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ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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Minority (202) 225-2927

June 9, 2025

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Subcommittee on Health Hearing on June 11, 2025

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, June 11, 2025, at 10:00 a.m. (ET) in 2123 Rayburn House Office Building. The hearing is entitled "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain."

II. WITNESSES

- **Mr. Patrick Cashman**, President, USAntibiotics
- **Mr. John Murphy, III**, President and Chief Executive Officer, Association for Accessible Medicines (*Minority*)
- **Dr. Ronald T. Piervincenzi, PhD**, Chief Executive Officer, United States Pharmacopeia
- **Ms. Dawn O'Connell**, Former Assistant Secretary for Preparedness and Response (*Minority*)
- **Mr. Josh Bolin**, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy

III. BACKGROUND

The health care supply chain is a complex and extensive network of systems, components, and processes involving a variety of stakeholders. This network facilitates the development, manufacture, distribution, and delivery of drugs, biologics, medical devices, and medical products and supplies that enable access to the critical care that Americans rely on.

The health care supply chain encompasses a wide array of entities that each play a vital role to ensure products are delivered to patients in a safe and efficient manner. As a result, each entity has the ability to dynamically influence the operation and success of the supply chain as a whole. This process often involves raw material or component suppliers (e.g., makers of

ingredients or subassemblies), producers or manufacturers (e.g., final assembly plants, fill-and-finish facilities), distributors, wholesalers, and group purchasing organizations, providers (e.g., health systems, pharmacies, retailers), and ultimately, patients.[1] Government agencies also have varied roles and responsibilities in the supply chain, both as a direct participant, policy maker, regulator, and consumer.[2]

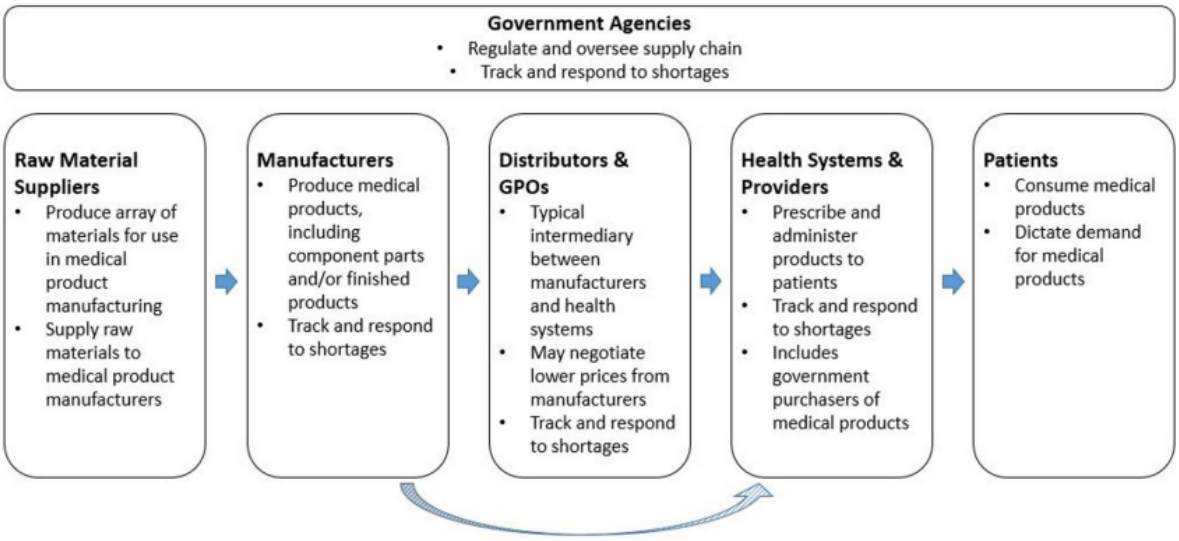


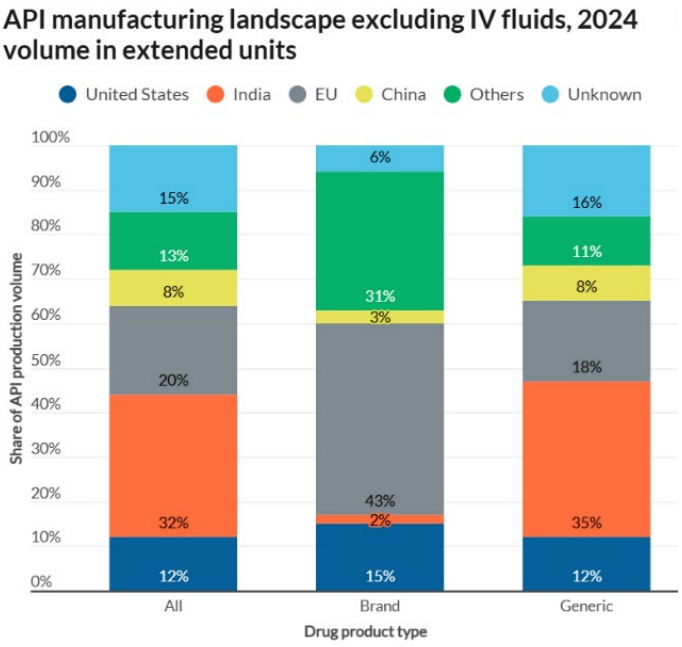
FIGURE 1-1 Stakeholders in a medical product supply chain.
NOTE: GPO = group purchasing organization.
SOURCE: Adapted from ASPR_TRACIE, 2019.

[3]

The health care supply chain often begins with a raw material supplier. Raw materials are the building blocks that eventually lead to the finished product. This can include key starting materials (KSM) that evolve into the active pharmaceutical ingredients (API) in medications, latex in personal protective equipment, or steel in medical devices. Depending on the industry, raw material suppliers can be geographically concentrated, increasing the risk of disruptions. A recent analysis showed around half of the APIs for prescription medicines in the U.S. come from India and the European Union (EU), with around 12 percent being manufactured domestically in the U.S.[4] While China contributes around 8 percent of the total API analyzed, they remain a dominant supplier of the KSMs utilized to produce APIs.[5] China is also the exclusive manufacturer of certain API and essential medicines, controlling much of antibiotic API production.[6] In terms of finished dose forms, the U.S. is the largest manufacturer of injectables with 45 percent of production volume, followed by the EU with 19 percent. For solid oral dosage forms, India has the majority of production volume at 60 percent, followed by the U.S. with 22

[1] National Academies of Sciences, Engineering, and Medicine (NASEM), *Building Resilience into the Nation's Medical Product Supply Chains,* THE NATIONAL ACADEMIES PRESS (2022), https://doi.org/10.17226/26420.
[2] *Id*.
[3] *Id.*
[4] Vimala Raghavendran et al., *Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union,* U.S. PHARMACOPEIA (USP) QUALITY MATTERS (Apr. 17, 2025), https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european.
[5] *Id.*
[6] U.S.-China Economic and Security Review Commission (USCC), *Section 3: Growing U.S. Reliance on China's Biotech and Pharmaceutical Products,* 2019 ANNUAL REPORT TO CONGRESS (Nov. 2019), at 253, https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf.

percent.[7] The U.S. remains the most common first-launch country for new drug products, with other country launches often lagging a year or more.[8]



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Manufacturers within the medical supply chain can include both small and large firms, and their involvement may span the entire production process of a product or be limited to contributing product components. A manufacturer that specializes in a specific stage of production is considered a contract manufacturing organization (CMO) or a contract development and manufacturing organization (CDMO). CMOs and CDMOs provide comprehensive services to coordinate and link together the various steps that lead to the final finished product.[10] CMOs and CDMOs can enable companies to scale operations efficiently and access specialized expertise, cutting development time and costs, and accelerating time-to-market.[11] A recent survey showed 79 percent of biopharma companies—two-thirds of the companies being small, emerging biotechnology companies—have at least one contract or product with a Chinese-based or China-owned CMO or CDMO.[12]

The sale and delivery of market-ready medical products may be facilitated by wholesale distributors or group purchasing organizations (GPO). A wholesale distributor purchases large

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[7] USP, *USP Annual Drug Shortages Report: Long-standing drug shortages persist in 2024*, USP MEDICINE SUPPLY MAP (May 2025), https://go.usp.org/2025drugshortagesreport.
[8] IQVIA Institute, *Global Trends in R&D 2025: Progress,* IQVIA INSTITUTE FOR HUMAN DATA SCIENCE REPORTS (Mar. 2025), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2025.
[9] Vimala Raghavendran, *supra* note 4.
[10] NASEM, *supra* note 1.
[11] Bhushan Pawar, *Contract Manufacturing Organization (CMO) Market Size, Share & Industry Analysis*, FORTUNE BUSINESS INSIGHTS (May 19, 2025), https://www.fortunebusinessinsights.com/contract-manufacturing-organization-cmo-market-102658.
[12] Biotechnology Innovation Organization, *Chinese biomanufacturing*, (May 9, 2024), https://www.bio.org/gooddaybio-archive/bio-survey-reveals-dependence-chinese-biomanufacturing.

quantities of a product directly from a manufacturer and resells the product to a health system, provider, secondary distributor, or a GPO. A GPO also serves as an intermediary between manufacturers and health systems, either serving in a purchasing role or as a negotiator of contracts for medical products on behalf of its members.[13] Before the product reaches the patient, it is generally delivered to a receiving health facility or system, which can include hospitals, pharmacies, nursing homes, clinics, or government agencies. Physicians, nurses, pharmacists, and other health care providers then utilize these products to diagnose, treat, and care for their patients.

While there are many factors for why different countries have developed varying capacities across the medical supply chain, China ascension into a critical player is not an accident. The People's Republic of China (PRC) has engaged in a concentrated and strategic effort to become the global leader in bio-medicine development and production.[14] The growing role of Chinese industry in the supply chain has generated significant concerns over American reliance on China and potential impacts on the dependability of the entire global supply chain.[15] Even India, which has made significant strategic investments in carving out for its own industry a major role in the medical supply chain, is dependent on China for an estimated 70 percent of their APIs.[16] As Congress considers the challenges and opportunities of strengthening domestic manufacturing and ensuring the stability of our medical supply chain, it is vital we keep the actions and ambitions of other global players front of mind.

The globalization of the medical supply chain has helped to promote access to quality medicines at a lower cost. However, the resulting trade-off is a more lengthy and fragmented supply chain, often leading to a lack of visibility across stages of the process and an increasingly unsustainable reliance due to vulnerability to overseas disruption, particularly for certain essential medicines.[17] When examining supply chain challenges and opportunities for improvement, it is important to consider supply and demand fluctuation in relation to events occurring both inside and outside of our nation's borders. A proactive approach to strengthening and supporting our health care supply chain, incentivizing and promoting domestic manufacturing, and examining regulatory modernization can help ensure access to reliable, safe, and sustainable care for American patients, and reinforce U.S. leadership in medical innovation.

IV. STAFF CONTACTS

If you have questions regarding this hearing, please contact Annabelle Huffman of the Committee staff at (202) 225-3641.

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[13] NASEM, *supra* note 1.
[14] McKinsey & Company, *Vision 2028: How China could impact the global biopharma industry*, LIFE SCIENCES PRACTICE (Aug. 2022), https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/vision%202028%20how%20china%20could%20impact%20the%20global%20biopharma%20industry/vision-2028-how-china-could-impact-the-global-biopharma-industry.a.
[15] USCC, *supra* note 6.
[16] Anna Nishino, *The great medicines migration,* NIKKEI ASIA (Apr. 5, 2022), https://asia.nikkei.com/static/vdata/infographics/chinavaccine-3/.
[17] USP, *supra* note 7; In Joon Noh, John Gray, George Ball, Zachary Wright & Hyunwoo Park, *Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events*, PRODUCTION AND OPERATIONS MANAGEMENT, SAGE JOURNALS (Jan. 20, 2025), https://interactive.wthr.com/pdfs/Final_published_POMs.pdf.