Written Testimony for Ronald T. Piervincenzi, Ph.D, CEO, United States Pharmacopeia (USP)

House Committee on Foreign Affairs
"The Hidden Chokepoint: China's Dominance in Pharmaceuticals"
November 19, 2026

Chairwoman, Ranking Member, and distinguished Members of the Committee, thank you for the opportunity to testify on behalf of the United States Pharmacopeia. USP's analysis indicates that 37% of U.S. medicines rely on at least one key starting material (KSM) sole sourced from China. We applaud the Committee's commitment to examining U.S. medicines supply chain dependence on China and identifying practical solutions to reduce associated risks.

USP is a private, scientific, global nonprofit organization founded in 1820 in the old Senate chamber, when 11 physicians took action to protect patients from poor-quality medicines. Our founders published the first U.S. Pharmacopeia, a national and uniform set of guidelines for medicines. Today, USP is governed by a Convention of over 450 member organizations from the healthcare, scientific, healthcare practitioner, patient, and regulatory communities. USP employs approximately 1,300 staff, most of whom are scientists, and 1,000 scientific experts who volunteer their time on USP committees that establish public quality standards for medicines.

USP also offers programs to help ensure the availability of quality medicines for Americans. The USP Medicine Supply Map tracks the upstream supply chain for medicines and their ingredients. USP's verification programs help confirm the quality of pharmaceutical ingredients and dietary supplements, and its advanced manufacturing initiatives help accelerate adoption of technologies that can support more resilient domestic and allied production. These programs are central to USP's work to strengthen the global supply chain so that the medicines on which Americans rely are available when needed and meet public standards for identity, strength, quality, and purity.

Developed through an open, transparent process and updated regularly to reflect evolving science and industry practice, USP maintains more than 6,000 standards for active pharmaceutical ingredients (APIs), drug products, and inactive ingredients. These standards help ensure medicines are safe, effective, and consistently manufactured. USP publishes them in the *United States Pharmacopeia–National Formulary (USP-NF)*, an official compendium under the Federal Food, Drug and Cosmetic Act (FD&C Act), and certain standards are required for compliance with the FD&C Act. USP works closely with the U.S. Food and Drug Administration (FDA) and other government agencies to support the quality and safety of products used by Americans.

USP also advances public-private partnerships that address systemic supply chain vulnerabilities and strengthen national health security, including work with the U.S. Department of Defense, the Advanced Research Projects Agency for Health (ARPA-H), the Administration for Strategic Preparedness and Response, and the Biomedical Advanced Research and Development Authority.

We are proud of these efforts because medicines supply chain resilience is not only a public health priority, but also a matter of national security. I will describe in my statement:

1. The overall China reliance problem and evidence of U.S. medicines' dependence
2. Resulting challenges and complications
3. USP's proposed comprehensive solution

1. Problem: The Vulnerability of the U.S. Medicines Supply

U.S. reliance on China for KSMs used to produce medicines creates significant national security vulnerabilities. Geopolitical conflicts, trade restrictions, natural disasters, or manufacturing failures could disrupt supplies, threatening patient care, emergency preparedness, military readiness, and economic competitiveness. This dependence provides China with economic leverage during trade or other confrontations with the United States, even without an actual interruption in supply.

The problem has two related components: recurring drug shortages that continually impact patient care, and the supply chain's concentrated dependence on China which is a major national security vulnerability.

First, the United States has experienced drug shortages for more than a decade. Shortages disrupt patient care, force clinicians to switch therapies, and reveal how little redundancy exists in the supply chain. A supply chain that struggles to absorb routine disruptions is poorly positioned to withstand a geopolitical one, with consequences for emergency preparedness and military readiness.

Second, 41 percent of the KSMs used for U.S.-approved medicines are sole sourced from China. This concentration means China's decisions, or a disruption within China, could affect the availability of medicines for Americans, and could give China leverage over U.S. foreign policy and economic decisions even without an actual interruption in supply.

The Situation: Reliance on China for KSMs for America's Medicines

A finished medicine is produced from one or more APIs, which are produced from KSMs. Looking at only one of these three inputs offers a misleading picture of supply chain security.

Today, U.S. patients rely on over 24,000 medicines to prevent, treat, and cure disease. Of these, USP recently analyzed 100 highly utilized and essential medicines to illustrate this multi-layered dependence, spanning every major therapeutic category, including anti-infectives (28 medicines), central nervous system medicines (25), cardiovascular medicines (11), and cancer and immune therapies (8).

All 100 medicines depend on China at the KSM layer: for each, China supplied more than half of the KSMs used to produce the API, yet only 12 percent have APIs primarily manufactured in China.

India's API production also relies heavily on KSMs made in China. While many of these medicines have their API or finished dose forms manufactured in India, China is positioned to use export restrictions, regulatory barriers, or threats to Chinese market access to discourage Indian companies from supplying certain pharmaceutical products to the United States. Moreover, China is a leading source of KSMs for manufacturing in India. This provides China with direct leverage over India-based production, and by extension, indirect leverage over supply to the U.S.

Visibility: Understanding Dependencies to Target Reforms and Investment

Pinpointing these vulnerabilities requires data on every layer of the supply chain, not just the finished product. The USP Medicine Supply Map currently maps approximately 94 percent of drug products and their ingredients supplied to the United States, and supporting analysis across medicines, APIs, KSMs, facilities, manufacturers, and geographies.

USP's Medicine Supply Map analysis demonstrates that global pharmaceutical manufacturing remains highly concentrated. Of the filings API manufacturers submit to FDA to supply ingredients for U.S. medicines found that China accounted for 44 percent of new filings in 2025 and its annual API filings more than tripled between 2021 and 2025. The United States accounted for only three percent of new filings in 2025 (and six percent of all active filings).

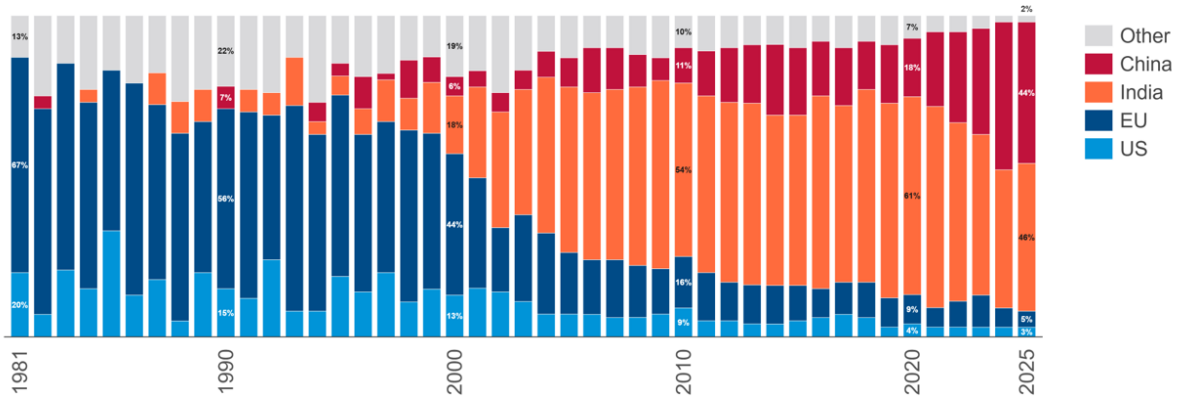


Figure 1: Proportion of Active API US Drug Master Files, by year of filing (1981-2025)
Source: USP Medicine Supply Map, 2025, www.USP.org/medicinesupplymap

Manufacturing volume analysis reveals related, but distinct, patterns:

- Over half of the APIs used in prescription medicines supplied to the U.S. market originate from India and the European Union.
- Generic medicines, which account for approximately 90 percent of U.S. prescription volume, rely primarily on API manufacturing in India.
- The United States accounted for approximately 13 percent of analyzed API volume.
- China represented approximately 10 percent. As previously noted, however, Indian API production depends heavily on China for its KSMs.

Finished-dose manufacturing exhibits a different pattern. The United States remains the largest manufacturer of injectable medicines supplied to the U.S. market, accounting for approximately 45 percent of production volume, while India accounts for approximately 60 percent of solid oral dosage-form production.

Because KSM sourcing, API filings, manufacturing volume, and finished doses each measure a different part of the supply chain effective policy solutions must be tailored to the specific medicine and the specific intersection where its vulnerability lies.

Hidden Single Points of Failure: The Zidovudine Example

USP's risk-assessment work illustrates how hidden dependencies can create strategic vulnerabilities. One example: In an end-to-end assessment of zidovudine, an antiviral medicine, USP identified a critical dependency on thymidine, a KSM used in the production of zidovudine and several related nucleoside-based antiviral medicines. USP found that commercially available thymidine production was concentrated in China, creating a significant geographic vulnerability.

This risk extends beyond zidovudine. Multiple manufacturers may produce finished antiviral products, yet all depend on a common upstream input, so a disruption affecting one KSM supplier can cascade across an entire therapeutic category. What appears to be a diversified market at the finished-product level may contain a critical single point of failure.

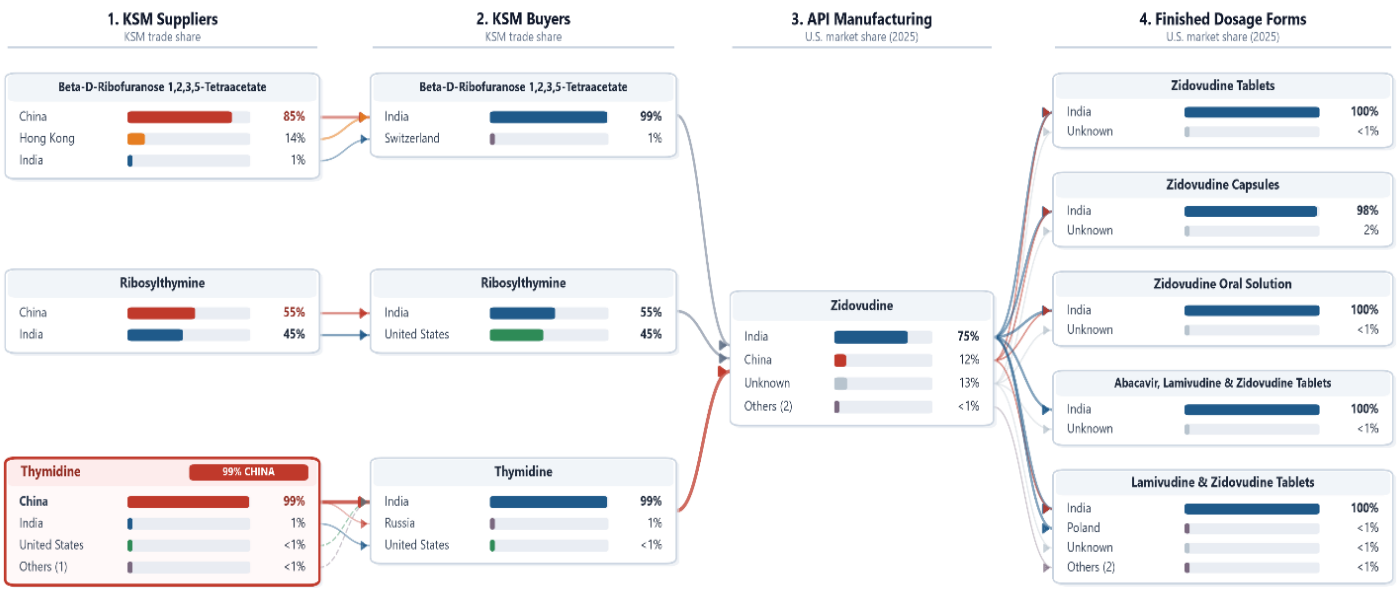


Figure 2: Downstream Zidovudine Supply Appears India-Centered, Masking Heavy Upstream Dependence on China for Key Starting Materials (2025)
Source: USP Medicine Supply Map, 2025, www.USP.org/medicinesupplymap.

3. Challenges and Complications: Why Comprehensive Solutions Are Needed

So many of the medicines Americans rely on depend on China for KSMs that narrow or piecemeal responses will not be enough. The 100 medicines USP analyzed are a sample, not the full extent of the exposure. Addressing only those 100 would leave the broader system vulnerable and would not reduce China's overall leverage over the U.S. medicine supply.

Substitutability of a given drug may also provide a false sense of security. In USP's recent analysis, 56 of the 100 medicines have limited substitutes. However, in some cases, even clinically interchangeable medicines, such as atorvastatin and rosuvastatin for cholesterol or losartan and lisinopril for hypertension, may rely on the same China-concentrated KSMs. A single disruption could affect both a medicine and its seeming "back up plan" alternative.

This underscores the need for a medicine-by-medicine approach. Not all foreign dependencies create equal risk, and targeted interventions should focus on the medicines and inputs for which a disruption would have the greatest consequences.

It is also important to note the bigger picture: China's prominent position in many upstream pharmaceutical inputs developed over decades, reflecting industrial policy that directed investment in chemical manufacturing, integrated industrial supply chains, and ultimately economies of scale.

With compressed margins on generic medicines in the U.S., manufacturers have relied on Chinese suppliers because of their cost competitiveness and manufacturing capabilities. Reducing concentrated dependence will therefore require economically viable alternatives across the supply chain, not just relocating individual facilities.

The United States will need systemic investments, reforms, and new trading arrangements that work together, rather than isolated fixes aimed at individual medicines.

3. Solutions

USP recommends a comprehensive approach that pairs targeted mitigation of specific risks with broader investments, policy reforms, and a realignment of trading partnerships.

The zidovudine example shows that a targeted solution can follow directly from identifying a hidden dependency. Because commercially available thymidine, a KSM for zidovudine and related antiviral medicines, was concentrated in China, USP chemists evaluated alternative synthesis pathways and advanced manufacturing technologies that could reduce reliance on a single foreign source. USP identified a pathway to synthesize thymidine domestically using continuous manufacturing and is working to scale its progress further.

The objective should not be to isolate the United States from global pharmaceutical trade or to manufacture every medicine domestically, but to reduce excessive dependence on any single

country, company, facility, or manufacturing process through targeted domestic capacity and production among trusted allies and nearshore partners.

Six Recommendations for the House Foreign Affairs Committee to Advance

The House Foreign Affairs Committee has an important opportunity to treat medicine supply chains as critical economic-security infrastructure, alongside semiconductors, energy, and critical minerals. Economic diplomacy, development finance, trade policy, regulatory partnerships, and internationally recognized quality standards can support more reliable production of APIs and KSMs. USP recommends the following six actions. Each can move forward on its own, and together they form a comprehensive, and feasible, approach.

Recommendation 1: Require an Annual Supply Chain Risk Assessment

The Committee should advance a requirement that the U.S. government map and assess the medicines supply chain at every stage, from KSMs and APIs to finished-dose manufacturing, to identify the nation's most significant vulnerabilities, including essential medicines sole sourced from adversarial nations or otherwise vulnerable to disruption. This plan is essential because there is not one U.S. drug supply chain, but thousands.

The assessment should be annual, not a one-time snapshot. It should analyze the factors driving vulnerabilities, measure year-over-year progress, and culminate in a report to the relevant congressional committees and federal departments and agencies that identifies the most significant risks and recommends mitigation strategies to guide federal decision-making and private-sector investment. An annual process would support more informed, data-driven, and cost-effective decision-making and practical reforms.

The Fiscal year (FY) 2026 State Department appropriations report language calls for an updated assessment and mitigation recommendations, with related language in the FY 2027 State Department appropriations reports. Establishing an enduring annual process in authorizing law would provide continuity and allow Congress to evaluate progress over time.

Recommendation 2: Develop Trusted Nearshore and Allied Manufacturing Capacity

The Committee should support expanded trusted nearshore and allied production of selected APIs and KSMs. China and India together accounted for 90 percent of new API DMF filings for U.S. pharmaceuticals in 2025. Existing capacity in Mexico, Canada, and across other Latin American countries provides opportunities to nearshore selected API or KSM production, including through targeted upgrades to facilities that can meet applicable quality and regulatory requirements.

Working with the Department of State, the Committee could explore how economic diplomacy, development finance, and technical assistance might support API and KSMs production in the Western Hemisphere, enhancing security and providing the ingredients needed for more finished-dose manufacturing in the U.S. These investments should be driven by identified vulnerabilities,

economic feasibility, sustainable demand, and the ability to maintain quality production, not by geography alone.

Recommendation 3: Align Quality Expectations and Regulatory Capacity

The Committee should promote harmonized quality expectations as a means of diversifying supply chains and reducing dependence on adversarial nations. Incorporating internationally recognized quality standards into trade and economic partnerships can support a more reliable medicine supply chain and help ensure that medicines are safe, effective, and consistently available. For instance, requiring adherence to USP quality standards in trade agreements with countries across the Western Hemisphere would elevate the quality of medicines produced throughout the hemisphere, making them significantly more nearshore-ready for the U.S.

The Committee should also support regulatory strengthening and quality-assurance systems in partner countries, through Department of State foreign assistance and partnerships, which can improve product quality and safety, facilitate trusted trade, and strengthen preparedness.

Recommendation 4: Use Targeted Economic and Trade Levers

The Committee should explore targeted incentives and trade measures to create alternative sources of supply. Over the past two decades, the U.S. and European shares of new API filings have declined substantially, indicating a long-term erosion of manufacturing capacity. Targeted incentives for nearshoring and ally-shoring could help create alternative API suppliers for generic drug manufacturers. Congress should also consider financial incentives, such as FDA user fee waivers, to encourage API suppliers in the U.S., in Latin America, Europe, or other countries recognized under a Mutual Recognition Agreement to register with FDA, expanding access to alternative API suppliers.

Trade and economic measures may also help make manufacturing in the Americas more competitive. They should be calibrated to avoid unintentionally increasing medicine costs or exacerbating shortages, and should prioritize measurable reductions in the concentration of KSM and API production from China.

Recommendation 5: Make Resilience Economically Sustainable

The Committee should encourage a market that rewards resilience and reliability alongside price. The U.S. generic drug market is one of healthcare's greatest economic successes; generics account for roughly 90 percent of prescriptions dispensed in the United States, but only about 12 percent of total medicine spending. Over the past decade, generic medicines have generated trillions of dollars in savings for the U.S. healthcare system and patients, and Americans pay, on average, 33 percent less for generics than patients in other high-income countries.

But affordable medicine has value materializes only if it is available when a patient needs it. The competitive forces that have made generic medicines so affordable have left too little room to

invest in redundancy, and manufacturers that invest in redundant capacity, alternative suppliers, robust quality systems, and geographically diverse production receive little recognition for those investments. We should preserve the value of generic competition while rewarding reliability.

USP proposes two central components. First, a data-driven Resilience Benchmark that enables purchasers to identify resilient products and manufacturers, incorporating measures of supply chain robustness, reliability, quality, manufacturing concentration, diverse and allied ingredient sourcing, and vulnerability indicators from manufacturers, the Medicine Supply Map, and other sources. Second, payment and contracting reforms that create measurable incentives for resilience investments.

Recommendation 6: Build the Next Generation of Pharmaceutical Manufacturing

The Committee should support alternative manufacturing routes, advanced manufacturing technologies, and novel production platforms, because resilience cannot be achieved solely by relocating existing manufacturing infrastructure.

Continuous manufacturing, alternative synthesis pathways, and other innovative technologies can shorten supply chains, reduce dependence on vulnerable inputs, and enable more geographically distributed production. The USP Advanced Technologies Laboratory and USP's participation in the ARPA-H-funded WHEAT project, which is exploring the use of wheat-germ extract and cell-free protein synthesis for API production, illustrate opportunities to reimagine pharmaceutical ingredient production.

Ultimately, the goal should not merely be to relocate yesterday's production model. It should be to build a more innovative, distributed, and responsive manufacturing network, including with trusted international partners.

Conclusion

No single policy will eliminate supply chain risk. The vulnerability of our medicine supply chain, from recurring drug shortages to heavy concentration in China at the KSM and API layers, is too broad for narrow fixes. The six recommendations outlined above give the Committee a practical agenda that draws directly on the foreign policy tools available to this Committee, including economic diplomacy, development finance, trade policy, and foreign assistance.

Medicine supply chain resilience is a national security imperative. No geopolitical conflict, trade disruption, natural disaster, or manufacturing failure should prevent American patients from receiving the medicines they need, and that no adversarial nation should be able to exert undue leverage over U.S. foreign policy.

USP thanks the Committee for its attention to this critical issue and looks forward to working together on practical solutions that strengthen our medicine supply chain and national security.