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The Hidden Chokepoint: China's Dominance in Pharmaceuticals

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Hearing on "The Hidden Chokepoint: China's Dominance in Pharmaceuticals."

Chair Kim, Ranking Member Bera, and distinguished Members of the Subcommittee, thank you for this opportunity to testify on America's dangerous dependence on China for the upstream inputs for pharmaceuticals and ways to build alternative and secure supply chains with allies and partners.

I am the Bloomberg Chair in Global Health at the Council on Foreign Relations (CFR) and a Professor of the Practice of Public Health at the Yale School of Public Health. My expertise is in the international trade and regulation of pharmaceuticals, biotechnology, and other medical technologies. I recently co-led a year-long CFR analysis with biopharmaceutical specialists, China scholars, and industrial policy experts to identify the true scope of U.S. pharmaceutical dependence on China and to recommend policies to reduce it.[1] My testimony builds on that analysis.

First, I begin by describing how U.S. dependence on China for upstream inputs of small molecule drugs emerged—largely through China running the same playbook it has deployed on critical minerals.

Next, I explain where the potential dependence on China for upstream pharmaceutical inputs poses risks for U.S. national security, public health, and patients.

Last, I conclude with a specific set of recommendations on how the United States can work with trusted allies and partners to build more resilient, secure pharmaceutical supply chains less dependent on China. We cannot return all key starting material and active ingredient production to the U.S., nor should we attempt to. We should divide the chokepoints in pharmaceutical supply chains with our allies, rather than doing it alone. A plurilateral trade deal for essential pharmaceutical inputs and cooperation on stockpiling and and production incentives will advance US goals.[2]

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The Origins of U.S. Dependence on China for Upstream Inputs of Small-Molecule Drugs

Most pharmaceuticals are built in stages. Key starting material (KSM)—the basic chemical building block—are produced in a process that often resembles industrial chemical manufacturing and is then converted into active pharmaceutical ingredient (API), the compound that produces the therapeutic effect. That API is combined with binders, stabilizers, and other inactive ingredients and made into a finished dosage form (FDF), such as a pill or vial.

The CFR *Pharma Chokepoint* report analyzed U.S. trade, customs, and ingredient-sourcing data to map the supply chain for U.S. essential medicines, tier by tier. Doing so revealed a consistent pattern: the supply chains for many essential U.S. medicines may appear diversified at the FDF level and, in some cases, even at the API level, but that apparent diversification in the supply chain disappears when moving one step upstream.

U.S. physicians issue sixty million prescriptions of the antibiotic amoxicillin each year, most commonly to treat pediatric infections or to protect seniors during routine medical procedures. At first glance, U.S. amoxicillin supply looks well diversified—APIs are manufactured in Austria, China, India, and Jordan; finished doses are produced in Canada, the European Union, India, Jordan, Turkey, and the United States. But those suppliers all depend on the same upstream material from China. China controls roughly 94 percent of global supply of the KSM for amoxicillin, 6-aminopenicillanic acid, and just five Chinese firms are responsible for more than four-fifths of its global production.

Heparin follows a similar pattern. It too is an essential drug that makes the modern practice of U.S. medicine possible, with more than twelve million hospitalized Americans receiving it each year during, kidney dialysis, asthma treatment, and common surgeries. At least six countries are involved in manufacturing heparin API, including Italy, Netherlands, New Zealand, and Spain. The United States itself produces more than half of its finished doses of heparin. Yet three quarters of the world's supply of crude heparin, the drug's underlying KSM, originates in China.[3]

This same pattern exists across the supply chain for many U.S. essential medicines, from norepinephrine, a low blood pressure and trauma treatment, to acetaminophen, the over-the counter pain medication, to dexamethasone, an immunosuppressive treatment for severe allergies and autoimmune disorders. U.S. Pharmacopeia estimates nearly seven hundred medicines that are approved for use in the United States depend on a KSM solely made in China.[4]

China's dominance over global KSM production did not emerge with market forces alone. It followed a playbook similar to its strategy with critical minerals, starting with a form of regulatory arbitrage. KSM manufacturing moved out of Europe and the United States over rising concerns over its toxic byproducts, occupational harms, and chemical runoff finding its way into riverbeds and feminizing fish. Chinese firms were able to enter the market because in China, KSM manufacturing is less closely regulated than API and FDF production, both of which are under strict good manufacturing practice (GMP) requirements. China offered weaker environmental laws, discounted water and power inputs, and, as more API and KSM became sourced there, enormous economies of scale.[5] The U.S. drug procurement system inadvertently benefited China, with government programs, wholesalers, and distributors incentivized to buy from the lowest-cost manufacturer, sometimes at the expense of quality and resilience.

The results were measurable and rapid. American amoxicillin production fell from one hundred percent of the domestic market to zero in twelve years.[6] A growing number of U.S. finished generic medicines are now imported directly from China, many with no ready substitute, including immunosuppressants that prevent rejections of a transplanted organ, a frontline hospital antibiotic, and a drug used in the treatment of heart failure, among others.[7]

Managing Risks to U.S. National Security, Public Health, and Patient Safety

When all downstream suppliers depend on the same concentrated input, policies to promote down-stream diversification (at the level of APIs or FDFs) provide little protection. U.S. pharmaceutical dependence on China is an end-to-end supply chain challenge, and policy responses must treat it as such, which requires greater transparency into the origin of upstream inputs and U.S. promotion of geographic diversification of that starting material sourcing, not just in downstream finished products.

The concentrated production of the upstream inputs of essential medicines in China is a particularly dangerous chokepoint because supply shocks for these inputs would affect all downstream production pathways, including in other nations. Therapeutic substitutes might not be readily available. Drugmakers must obtain FDA approval for new manufacturing facilities or production lines to address supply shortfalls, and new production facilities are expensive and time-consuming to establish. The FDA can authorize temporary importation of foreign unapproved versions of medicines in short supply, but only as a last resort and after months of delay.[8] In the meantime, patients and providers must resort to substitute medicines, which can lead to adverse drug reactions, raise hospital costs, and spur new shortages for the substituted medicine, creating secondary harmful effects for the U.S. healthcare system.

The risk of concentration of upstream pharmaceutical supplies in China are not hypothetical. Contaminated Chinese heparin killed eighty-one Americans in 2007 and 2008.[9] U.S. FDA inspectors recently discovered black and "gross contamination" at two Chinese factories making key components for the compounded GLP-1 drugs widely used in the United States.[10] Beijing has already demonstrated a willingness to weaponize pharmaceutical supply chains for diplomatic, trade, and geopolitical leverage. China has previously imposed export controls on dual-use products shipped to Japan, including those used in pharmaceutical manufacturing, after remarks by Japan's prime minister on Taiwan.[11] Chinese producers flooded the market with below-cost exports to cripple India's domestic API and KSM suppliers that its government had begun to establish to fortify its pharmaceutical resilience.[12]

If China were to withhold upstream inputs to amoxicillin for geopolitical reasons, as it has with critical minerals and agricultural products, or deliberately or accidentally contaminate supplies of these critical medical inputs, or if a natural disaster were to strike the three Chinese provinces dominating supply manufacturing, every U.S. hospital, pharmacy, and pediatric practice would feel the effects within weeks.

Allied Coordination as Force Multiplier for US Pharmaceutical Resilience

U.S. dependence on China for upstream inputs for essential pharmaceutical supplies emerged as the product of decades of coordinated Chinese state intervention. It will require an equal, coordinated, and sustained U.S. response, but America cannot go it alone, and nor does it need to.

The United States is not the only nation seeking to reduce dependence on China for pharmaceutical inputs. The European Union, under the Critical Medicines Act, has expedited approvals for manufacturing critical medicines and inputs that are dependent on Chinese supply chains.[13] Japan has been restarting and upgrading its production of critical antibiotics produced via fermentation.[14] India launched, with limited success, new incentive schemes to build domestic capacity for KSM, intermediates, and APIs.[15] Canada and Mexico have manufacturing capacity for some

essential medicine inputs, including acetaminophen and fermentation-based API for antibiotics. South Korea has strong contract development and manufacturing organizations that could help reduce dependence on China.

First, the United States should conclude a plurilateral trade bloc for essential pharmaceutical inputs offering preferential terms to trusted allied nations and like-minded trading partners, similar to the Agreement on Trade in Critical Minerals that U.S. trade officials are currently negotiating. A trade bloc that leverages the existing U.S. agreements with many of these partners and is paired with mutual recognition agreements for GMP inspections could enable greater allied sharing and purchasing of critical KSM and APIs. If the participating nations standardize their disclosure requirements for the sake of supply chain transparency, they could better pinpoint where KSMs are concentrated—particularly when transshipment routes are used to obscure that those materials came from China.[16]

Second, U.S. allied cooperation should establish functional emergency stockpiles, with allied partnerships focused on sourcing medicines and ingredients where we have true upstream chokepoints. Congress should fund the new Strategic API Reserve (SAPIR), while securing the fill-and-finish capacity required to convert those stockpiled ingredients into administrable medicine.[17] The FDA should also more readily authorize temporary API importation from well-regulated allied markets. Although that is already permitted, the FDA only does so as a last resort after months or even years of delay. [18] The agency should proactively identify and assess foreign sources for essential medicines where China holds a concentrated market dominance.

Third, we should build more cost-effective KSM and API manufacturing capacity. That means funding advanced manufacturing technologies (AMTs)—including continuous flow manufacturing, enzymatic and cell-free synthesis, and green chemistry—to end our reliance on cheap and polluting chemistry overseas. Even just reducing the cost of API manufacturing would create room to absorb the higher cost of domestically produced KSMs, leveraging existing U.S. chemical industrial capacity. FDA can help by providing clearer guidance to manufacturers that are otherwise reluctant to adopt AMTs for low-margin generics because of their up-front costs and regulatory uncertainty.

Fourth, we should extend low-cost capital to manufacturers here and with our allies to address upstream chokepoints. The U.S. International Development Finance Corporation (DFC) and the Export-Import Bank should offer low-interest financing to projects that build API and KSM capacity in lower-cost allied nations, such as Argentina, Brazil, and Mexico. Congress should ensure the same authority promotes production in other trusted allies as well, such as Europe. A fifty-million-euro grant helped make an Austrian plant cost-competitive with Chinese penicillin-makers.[19]

Fourth, we need to realign procurement incentives. Federal purchasers—Medicare, the Department of Veterans Affairs, and the Department of Defense—should reward supply reliability rather than price alone, and should favor trusted, non-Chinese sources of supply.

We need to be ambitious. Within five years, the U.S. Administration for Strategic Preparedness and Response, DFC, and FDA should collaborate to qualify at least one allied-nation KSM and API supplier for each U.S. priority essential medicine. Within a decade, our goal should be to ensure domestic or allied production is capable of meeting at least fifty percent of the normal U.S. demand for priority medicine KSMs or APIs. The time to act is now.

I thank the Subcommittee for its attention and leadership in elevating U.S. pharmaceutical supply chain resilience as a national priority. I stand ready to answer your questions and to assist anyway I can.

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