Written Testimony by **Dr Chandresh Harjivan, PharmD, MPH, MBA**

before the

U.S.–China Economic and Security Review Commission

concerning

India, China, and the Balance of Power in the Indo-Pacific

Tuesday, February 17, 2026

Introduction

Chairman, Vice Chairman, and Members of the Commission, thank you for the opportunity to submit this written testimony on the implications of China–India relations for biotechnology and pharmaceutical supply chains for U.S. national security. Leadership in biotechnology and the security of America's medicine supply is no longer a narrow health policy issue. It has become a core question of economic certainty, technological leadership, and strategic resilience. Decisions made in Beijing and New Delhi increasingly shape the development, availability, affordability, and integrity of essential medicines relied upon daily by the American public, the U.S. health system, the U.S. military and the World.

This testimony builds on three key observations. First, the global pharmaceutical supply chain is structurally concentrated at its upstream layers, particularly in the production of active pharmaceutical ingredients (APIs), key starting materials (KSMs), and chemical intermediates. While finished medicines come from dozens of countries, the raw materials originate largely from a few. Second, India and China operate as a coupled system: China serves as the world's primary source of bulk pharmaceuticals and chemical building blocks, while India formulates those inputs into finished medicines that supply much of the world. Third, the convergence of AI and biology (AIxBio) is driving a profound revolution in life sciences; an industry that will provide strategic global dominance for the country or countries that lead it. This interdependence means that U.S. security hinges on decisions made now.

Global Concentration and Hidden Dependencies

The anatomy of a medicine

Most medicines consumed in the United States begin life in the form of raw chemical substances derived from basic petrochemical feedstocks, fermentation-based precursors, or biologic cell lines. These substances are refined into KSMs and then converted into APIs through complex chemical reactions, purification, and crystallization steps. Finally, APIs are formulated into tablets, capsules, injectables, and inhalers. Although the final dosage form carries a label indicating its country of manufacture, the origin of its active ingredient is often opaque to payers, providers and patients.

In the last three decades, cost pressures and procurement practices in high-income countries have driven an unprecedented offshoring of upstream pharmaceutical manufacturing. The US has never been a big API manufacturer. Before India, Europe produced most of the world's API. But China offered low labour costs, generous tax incentives, lax environmental enforcement, and scale economies. India offered regulatory agility, low infrastructure costs, technological proficiency in formulation, and an English-speaking scientific workforce. Companies responded by relocating chemical synthesis and intermediate production to China and formulation to India. **The result is a global supply chain that appears diversified at the finished-product level but is highly concentrated at the foundational level.**

According to an April USP report, for U.S. generic API, 8% comes from China and 35% comes from India.[i] A recent report to this Commission warns that while only 3 percent of finished oral doses and 9 percent of injectables consumed in the United States are imported directly from China, the nation is "substantially more exposed to Chinese raw pharmaceutical ingredients," with India often serving as a conduit[ii]. If 50% of the API used in production in India is made in India, then China accounts for ~33% of India's total API requirement. India domestically produced 50% of the total quantity of 68 critical APIs used in Indian production[iii].

India excels in formulation and finished dosage production. It has the largest number of U.S. FDA-approved manufacturing facilities outside the United States and supplies approximately 20 percent of the world's generic medicines by volume[iv]. Indian manufacturers also fulfill around 60 percent of global vaccination demand and supply 55–60 percent of UNICEF's vaccines while meeting 99 percent of the WHO's diphtheria–pertussis–tetanus (DPT) vaccine requirement[v]. Over 80 percent of antiretroviral drugs used globally are supplied by Indian firms. The reduced costs of generics has increased overall access to critical medications globally. This capacity rests on a domestic ecosystem comprising roughly 3,000 drug companies and 10,500 manufacturing units[vi]. In fact, **one out of every three tablets consumed worldwide is made in India**, underscoring the country's importance in meeting global health needs.[vii]

U.S. reliance on India is intensified in the treatment of chronic conditions, such as cardiovascular disease and diabetes. India manufactures 47% of all API volume used for chronic conditions in the U.S., compared to just 6% produced domestically according to USP Medicine Supply Map (MSM) calculations. Additionally, India holds the largest manufacturing footprint for Essential APIs, producing 27% of the US supply—an API is considered essential if it was listed on either the FDA's Essential Medicines, Medical Countermeasures, and Critical Inputs list or the WHO's Essential Medicines List.

Yet this masks hidden dependencies. Because many Indian formulations are destined for the U.S. market, this indirect dependence exposes U.S. patients to supply shocks originating in China. **Worst, because the supply chain lacks transparency; poor data visibility makes it difficult to determine exact, current dependencies**. Without access to accurate supply chain mapping, policymakers struggle to prioritize resources or enact contingency plans. If dossiers were digital, supply chain information would be easily accessible and readable to a broad set of stakeholders. The proposed Clear Labels Act

introduced early February would require manufacturers to list unique facility identifiers for API facilities in their labeling information[viii].

Supply shocks and systemic risk

The COVID-19 pandemic provided a live stress test for these dependencies. When Chinese factories shut down, shipments of KSMs to India slowed dramatically. I don't think it was deliberate government policy but rather due to Chinese lock down policy where they shut down pharmaceutical factories (and related factories). India responded by restricting the export of 26 medicines and ingredients, including widely used drugs like paracetamol, to protect domestic supplies[ix]. Those restrictions highlighted how quickly upstream disruptions can cascade into downstream shortages. **While the restrictions were lifted within weeks, they revealed the fragility of a system that relies on a single country for its upstream inputs and another for its finished products.**

Because there is little surge capacity in the system, shortages are even now routine and translate into rationing, price spikes, and potential harm to patients. Moreover, China's ability to exploit these dependencies for political leverage cannot be discounted. This is a risk mainly for key intermediates used in antibiotic production. Although China has not weaponized pharmaceutical exports, its behaviour in other sectors, such as rare earth elements and critical minerals, demonstrates potential to use supply chains as instruments of influence.

India's Pharmaceutical Industry: Strengths and Constraints

Scale and scope

The Indian government has nurtured this industry through supportive patent laws, export incentives, and public-sector investments. The 1970 Patents Act allowed Indian companies to reverse-engineer patented drugs using alternative processes, fostering a vibrant generics sector. More recently, initiatives like the Production Linked Incentive (PLI) scheme and the establishment of bulk drug parks signal a shift towards rebuilding upstream capacity. This was a direct response to China putting export restrictions on antibiotic intermediates. China is trying to stifle the PLI by dumping KSM and other fine chemicals in the market. India has applied anti-dumping tariffs on China in response. **This is a trade "war" between the two countries over who controls drug manufacturing.**

The cost advantage and quality challenge

India's cost advantage stems from lower labour and infrastructure costs, economies of scale, and an ecosystem of specialized suppliers. The average cost of producing a generic drug in India can be half to one-third of the cost in Western countries. This has made India a critical supplier of affordable medicines not only to developed nations but also to low- and middle-income countries reliant on international aid.

However, the cost advantage has sometimes come at the expense of quality. Instances of adulterated or substandard drugs produced by unscrupulous manufacturers have damaged India's reputation. U.S. and European regulators have issued warning letters and import alerts against Indian facilities that failed Good Manufacturing Practice (GMP) standards. **FDA inspections have notably higher OAI outcomes in India (13%) compared to Europe (2%), China (7%) or US (8%)[x].** The Central Drugs Standard Control Organization (CDSCO) has increased unannounced inspections and adopted risk-based surveillance, but level of enforcement and fines are debatable. Further investments in quality systems and workforce training are required.

Dependence on Chinese inputs

Despite its scale, India's formulation industry relies heavily on imports for raw materials. According to industry analyses, Indian firms source around two-thirds of their key APIs from China, and the dependence is even higher for specific categories like antibiotics and vitamins[xi]. In 2018, approximately 67.5 percent of the raw materials for drug formulations by value were imported from China; by 2024 this figure had risen to 87 percent for antibiotic ingredients[xii]. **Chinese suppliers hold near-monopolies on penicillin and cephalosporin intermediates.**

This dependence exists because China offers economies of scale and infrastructure that India currently lacks. Decades of underinvestment in domestic chemical manufacturing, coupled with environmental regulations and high capital costs, have made it difficult for Indian firms to produce APIs competitively. The Indian government has sought to address this by launching the PLI scheme for bulk drugs. Introduced in 2020, the scheme offers financial incentives to companies that set up or expand domestic production of critical APIs, KSMs, and medical devices. As of 2024, the PLI program had facilitated 32 projects with a total annual capacity of 56,679 metric tonnes[xiii]. Additional projects are underway to produce crucial antibiotics, vitamins, and hormones. And they do not compete with China on fine chemical production.

Innovation and emerging capabilities

Historically, Indian pharma excelled in process chemistry and reverse engineering. However, the landscape is changing. Many Indian companies now invest heavily in R&D, biosimilars, novel formulations, and digital health. Start-ups and multinational collaborations are exploring mRNA vaccines, gene therapies, and cell-based treatments. **India's biotech sector ranks third in Asia and is projected to reach US$300 billion by 2030.** Domestic venture funding has increased, and companies like Biocon, Dr. Reddy's, and Zydus Lifesciences are entering global clinical trials with innovative molecules.[xiv]

Government initiatives complement these trends. The Bioeconomy Mission seeks to develop human capital in synthetic biology and genomics. The National Medical Devices Policy aims to reduce import dependence for equipment. These programs signal a shift towards a broader life sciences ecosystem that goes beyond generics[xv].[xvi]

As of September 2025, production capacities have been created for 38 critical APIs and 26 KSMs/DIs/APIs, which were earlier primarily imported from China are now produced

domestically. These initiatives flipped pharma trade from import dependence to surplus and sustained export momentum into FY25-26 (April-Dec: USD 23.1B, +6.5%), positioning India as the third-largest drug producer by volume[xvii].

The Biopharma SHAKTI scheme is a new government initiative announced by Finance Minister Nirmala Sitharaman in the Union Budget 2026-27, presented February 1, 2026. **This scheme builds on existing efforts (BioE3 Policy, PLI schemes) but represents a targeted, large-scale push specifically for high-value biologics manufacturing and innovation.** The Indian government just last week announced an allocation of $1billion over the next 5 years for scaling up biotech manufacturing in India, so expect increased capabilities and capacity over the next 10 years.

China's Upstream Dominance and Strategic Leverage

Growth of the Chinese API industry

China's rise as the world's primary supplier of APIs and KSMs can be traced to targeted industrial policies, aggressive pricing, and environmental externalities. **Beginning in the 1990s, China designated pharmaceuticals as a strategic sector.** It offered tax holidays, preferential lending, and industrial parks dedicated to chemical synthesis. Provincial governments competed to attract manufacturers, building clusters in coastal provinces like Zhejiang, Jiangsu, and Shandong.

Chinese companies achieved economies of scale through consolidation. Hundreds of small producers merged or exited the market as larger firms like Zhejiang Huahai, CSPC, and Shijiazhuang Pharma Group expanded. Vertical integration allowed them to control multiple stages of production, from raw material extraction to finished APIs. Meanwhile, limited enforcement of environmental regulations kept costs low. The cumulative result is a global industry dominated by Chinese suppliers. For example, China provides nearly all of the world's supply of aspirin and acetaminophen intermediates.

The vulnerability is best illustrated by Amoxicillin, the second most prescribed oral antibiotic in the U.S. At first glance, its US supply appears diversified – numerous manufacturers around the world, including India, China, Austria, Spain, Italy, and Singapore produce amoxicillin API and formulate it into finished oral dosage forms in India, Canada, Jordan, Slovenia, Austria, and the US. Some of the intermediate KSMs are made in India and elsewhere. However, its synthesis ultimately depends on four KSMs—each produced almost entirely in China. The most critical, 6-aminopenicillanic acid (6-APA), is also essential for other penicillin-based antibiotics such as Ampicillin, Dicloxacillin, Nafcillin, Oxacillin, and Piperacillin. **Because China effectively holds the key to 6-APA, any factory shutdown or restriction in China would cascade through the Indian manufacturing sector and result in acute shortages of these essential antibiotics in the United States.**[xviii] The question is them whether the US chemical industry could compete with China. KSM's are energy intensive and China subsidises energy costs. Europe struggles to compete on energy prices but the US fine chemical industry could. There is also need to be subsidies for technology because fluorination and that kind of process is dirty. In addition, there could be support for some KSMs to be made from biofuels instead of

petroleum. There are regulatory constraints on doing this but no scientific reason why this could not be done.

Subsidies and state support

The Chinese government continues to nurture its pharmaceutical sector through subsidies, export credits, and support for mergers and acquisitions. Local governments often provide free land, infrastructure, and utilities to large manufacturers. Firms can access low-interest loans from state-controlled banks. When environmental regulations tightened in 2017, many small producers closed, but larger firms moved to compliant facilities with government assistance. In addition, national strategies such as the "Made in China 2025" initiative prioritize biopharmaceuticals and emphasize innovation and indigenous technology.

While American biotech struggles under this funding model, international competitors have built innovation models which thrive. Chinese biotech firms achieved up to 80% cost reductions with deal sizes 40-50% lower compared to US[xix]. Their development costs average $20 million versus our $100 million-plus[xx]. This isn't marginal efficiency—it's a fundamentally different model. The implication is stark: A Chinese biotech asset is profitable at a $200 million valuation. An American equivalent is considered a failure unless it hits $1 billion. **This imbalance transforms the entire calculus of global capital allocation. In Q1 2025, Chinese biotech captured 32% of global licensing deal value, up from virtually zero 6 years ago[xxi].** American pharmaceutical companies invested in Chinese partnerships in 2025—not by choice, but by economic necessity. Companies like WuXi AppTec and WuXi Biologics now offer globally competitive R&D and manufacturing services, attracting Western clients. While these developments signal China's move up the value chain, they also heighten U.S. dependence on Chinese talent and infrastructure.

China is already developing hundreds of best in class or even first in class molecules across the modality and therapeutic landscape. They already have leveraged their dominance in the downstream aspects of biopharma development and manufacturing to move up the value chain aggressively. The battle for the "innovation supply chain" has already begun. With its own IP, China can apply patents and for FDA approval of pharmaceutical products in the U.S. market. The Chinese market, while large, is not very profitable - the government pays very little for drugs. So essentially access to the US market allows China to both keep its spending low while boosting its domestic firms' profitability and their competitive advantage over US biotechs.

As China strengthens its role in the pharmaceutical industry, it could shape development of global pharmaceutical standards and pharmaceutical regulations through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other venues, including those related to drug approval and patent protection, aligning them more closely to its own domestic view of appropriate standards. Along with support leveraged from its allies and other economically and technologically dependent nations it could further consolidate China's

influence over global pharmaceutical markets. **U.S. and its democratic allies need to engage within the international regulatory harmonization space, if not, it furthers China's ability to shape standards to their benefit.**

Analysts note that the Biosecure Act, introduced in the U.S. Congress, aims to reduce reliance on Chinese biomanufacturing by restricting government contracts with companies that use Chinese biotechnology services or equipment. This reflects growing recognition of the security dimensions of pharmaceutical supply chains. Yet decoupling from China without building alternative capacity could exacerbate shortages, and in fact a diversified sourcing across the supply chain that includes China helps reduce drug costs.

Interdependence: India, China, and the United States

The triad of supply

A China→India→United States pipeline creates multiple points of vulnerability. Disruption at any stage of this triad can lead to shortages.

Case studies of disruption

- **Valsartan contamination (2018)**: Several Chinese manufacturers of valsartan, a widely used blood-pressure medication, were found to have contaminated the API with a carcinogenic impurity. The U.S. FDA and European authorities issued recalls. Because only a few alternative suppliers existed, shortages ensued, and prices spiked.
- **Heparin contamination (2008)**: Contaminated heparin produced in China caused dozens of deaths in the United States. The adulteration—replacing porcine intestine-derived heparin with cheaper oversulfated chondroitin sulfate—highlighted quality risks in global supply chains.
- **COVID-19 disruptions (2020)**: Temporary shutdowns of Chinese factories led to global shortages of APIs for antibiotics, antipyretics, and antivirals. India's export restrictions compounded the problem. Hospitals in the United States reported shortages of common drugs like azithromycin and hydroxychloroquine.

These cases illustrate that the risk is not hypothetical. They also demonstrate that supply chain resilience cannot rely solely on market forces; it requires deliberate policy intervention to ensure diversification.

The cost of redundancy

A common objection to reshoring or diversifying pharmaceutical manufacturing is cost. Building domestic API plants in the United States or Europe may involve higher labour costs, stricter environmental regulations, and longer permitting timelines. However, cost comparisons often ignore the externalities of supply disruptions: hospital closures, delayed surgeries, treatment interruptions, and increased morbidity. The COVID-19 pandemic revealed that when supply chains fail, the economic and human costs dwarf the savings gained from sourcing the cheapest supplier. To correct this market failure, industrial policy

and federal purchasing must explicitly value resilience: **through advanced market commitments, multi-award and geographically diversified contracts (with our allies through initiatives like the Bio5 framework with the EU, Japan, South Korea and India), resilience-weighted reimbursement, and strategic stockpiling linked to allied manufacturing capacity.** In this framework, diversification across the United States and BIO5 partners is not an inefficiency—it is a necessary investment in national and allied health security.

The Promise of AI-Enabled Biomanufacturing

Process intelligence and optimization

Artificial intelligence (AI) is transforming pharmaceutical R&D, clinical trials, and supply chain management, but its impact on manufacturing may be the most revolutionary. AI systems can process vast amounts of historical and real-time data from sensors, reactors, and quality control instruments. By identifying patterns and correlations, AI models can optimize reaction conditions, predict yield outcomes, and reduce variability. This is particularly important for fermentation-based APIs and biologics, where small changes in temperature, pH, or nutrient concentrations can drastically affect yield and quality. AI thus enables tighter control, higher yields, and lower waste.

A recent industry report notes that AI systems analyze patterns across historical and real-time data, helping manufacturers anticipate deviations and optimize processes; these capabilities improve process stability and product quality[xxii]. Furthermore, AI can shift quality control from reactive to predictive. **By monitoring deviations in real time and identifying early warning signals, AI allows proactive interventions that prevent batch failures and reduce costs**[xxiii]. AI will lock in manufacturing advantages by the countries that define standards, IP and platforms.

Predictive resilience and supply chain visibility

AI can also enhance supply chain resilience by integrating data on demand forecasts, inventory levels, manufacturing schedules, and supplier performance. Machine-learning algorithms can forecast shortages months in advance, enabling distributors and policymakers to allocate resources proactively. For example, combining prescription data, hospital utilization, and supplier output can predict when demand for a critical antibiotic will outstrip supply. **Such insights allow biosurveillance, strategic stockpiling or surge production before a crisis hits.**

Digital twins—virtual replicas of manufacturing processes and supply networks—offer another tool. By simulating disruptions (e.g., a plant closure or raw material shortage) and modeling mitigation strategies, digital twins help decision-makers evaluate options without risking real production. These capabilities are especially valuable for complex biologics manufacturing, where lead times are long and scale-up is costly.

Regulatory confidence and continuous manufacturing

AI supports regulatory compliance by providing granular data and process transparency. Continuous manufacturing—where APIs and finished drugs are produced in a non-stop

flow rather than in batch sequences—creates massive data streams. AI can analyze these streams, flag anomalies, and document adherence to critical quality attributes. This aligns with the FDA's quality-by-design and PAT (Process Analytical Technology) frameworks, which encourage manufacturers to understand and control variability. AI-enabled control systems can demonstrate consistent performance, potentially reducing inspection burdens and speeding approvals.

Congress should support programs like the FDA's proposed PreCheck to expedite facility approvals and streamline environmental permitting. Technoeconomic incentives modeled on the CHIPS Act (tax credits, grants, and low-cost loans) should support continuous manufacturing and AI-optimized production, with a goal of achieving meaningful domestic API capacity within three to five years. **NIST and the FDA should convene regulatory and standards groups in the US to accept and incentivize the next-gen technology.** CDER ETP (https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program-etp) is an example.

Strategic implications

AI-driven manufacturing is not merely an efficiency tool; it is a strategic differentiator. China is investing heavily in AI-enabled bioprocessing and digitalization. Its state-owned enterprises and private firms are embedding AI in continuous production lines for antibiotics, vitamins, and biologics**. If the United States and its allies fail to adopt similar technologies, they risk losing competitiveness and remaining dependent on Chinese innovation.** Conversely, leadership in AI-enabled manufacturing could allow the U.S. to reclaim some of the value chain.

Policy and Financial Incentives

Current U.S. efforts in pharmaceuticals are limited to narrow funding for manufacturing innovation. During the first Trump Administration, an interagency task force that included U.S. Department of Health & Human Services (HHS) (including FDA), CMS, Department of Defense (DoD), and FTC concluded that a primary "root cause" of drug shortages was the "lack of incentives to produce less profitable drugs." Current contracting practices contribute to a 'race to the bottom' in pricing. The downward pressure on prices resulting from asymmetrical power of purchasers has also increased the risk of shortages, as discussed in further detail below. Most pharmaceutical shortages are found in the generic drugs market, particularly those with a per unit price of less than $1. **Many such shortages are the result of unsustainably low reimbursement for older, lower margin products, which may lead to their discontinuation.** Indeed, there have been more than 3,000 generic product discontinuations since 2010. Other countries, which generally pay more for their generic drugs, do not have as many drug shortages. Researchers have pointed to these structural features as a source of fragility in the U.S. drug market. The Senate Finance Committee proposal is a means to correct this[xxiv]. The roadmap to self-sufficiency requires regulatory, trade, and technoeconomic tools to be deployed in tandem.

A framework for sustained investment

Based on the analysis presented, I respectfully recommend the following ten actions for consideration by the Commission and Congress

1. **Designate pharmaceuticals as strategic infrastructure**: Recognize vulnerable medicines as part of the nation's critical infrastructure. This designation would justify robust federal support, akin to what is provided to semiconductors, energy, and transportation.

2. **Greater visibility into the supply chain:** The federal government currently lacks a comprehensive, shareable real-time database of where each API and finished drug is made[xxv]. You cannot stockpile what you cannot see. Congress should amend existing law to require manufacturers to report tier-2 and tier-3 suppliers, while real-time supply mapping to the FDA give decision-makers visibility into chokepoints. This recommendation draws on current legislative proposals to enhance reporting requirements. Mechanisms need not be burdensome and can align with other industries. With better data, the government can identify single points of failure and work with companies to address them before crises hit. If the Clear Labels Act passes, non-governmental third parties can fairly easily create databases that include mapping of FDFs and APIs. USP's mapping of KSMs would still need to continue

3. **Foster regional alliances**: Negotiate a health security trade treaty and implement the Bio5 framework that includes the EU, Japan, South Korea, India; and expand to include other democracies to build distributed supply and aggregated demand. Coordinate regulatory approvals and share best practices in AI and continuous manufacturing. This diversification reduces the risk of any single country becoming a chokepoint. Combining Indian and European fine chemistry and API production materially reduces the risks of dependence on China. The current administration's playbook on the critical mineral deal offers a template.

4. **Guaranteed offtake**: Advanced purchase commitments by Tricare and the Veteran's Health Administration for vulnerable medicines and strategic APIs. They should commit to buying a minimum volume over a fixed period at a fair price, providing revenue certainty. The US hospital market is a tender spot market. There is no incentive to invest in long-term manufacturing investments. Long-term contracts is a better solution. This gives predictability to invest in production. CMS reimbursement reforms with incentives for buying products made with domestic API or KSM – can have a larger impact than direct government procurement [xxvi].

5. **Risk-sharing mechanisms**: Multi-year tax credits for capital investment in API and biologics facilities; subsidized financing for manufacturing equipment; accelerated depreciation for pharmaceutical infrastructure. Public-private partnerships that share the costs and benefits of developing new production technologies (e.g., continuous flow reactors, AI-driven control systems). The U.S. International Development Finance Corporation and the Export-Import Bank could extend low-interest financing to projects that build API capacity in India but also other countries, provided they reduce

single country dependence. Such collaboration would enhance supply chain resilience. At the same time, the U.S. should encourage Indian firms to invest in manufacturing in the United States.

6. **Monitor and Mitigate Proactively:** An interagency task force should continuously identify which critical drugs are single-sourced and develop contingency plans for each. Establishing playbooks that activate stockpiles and rationing protocols, diversify sourcing through emergency trade pacts, expedite import approvals, leverage compounding pharmacies, and encourage clinical substitutions when certain drugs run short. The FDA's drug shortage task force, along with intelligence community input, should periodically simulate a scenario of Chinese API export curbs to predict which U.S. medicines would run short in weeks versus months. This will inform stockpile priorities. Congress should continue to reinforce and provide additional funding to the Administration for Strategic Preparedness and Response's office of Industrial Base Management and Supply Chain (IBMSC) as well as the agency's Strategic National Stockpile (SNS) to procure essential medicines, not just finished drugs but also key API ingredients that could bottleneck production. The IBMSC should collaborate with industry to rotate stock of critical APIs that have shelf-life limitations.

7. **Strengthen quality assurance:** Increase funding for the FDA's inspections of foreign manufacturing facilities and work with USP to expand training and adoption of quality standards. Create an international consortium to share inspection data and harmonize quality requirements. Point of care quality testing is not too expensive and is another tool to ensure safety of medicines.

8. **Fund Innovations:** Accelerate advancements like continuous flow manufacturing (reducing production time by 50-70% through automated, efficient processes) and green chemistry (using biocatalysts for sustainable synthesis, lowering environmental impact and costs). Patented innovations, such as improved synthesis could enable faster, higher-purity production. These could be deployed via public-private partnerships to retrofit existing facilities, potentially cutting setup times by 20-30%. Fund public-private partnerships to develop AI-driven process control, digital twins, and predictive analytics for pharmaceuticals. Prioritize projects that demonstrate measurable improvements in yield, quality, and energy efficiency. This is not a solution and will take time, but should be part of the portfolio of recommendations.

9. **Regulatory harmonization and innovation:** Streamlined regulatory pathways for facilities that adopt advanced manufacturing and AI. For example, mutual recognition agreements with trusted partners could reduce duplicate inspections and accelerate market entry. Facilitate regulatory acceptance of AI tools by creating clear guidance and pilot programs with the FDA. 'Leapfrog innovation' for US manufacturing: recognize that the US cannot compete with lower labor costs and subsidized CAPEX in China, which is already there. Propose smaller manufacturing footprints (more efficient tech, like continuous manufacturing), more automation (less workers

needed), more modular production facilities, in house and in-process quality testing and others.

10. **Create Research Development Companies (RDCs) for biotechnology**: The United States should establish new investment vehicles that provide permanent capital for research-stage biotech assets. Such RDC structures—modeled on Business Development Companies but tailored to long drug-development timelines—would allow pension funds and institutional investors to invest with adjusted risk-weighting and fiduciary safe-harbor protections. Permanent capital would free biotech innovators from the boom-and-bust cycles of venture funding and reduce pressure to outsource R&D to low-cost jurisdictions.

Conclusion

While this testimony examines geopolitical and industrial dynamics, the consequences of supply chain vulnerabilities are felt first, and most acutely, by US patients. Drug shortages lead to delayed cancer treatments, rationed antibiotics in hospitals, forced substitutions with inferior outcomes, and moral distress for care teams compelled to decide who receives care. Supply chain resilience is therefore not only a matter of national security, but also a matter of patient survival.

The United States stands at a crossroads. For decades, global supply chains have delivered inexpensive medicines to American patients. This model kept prices low but created hidden dependencies and vulnerabilities. China's dominance of upstream pharmaceutical ingredients and India's reliance on Chinese inputs mean that U.S. health security is contingent on geopolitical stability in Asia. The COVID-19 pandemic exposed these fault lines.

At the same time, technological advances—particularly in artificial intelligence and continuous manufacturing—offer an opportunity to redesign supply chains for resilience. By investing in AI-enabled production, building domestic and allied capacity, and supporting partners like India in reducing single source dependence, the United States can transform pharmaceuticals from a vulnerability into a strategic strength.

I thank the Commission for its attention to this critical issue and for its leadership in elevating pharmaceutical supply chain security as a national priority. I stand ready to assist with further analysis and implementation of the recommendations outlined here.

i https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european
ii U.S. pharmaceutical import reliance: 25% of U.S. generic APIs may originate from China and up to 50% rely on Chinese key starting materials via India. The Pharmaceutical Commerce summary of a U.S.–China Economic & Security Review Commission report explains that nearly one-quarter of APIs in U.S. generic drugs could originate from China and that Chinese key starting materials underpin as many as 50% of U.S. generic drugs.

[iii] Government of India, Department of Pharmaceuticals. Indian Pharmaceutical Industry: Global Supply Role.

Ministry of Chemicals and Fertilizers.

iv Global share of generics and vaccinations: India provides 20% of the worldwide supply of generic medicines and fulfills around 60% of global vaccination demand. A Financial Express article reports that India supplies about one-fifth of the world's generic medicines and meets roughly 60% of the global demand for vaccines.

v UNICEF and WHO vaccine supply: As of May 2025, India supplies 55–60% of UNICEF's vaccines, meets 99% of the WHO's DPT vaccine demand, and provides 52% of BCG and 45% of measles vaccines, supported by around 3,000 drug companies and 10,500

v Global share of generics and vaccinations: India provides 20% of the worldwide supply of generic medicines and fulfills around 60% of global vaccination demand. India's generic manufacturers supply roughly one-fifth of all generic medicines consumed worldwide and about 60% of global vaccine demand, according to the Financial Express.

vi UNICEF and WHO vaccine supply: As of May 2025, India supplies 55–60% of UNICEF's vaccines, meets 99% of the WHO's DPT vaccine demand, and provides 52% of BCG and 45% of measles vaccines, supported by around 3,000 drug companies and 10,500 manufacturing units. The IBEF analysis reports that India supplies 55–60% of UNICEF vaccines, 99% of WHO's DPT vaccines, 52% of BCG vaccines, and 45% of measles vaccines.

[vii] McKinsey & Company. India Pharma 2020: Propelling Access and Acceptance, Realizing True Potential

viii https://www.aging.senate.gov/imo/media/doc/clear_labels_act2.pdf

ix Supply shocks: In March 2020, India restricted the export of 26 drugs—including paracetamol and antibiotics—to avoid domestic shortages when key starting materials stopped arriving from China. A Guardian report from March 2020 explains that India temporarily restricted exports of 26 drugs (including paracetamol and several antibiotics) to prevent shortages after supply disruptions in Chinese ingredients.

x https://www.fda.gov/media/188153/download

xi India's import dependence on China: around two-thirds of India's key active pharmaceutical ingredients are sourced from China, and by 2024 about 87% of India's imported antibiotic ingredients by value came from China. See [^8].

xii India's import dependence on China: around two-thirds of India's key active pharmaceutical ingredients are sourced from China, and by 2024 about 87% of India's imported antibiotic ingredients by value came from China. See [^8].

xiii Production Linked Incentive (PLI) scheme: India's government launched the PLI scheme in 2020 for domestic manufacturing of bulk drugs (APIs), KSMs and medical devices; as of 2024, the scheme has completed 32 projects with an annual capacity of 56,679 metric tonnes. An ETManufacturing report from August 2024 notes that 32 projects under the PLI scheme for bulk drugs have been completed, creating a cumulative installed capacity of 56,679 metric tons per year.

xiv https://pharma-dept.gov.in/sites/default/files/Revised%20list%20of%20applicant%20-%20PLI%20for%20Ph…

xv https://pharmexcil.com/uploadfile/Hand_Book_14_06_2025_final.pdf

xvi https://dbtindia.gov.in/sites/default/files/Annexure-I-Implementation%20Plan%20for%20BioE3.pdf

xvii https://www.pib.gov.in/PressReleasePage.aspx?PRID=2222079&reg=3&lang=2

xviii U.S. Pharmacopeia. "Concentrated Origins, Widespread Risk: New USP Insights on Key Starting Materials." Quality Matters, October 2025. https://qualitymatters.usp.org/concentrated-origins-widespread-risk-new-usp-insights-key-starting-materials.

[xix] Boston Consulting Group. Biopharma Dealmaking in China

[xx] https://media.nature.com/original/magazine-assets/d41586-025-01927-x/d41586-025-01927-x.pdf

[xxi] https://www.bioworld.com/articles/727503-china-made-products-account-for-30-of-global-deals-in-2025#:~:text=See%20today's%20BioWorld%20Asia,off%20at%20much%20higher%20prices.

xxii AI in pharmaceutical manufacturing: AI systems analyze historical and real-time data to anticipate deviations and optimize processes, improving process stability and quality outcomes; they enable predictive quality control by identifying patterns and early warning signals, shifting manufacturing from reactive to proactive.

xxiii AI in pharmaceutical manufacturing: AI systems analyze historical and real-time data to anticipate deviations and optimize processes, improving process stability and quality outcomes; they enable predictive quality control by identifying patterns and early warning signals, shifting manufacturing from reactive to proactive.

xxiv https://healthpolicy.duke.edu/publications/addressing-root-causes-drug-shortages-next-steps-congress

[xxv] https://www.uscc.gov/sites/default/files/2025-06/Stephen_Schondelmeyer_Testimony.pdf#:~:text=shortages%20in%20the%20market,relative%20risk%20of%20drug%20shortages

xxvi https://www.cms.gov/newsroom/press-releases/cms-seeks-public-input-strengthening-domestic-supply-chain-ppe-essential-medicines