overseas plants went five years or more without an inspection. [23] [24] The failures reached American patients. Beginning in 2018, tens of millions of blood-pressure pills were recalled after a probable carcinogen was found in valsartan ingredient made by China's Zhejiang Huahai. [25] At India's Intas Pharmaceuticals, which made about half of the U.S. supply of the chemotherapy

drug cisplatin, FDA inspectors found quality-control records being destroyed, and the plant's shutdown led to a national shortage in 2023. [26]

Exposure among partners. China's upstream dominance exposes not only the United States but our allies as well. China supplies 67% of antibiotic API imports into the European Union and EFTA countries. [5] European suppliers face the same low-cost undercutting from China, but they could be critical partners in expanding non-Chinese and non-Indian capacity. In antibiotics, for example, the Sandoz plant in Kundl, Austria is the last large-scale, fully integrated penicillin production site in Europe or the United States. [27] In May 2026, the EU reached a provisional agreement on its Critical Medicines Act, which directs public buyers to favor EU manufacturing where dependence on a small number of third countries is high. [28]

IV. The Cost of Rebuilding Capacity

A 2026 peer-reviewed study projects that production costs rise by at least 35% to 40% when generic output moves from China or India to the United States or Europe. [29] Production, however, is a small share of the final retail price. About 36 cents of each retail generic dollar reaches the manufacturer, and production cost accounts for about 16 cents; the rest is captured by middlemen, including pharmacy benefit managers, wholesalers, insurers, and pharmacies. [30] [29] A 40% premium on that cost base adds only about 6.6 cents per retail dollar. CPA's new pharmaceutical cost-benefit analysis estimates that producing half of all U.S. generic prescriptions domestically would cost about $3.2 billion a year, or $0.82 per prescription. That is only 0.9% of the roughly $350 billion in annual value that a stable generic supply, free of shortages, preserves for patients and payers. [31]

V. Policy Recommendations

Supply security should be assessed by the origin of the chemical inputs in addition to the location of final formulation. CPA recommends five actions.

1. Establish a price floor to protect the domestic market through specific tariffs on critical supply. Specific duties, set per dose or per kilogram, should apply to KSMs, APIs, and finished-dose medicines from high-risk countries outside the FDA's Mutual Recognition Agreements (MRAs), principally China and India. Trusted MRA supply from the European Union, the United Kingdom, and Switzerland should enter at low or zero rates. [32] Origin should be documented to the API and KSM level, because a tariff limited to China would be avoided through final processing in India. Generic drugs currently carry a zero Section 232 rate, and the tariffs announced in July 2026 for 2028 and 2029 have not been formalized. [33] [34] That schedule should be made binding, extended to the ingredient level, and brought forward.

2. Finance domestic capacity through the PILLS Act. The bill (H.R. 1396 and S. 1891) provides production and investment tax credits for U.S.-made generics, APIs, and

biosimilars, which would jumpstart domestic capacity and enable redundant and safer supply. [35] Congress should enact it and pair it with prioritized FDA review of applications for U.S.-made generics.

3. Build upstream production capacity with trusted partners. The United States and its MRA partners should invest jointly in fermentation and chemical synthesis capacity, beginning with penicillin-class antibiotics; align procurement around sustainable and reliable supply across the Department of Veterans Affairs, the Department of Defense, and European health systems; and incorporate pharmaceutical supply into NATO and allied readiness planning.

4. Apply the domestic oversight standard to foreign plants and require origin reporting. Since FDA expanded unannounced foreign inspections in 2025, the unannounced share has risen to 87% in India and 61% in China. [36] Congress should codify that practice and adopt the U.S.-China Economic and Security Review Commission's recommendation to authorize FDA to require reporting of the ultimate origin of APIs and KSMs, including Chinese content routed through third countries. [16] The United States should also adopt independent batch testing of pharmaceutical imports as is already done in the European Union to further ensure a safe, high-quality drug supply, rather than relying on Chinese and Indian manufacturers' records and self-reported data, even when those records are reviewed by the FDA.

5. Use federal purchasing to reward reliability. Federal purchasers should give preference to U.S.-made critical generics, with "domestic" defined to the API and KSM level, and offer long-term anchor contracts with guaranteed volume. The Strategic Active Pharmaceutical Ingredients Reserve should be expanded and filled with U.S. and trusted MRA production. [37]

VI. Conclusion

China's position in the pharmaceutical supply chain was built through sustained subsidy and scale over roughly twenty-five years. It reflects policy choices and can be reversed by policy. The United States retains the scientific base, workforce, and regulatory system needed to produce its essential medicines, and its MRA partners retain the remaining upstream capacity outside China. Rebuilding domestic production, so that output, employment, and wages rise together, and anchoring remaining needs with trusted partners would convert a concealed vulnerability into a source of American and allied strength.

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