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MAKING MEDICINE IN AMERICA AGAIN:

Why Breaking Monopolies Is Key to Building a Resilient U.S. Pharmaceutical Manufacturing Base

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CONTENTS

BREAKING THE COMMODITIZATION LOOP

Over several decades, federal policymakers have enabled and incentivized profit-maximizing corporations to offshore the production of pharmaceuticals, systematically dismantling domestic manufacturing capacity. Through the 1960s, pharmaceutical products consumed in the United States largely were manufactured within the country's borders.[1] Today, whether it is antibiotics, antivirals, analgesics, or most of the essential medicines used in acute and intensive care settings, the majority of critical medicines used by Americans are not made in the United States.

Domestic pharmaceutical production capacity is so gutted that we lack the ability to manufacture many generic antibiotics, including those used to treat children's ear infections, strep throat, pneumonia, urinary tract infections, sexually transmitted diseases, Lyme disease, and other infections.[2] The United States depends on China for generic drug categories that include antibiotics, antidepressants, oral contraceptives, chemotherapy drugs, and medicines for diabetes, Parkinson's, epilepsy, HIV/AIDS, and Alzheimer's.[3]

Overreliance on medicine from any one or a few distant countries is a threat to public health. Climate disasters, geopolitical conflicts, and global pandemics necessitate onshoring and diversifying pharmaceutical supply chains. Dependence on Chinese medicine imports additionally represents a critical national security vulnerability. These risks demand urgent policy interventions. Onshoring production of essential drugs and their components — key starter materials (KSMs), intermediates, and active pharmaceutical ingredients (APIs) — is vitally important for America's national security and public health. Essential drugs with the greatest risk of shortage, which are almost entirely generic drugs, must be the top priority.

The reason the United States does not produce drugs or their components domestically is simple. It is no longer profitable to do so. This situation is a result of policy choices made at home and abroad. On the supply side, foreign countries, especially China, subsidize their own industries in strategic ways that undermine U.S. production.[4] But U.S. tax policy also encourages the offshoring of production, as does the absence of any labor or environmental standards for imports. On the demand side, dominant middlemen, like group purchasing organizations (GPOs) and wholesale drug distributors, use their buyer power to flatten existing domestic generic manufacturers' profit margins to razor-thin or negative levels.[5]

Middlemen buyer power, together with the inability of generic drugs to compete on quality, has created what experts call "the commoditization loop," where downward price pressure drives manufac-

1 Arthur Daemmrich, "Pharmaceutical Manufacturing in America: A Brief History," American Institute of the History of Pharmacy, 2017, https://repository.si.edu/server/api/core/bitstreams/75a66d01-ba23-476b-996c-84ab0812b0f6/content; Stephen Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities," p. 9, U.S.-China Economic and Security Review Commission, June 5, 2025, https://www.uscc.gov/sites/default/files/2025-06/Stephen_Schondelmeyer_Testimony.pdf.

2 "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," p. 231, The White House, June 2021, https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

3 See above.

4 "2019 Annual Report to Congress, Chapter 3 Section 3 - Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," U.S. China Economic and Security Review Commission, November 2019, https://www.uscc.gov/sites/default/files/2019-11/Chapter%203%20Section%203%20-%20Growing%20U.S.%20Reliance%20on%20China%E2%80%99s%20Biotech%20and%20Pharmaceutical%20Products.pdf.

5 Sara Sirota, "The Dirty Secret of Drug Shortages," American Economic Liberties Project, October 2023, https://www.economicliberties.us/wp-content/uploads/2023/10/20230720-AELP-DrugShortages_Brief_v7.pdf.

turing overseas, further concentrating production in low-cost countries.[6] Other dominant middlemen, pharmacy benefit managers (PBMs), control access to pharmaceutical markets and engage in anti-competitive tactics to disadvantage certain generic drugs.[7] Creating functional markets so that firms can invest in domestic production and make money doing so requires assessing and addressing each of these problems. Attempts to fix the problem piecemeal are doomed to fail.

To address the hollowing out of U.S. pharmaceutical production capacity, the Trump administration is focused mainly on tariffs.[8] Strategic tariffs, designed to create a viable market for domestically produced products and encourage domestic manufacturing of essential medicines and their ingredients, are among the policy tools the U.S. government should consider. Yet tariffs — if they are not phased in methodically over time, as important competition and industrial policies are implemented — will not only fail to promote onshoring but could also create dangerous drug shortages and raise drug prices. Targeted tariff policies can also help diversify the countries from which the United States imports, focusing on near- and friend-shoring medicines and their components to increase resilience beyond greater domestic production capacity.

For domestic manufacturers of essential generic drugs to have access to open markets, competition policy is needed to break up dominant middlemen. GPOs, wholesalers, and PBMs all extract money from the drug supply chain, effectively charging tolls to manufacturers.[9] The bankruptcy filings and investor documents of generic pharmaceutical producers are littered with statements discussing their dependency on dominant distributors, and the high fees these middlemen charge them for access to markets.[10]

In addition to competition policy, industrial policies that create demand for domestic medicines and ingredients, and that directly support the development of a domestic manufacturing base, must accompany tariffs. On Aug. 13, 2025, President Donald Trump issued the Executive Order "Ensuring Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve," which aims to stockpile a six-month supply of APIs on an updated essential medicines list.[11] This is an important emergency measure to protect against life-threatening shortages. But rebuilding America's manufacturing base to create durable independence will take time. Although existing U.S. manufacturing facilities are underutilized, with only about half of current generic production capacity in use,[12] it will take at least two years to repurpose idle capacity in the API and finished-medicines sectors.[13]

6 Anthony Sardella, "US Generic Pharmaceutical Industry Economic Instability," Center for Analytics and Business Insights, April 21, 2023, https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf; Andrew Rudman, "A Bilateral Approach to Address Vulnerability in the Pharmaceutical Supply Chain," Center for Strategic & International Studies, Nov. 18, 2024, https://www.csis.org/analysis/bilateral-approach-address-vulnerability-pharmaceutical-supply-chain.

7 "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies," Federal Trade Commission, July 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

8 William Burkhart and Keigh Hammond, "Presidential 2025 Tariff Actions: Timeline and Status," Congressional Research Service, Sept. 16, 2025, https://www.congress.gov/crs-product/R48549; Talya Minsberg, "A Timeline of Trump's On-Again, Off-Again Tariffs," The New York Times, updated Oct. 14, 2025, https://www.nytimes.com/2025/03/13/business/economy/trump-tariff-timeline.html.

9 See infra "Section II: Competition Policies to Restructure Pharmaceutical Markets and Rein in Anti-Competitive Middlemen," pp. 30-34.

10 "Form 10-Q," Akorn, Inc., Aug. 7, 2020, https://www.sec.gov/Archives/edgar/data/3116/000162828020012156/akrx-20200630.htm; "Form 10-K," Teva Pharmaceuticals Industries Limited, Feb. 10, 2021, https://www.sec.gov/Archives/edgar/data/818686/000119312521036239/d102112d10k.htm#toc102112_4; Arthur Allen, "Drugmakers Are Abandoning Cheap Generics, and Now US Cancer Patients Can't Get Meds," KFF Health News, June 21, 2023, https://kffhealthnews.org/news/article/drugmakers-are-abandoning-cheap-generics-and-now-us-cancer-patients-cant-get-meds/.

11 "Ensuring American Pharmaceutical Supply Chain Resilience by Filling the Strategic Pharmaceutical Ingredients Reserve," The White House, Aug. 13, 2025, https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/.

12 "Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains," U.S. House Committee on Energy and Congress Subcommittee on Oversight and Investigations, May 11, 2023, https://www.congress.gov/118/chrg/CHRG-118hhrg55967/CHRG-118hhrg55967.pdf.

13 Anthony Sardella, "U.S. Generic Pharmaceutical Manufacturer Available Capacity Research Survey," Center for Analytics and Business Insights, Sept. 30, 2022, https://wustl.app.box.com/s/32e1w52bgajp6pz22gf4vjotj78997uk.

Estimates for establishing new production capacity range from five to 10 years.[14]

In pursuing industrial policies to remake America's pharmaceutical manufacturing base from the ground up, policymakers should seek to build deconcentrated market structures that create lasting resilience. America needs a thriving, competitive, and deconcentrated pharmaceutical manufacturing base that enables innovation, diversified risk, and shared prosperity. This means manufacturers should be located in many regions across America and receive government funding to adopt advanced manufacturing technologies. We need more domestic makers at each stage of essential medicine production: KSMs, intermediate materials, APIs, and finished medicines.

Part One of this paper explains the risks of U.S. dependence on foreign countries for essential medicines and tells the history of how we got here. Part Two discusses how successful onshoring of pharmaceutical manufacturing requires restructuring markets by reining in the market power and anti-competitive practices of pharmaceutical middlemen. Part Three sets forth a vision and plan for incorporating antimonopoly by design to build deconcentrated pharmaceutical manufacturing market structures. Part Four briefly discusses trade policies to be implemented as competition policies restructure markets and as industrial policies invest in, and create reliable demand for, domestic manufacturing.

Many hundreds of pages of ink have been spilled, and hours of congressional testimony have been given, addressing the problem of fragile pharmaceutical supply chains.[15] Yet the conversation has largely lacked an antimonopoly lens. Missing from the discussion is the fact that the current crisis cannot be fixed without addressing anti-competitive market structures and practices. Also absent is a vision of building a deconcentrated, resilient manufacturing base that spans the country and does not buttress Big Medicine's corporate power. The goal of this report is not to lay out a detailed plan for everything that must be done to onshore pharmaceutical manufacturing but rather to contribute the antimonopoly perspective in the areas where it is most needed. In addition to trade policies, including strategic tariffs, onshoring manufacturing will necessarily involve a comprehensive suite of industrial policies, including direct subsidies, tax benefits, grants, loans, and other incentives, the precise contours of which are beyond the scope of this report.

14 Andrew Rudman and Jerry Haar, "Strengthening US-Mexico Quality Pharmaceutical Supply Chains," Wilson Center, June 11, 2024, https://www.wilsoncenter.org/article/strengthening-us-mexico-quality-pharmaceutical-supply-chains.

15 See, e.g., 2, 4, and 12; "Essential Medicines Supply Chain and Manufacturing Resilience Assessment," Appendix A, Advanced Regenerative Manufacturing Institute, May 2022, https://www.armiusa.org/wp-content/uploads/2022/05/ARMIEssentialMedicinesSupplyChainReport_May2022.pdf; "National Strategy for a Resilient Public Health Supply Chain," Administrative for Strategic Preparedness and Response, July 2021, https://aspr.hhs.gov/MCM/IBx/2022Report/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf; "Building a Resilient Domestic Drug Supply Chain: The Path to National Health Security," API Innovation Center, March 25, 2025, https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf; "Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security," U.S. China Economic and Security Review Commission, June 5, 2025, https://www.uscc.gov/hearings/dominance-design-china-shock-20-and-supply-chain-chokepoints-eroding-us-security; Anthony Sardella, "The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security," Center for Analytics and Business Insights, Aug. 1, 2021, https://apicenter.org/wp-content/uploads/2024/07/The-US-Active-Pharmaceutical-Ingredient-Infrastructure.pdf; "Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," U.S.-China Economic and Security Review Commission, July 31, 2019, https://www.uscc.gov/hearings/exploring-growing-us-reliance-chinas-biotech-and-pharmaceutical-products; Janet Woodcock, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program," U.S. House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, Dec. 10, 2019, https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019; Janet Woodcock, "Safeguarding Pharmaceutical Supply Chains in a Global Economy," U.S. House Committee on Energy and Commerce Subcommittee on Health, Oct. 30, 2019, https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019; "Rebuilding the U.S. Medical Supply Chains," Brookings Institution, June 11, 2021, https://www.brookings.edu/wp-content/uploads/2021/06/gs_20210611_medical_supply_transcript.pdf.

DEFINITIONS

Key starting materials (KSMs) are the fundamental chemical compounds that serve as the foundation for manufacturing pharmaceutical drugs.[16]

Pharmaceutical intermediates are chemical compounds produced at various stages during the multi-step synthesis of active drug ingredients. These are transitional molecules that undergo further chemical transformations before becoming the final therapeutic compound.[17] Like components in an assembly line, intermediates represent partially completed products that must be processed further. They have no medicinal value on their own but are essential stepping stones in creating the drug.

Active pharmaceutical ingredients (APIs) are the chemically active compounds in medications that produce the intended therapeutic effects. These are the molecules that treat disease, relieve symptoms, or provide the desired biological response when administered to patients. For example, acetaminophen is the API in Tylenol that reduces pain and fever.[18]

Finished drug forms are complete pharmaceutical products in their final, patient-ready state. These represent the end result of the manufacturing process where APIs are combined with inactive ingredients and formulated into specific delivery systems like tablets, capsules, injections, or topical preparations.[19]

16 "Sourcing Key Starting Materials (KSMs) for Pharmaceutical Active Pharmaceutical Ingredients (APIs): A Strategic Imperative for Resilience," DrugPatentWatch, July 23, 2025, https://www.drugpatentwatch.com/blog/sourcing-the-key-starting-materials-ksms-for-pharmaceutical-active-pharmaceutical-ingredients-apis/.

17 "Pharmaceutical Intermediates: Definition, Types & Applications in Drug Synthesis," BOC Sciences, accessed Oct. 17, 2025, https://www.bocsci.com/resources/pharmaceutical-intermediates-definition-types-applications-in-drug-synthesis.html; "Pharma Intermediates: Why Quality and Key Factors Matter," Global Pharma Tek, accessed Oct. 17, 2025, https://www.globalpharmatek.com/blog/pharma-intermediates-why-quality-and-key-factors-matter/.

18 Jonathan Agbenyega, "Understanding Active Pharmaceutical Ingredients," International Union of Crystallography," accessed Oct. 17, 2025, https://www.iucr.org/news/research-news/understanding-active-pharmaceutical-ingredients; 21 U.S.C. § 207.1-207.13.

19 "Finished Dosage Forms and APIs: How Are They Different?," Zeal & Innovation in Medicine, accessed Oct. 17, 2025, https://www.zimlab.in/blog-posts/finished-dosage-forms-and-apis-how-are-they-different.

THE FOREIGN DEPENDENCE CRISIS AND HOW WE GOT HERE

PUBLIC HEALTH AND NATIONAL SECURITY AT RISK

U.S. Highly Dependent on Imported Essential Medicines and Key Ingredients

The APIs needed for more than four out of five of the top 100 generic drugs prescribed have no U.S.-based manufacturing source, according to a recent study published by the Olin Business School at Washington University.[20] That includes the APIs needed to produce 97% of antivirals and 92% of antibiotics. Eighty-three percent of the top 100 generic drugs have no U.S. source of API.[21]

A startling share of APIs used worldwide originates in China, regardless of where finished medicines are produced. Globally, China supplies over 80% of APIs or their KSMs for essential drugs like antibiotics, fever reducers, painkillers, and diabetes medications.[22] China manufactures over 2,000 API molecules and had more than

20 See "The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security" at 15.

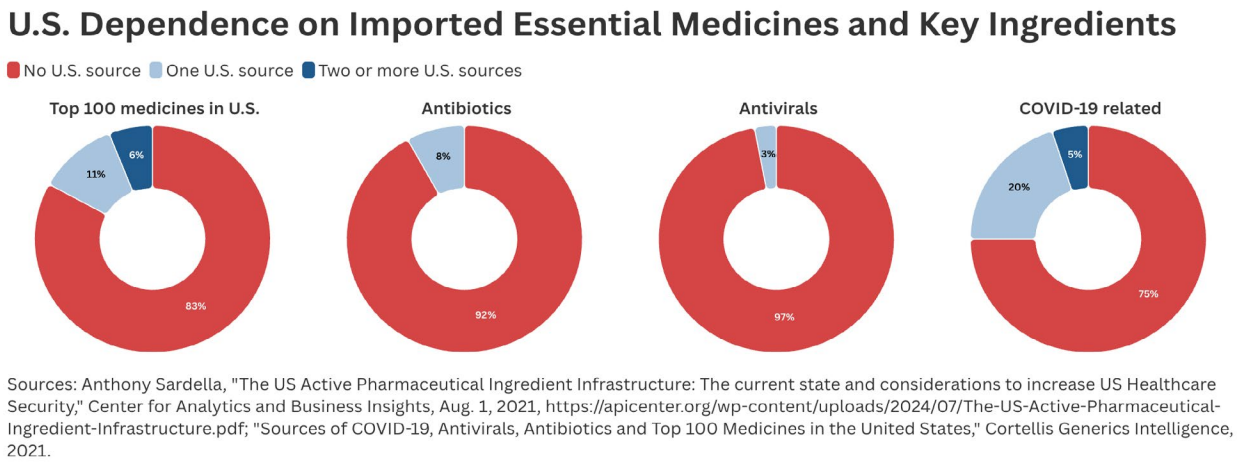
21 See "The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security" at 15.

22 "The Role of China in the Global Generic Drug API Market," DrugPatentWatch, March 25, 2025, https://www.drugpatentwatch.com/blog/the-role-of-china-in-the-global-generic-drug-api-market/; Yangzong Huang, "U.S. Dependence on Pharmaceutical Products from China," Aug. 14, 2019, Council on Foreign Relations Blog, https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

7,000 API manufacturers as of 2020.[23]

Figures about European pharmaceutical imports underestimate U.S. dependence on China. A recent news report, for example, stated that 60% of U.S. pharma imports came from Europe in 2024.[24] This figure represents imports by dollar value, not volume. European countries, and Ireland in particular, predominantly make high-dollar branded pharmaceuticals, including weight loss drugs, rather than the critical low-cost generic drugs that are the focus of this report.[25] And although European countries account for 30% of global API production, they are dependent on China for 70% of their APIs and KSMs.[26]

China is also the dominant manufacturer of KSMs, supplying over 60% of the global market, as well as approximately 70% of the intermediates used in the manufacture of APIs.[27] Even India depends on China for an estimated 70-80% of its APIs and KSMs.[28]



Sources: Anthony Sardella, "The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security," Center for Analytics and Business Insights, Aug. 1, 2021, https://apicenter.org/wp-content/uploads/2024/07/The-US-Active-Pharmaceutical-Ingredient-Infrastructure.pdf; "Sources of COVID-19, Antivirals, Antibiotics and Top 100 Medicines in the United States," Cortellis Generics Intelligence, 2021.

23 "Indian API Industry: Reaching the Full Potential," KPMG and the Confederation of Indian Industry, 2020, https://www.cii.in/PublicationDetail.aspx?enc=8WtPUf8Nh6hH4VSx3flm9WsCJHK9xxqz+uAO/6yie0Y71YAOu6zRjufengxfioBHdZmlRkhj64IdxNjT/mh94bOUGTPGZWN/tmx77sUzbFCqHhOxkeuIgmCJvlEvLf4y543QjSZXzXapfqDnR+nhvabbnOLine0RFdIBIuUNL2s=.

24 Gregor Hunter and Andrew Silver, "US, European pharma stocks steady after Trump's tariff move, Asia slips," Reuters, Sept. 26, 2025, https://www.reuters.com/business/healthcare-pharmaceuticals/shares-asian-drugmakers-drop-after-trump-threatens-tariffs-2025-09-26/.

25 John Fitzgerald, "The Irish pharmaceutical sector," pp. 10-11, Economic & Social Research Institute, Autumn 2025, https://www.esri.ie/system/files/publications/RN20250301.pdf.

26 "EU Fine Chemical Commercial KPI," IQVIA, Dec. 11, 2020, https://efcg.cefic.org/wp-content/uploads/2021/06/20201211_IQVIA-for-EFCG_Executive-summary.pdf.

27 See 16; "The Role of China in the Global Pharmaceutical Supply Chain: Key Starting Materials and Active Pharmaceutical Ingredients," World Health Organization, 2020, pp. 55-69; G. Liu and S. Zhou, "China's Dominance in Key Starting Materials: Production and Export Dynamics in the Pharmaceutical Industry," pp. 45-62, World Trade Journal, 2019.

28 "The Pharmaceutical Gambit: An Analysis of Why India Lags China and a Roadmap to Competitive Parity," DrugPatentWatch, Aug. 28, 2025, https://www.drugpatentwatch.com/blog/the-pharmaceutical-gambit-an-analysis-of-why-india-lags-china-and-a-roadmap-to-competitive-parity/; see 26.

Precise market share estimates vary, and the U.S. government has a worrying lack of data delineating what percentage of what categories of essential medicines used in the United States originate domestically or from what import source. In the Biden White House report "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," published in June 2021, which included a review by the U.S. Department of Health and Human Services, the federal government admitted it lacks the necessary data: "Without knowing the volume of production in each facility in real-time, it is difficult to draw conclusions about what the supply chain actually looks like."[29]

The combination of concentration, offshoring, and trade secret protections means accurate information about which plants make which medicines in what quantities is unknown, even to the FDA: "In the generic market, 87% of API facilities are outside the United States, but FDA does not have data on the volume of API that is produced outside the United States, which could be lower or higher."[30] The lack of transparency means the U.S. government is in the dark about the true extent of our dependence on China and other foreign nations for essential medicines and their APIs.[31] The closest approximation is information on the geographic location of production facilities that the FDA has inspected, yet that data provides no insight into the types or volume of medicines or APIs being produced.

The COVID-19 pandemic exposed the fragility of these concentrated supply chains. When workers in China, India, and Italy became ill with COVID-19 and factories shut down, worldwide shortages escalated quickly because China produces both a large amount of finished drugs and APIs, India produces many generic medicines sold worldwide, and Italy produces a significant share of finished antibiotics.[32] As University of Minnesota Professor Stephen Schondelmeyer noted, "Out of 21 antibiotics that would be critical for treating secondary infections in COVID-19 patients, 18 antibiotics have greater than 80% of their supply coming out of either China, India or Italy—all places that have had production disruptions."[33]

In addition to the threats posed by pandemics or natural disasters, China has demonstrated willingness to weaponize its control over critical supply chains. In April 2025, the Chinese government announced it would ban the export of critical minerals and magnets needed to make cars, planes, semiconductors, and military equipment. [34] Similar restrictions on pharmaceutical exports could prove catastrophic for American patients.

Even domestic production faces concentration risks: When Hurricane Helene devastated a single North Carolina factory that produces 60% of the country's IV bags, one weather event created na-

29 See 2, p. 222.

30 See 2, p. 214.

31 We surveyed multiple data sources to try to obtain the needed API import data, including speaking to proprietary data analytics companies and former health care regulators, and we did not find any sources that had the data or the full set of building blocks needed to construct a data set.

32 See 22; Lori Wallach, Testimony before the U.S.-China Economic and Security Review Commission, April 14, 2022, https://www.uscc.gov/sites/default/files/2022-04/Lori_Wallach_Testimony.pdf; "EU production and trade of antibiotics," Eurostat, Nov. 18, 2019, https://ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20191118-2.

33 Knvul Sheikh, "Essential Drug Supplies for Virus Patients Are Running Low," The New York Times, April 2, 2020, https://www.nytimes.com/2020/04/02/health/coronavirus-drug-sho rtages.html.

34 China announced additional restrictions — including ending exports of five more rare earth minerals as well as rare earth processing equipment — in early October 2025. Keith Bradsher, "China Halts Critical Exports as Trade War Intensifies," The New York Times, April 13, 2025, https://www.nytimes.com/2025/04/13/business/china-rare-earths-exports.html; Keith Bradsher, "Step by Step, How China Seized Control of Critical Minerals," The New York Times, Oct. 27, 2025, https://www.nytimes.com/2025/10/27/business/china-rare-earth-export-controls.html. See also Garphil Julien and Audrey Stienon, "China's Active Pharmaceutical Ingredient (API) Manufacturing System," Open Markets Institute, Dec. 15, 2025, https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/693b2bb39262937bfac527e6/1765485491967/China%E2%80%99s+Active+Pharmaceutical+Ingredient+%28API%29+Manufacturing+System+Report+WEB.pdf.

tionwide shortages.[35] This demonstrates how concentration — whether foreign or domestic — creates systemic vulnerabilities.

That's why, in addition to onshoring, securing pharmaceutical supply chains requires avoiding concentration by diversifying U.S. import sources. This can be achieved with policies that incentivize shifting sourcing to nearby countries that have manufacturing infrastructure, like Canada and Mexico, known as "near-shoring," as well as intentionally creating redundancies in supply with imports from countries with domestic medicine production capacity but limited U.S. sales, like Brazil, Argentina, Columbia, and Chile.[36]

Prioritizing Essential Medicines and Ingredients in Shortage for Onshoring

Drug shortages in America are a persistent problem. A decade before the COVID-19 crisis, the National Institutes of Health was already reporting growing shortages of commonly used medicines.[37] The Food and Drug Administration (FDA) was reporting shortages in more than 100 essential drugs at the end of 2019.[38]

Generic drugs are more likely to face shortages than higher-priced branded drugs. According to a 2023 IQVIA study, 11% of drugs priced less than $1 per unit were in shortage, compared to 1.3% of drugs priced more than $500 per unit.[39] This occurs because generic drugs account for 90% of prescriptions in America, but represent a small share of total drug spending, with estimates ranging from 12% to 18%.[40] Generic manufacturers have thin margins that cannot support redundancy and buffer stock.

Onshoring manufacturing should follow a phased approach that prioritizes essential medicines with the greatest supply chain vulnerabilities. Policymakers should initially focus on those essential medicines that have the greatest risk of shortage and the greatest offshore dependence.[41] The Advanced Regenerative Manufacturing Institute (ARMI) in the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR) created a prioritized list of 86 drugs in May 2022 that are critical for acute care with no comparable alternatives available. The drugs fell in the following therapeutic categories:

35 Joseph Leonard, "Western North Carolina IV plant still shut down. Supply shortage 'affecting hospitals across the United States,'" WCNC Charlotte, Oct. 13, 2024, https://www.wcnc.com/article/news/local/hospitals-across-country-worry-over-iv-shortage/83-3374c97f-ef12-4f6c-af32-8419b12d34ab.

36 See "Statement on Designing a Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities," p. 34, at 1; see also Thomas Roades et al., "Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of Geographic Diversification," Margolis Institute for Health Policy, Nov. 8, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-11/Building%20a%20Resilient%20and%20Secure%20Pharmaceutical%20Supply%20Chain.pdf; Meredith Broadbent, "Securing Medical Supply Chains with Trusted Trade Partners: Western Hemisphere Case Studies," Center for Strategic and International Studies, 2022, https://www.jstor.org/stable/pdf/resrep40538.pdf.

37 C. Lee Ventola, "The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies," Pharmacy and Therapeutics, November 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/.

38 "FDA Drug Shortages," U.S. Food and Drug Administration, accessed Oct. 17, 2025, https://dps.fda.gov/drugshortages.

39 "Drug Shortages in the U.S. 2023," IQVIA Institute for Human Data and Science, November 2023, https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023.

40 "The U.S. Generic & Biosimilar Medicines Savings Report," Association for Accessible Medicines, September 2025, https://accessiblemeds.org/resources/reports/2025-savings-report/; "Generic Drugs Market Size, Research, Trends and Forecast," Towards Healthcare, updated May 8, 2025, https://www.towardshealthcare.com/insights/generic-drugs-market.

41 See "Essential Medicines Supply Chain and Manufacturing Resilience Assessment" at 15.

Analgesics	Antipyretics	Hormones
Anesthetics	Antiseptics/Disinfectants	Immune Globulins
Anticoagulants/Anti-platelets	Antivirals	Paralytics
Anticonvulsants	Chemotherapies/Immunosuppressants	Psychiatric Agents
Antiemetics	Dialysis Agents	Pulmonary
Antihistamines	Endocrine	Sedatives/Hypnotics
Antihypertensives/Cardiovascular	Gastrointestinal Agents	Steroids
Additives	Glycemic Control	Vasopressors
Antimicrobials		

The August 2025 Executive Order requires the ASPR to update this list within 90 days, which had not yet occurred at the time of publication, to provide a plan for sourcing the drugs domestically, where possible, and to maintain a six-month supply of APIs for these drugs. The order also requires the ASPR to develop a list within 30 days of 26 drugs that are "especially critical to the health and security interests of the Nation," and to maintain a six-month supply of APIs for these drugs.[42] As of publication, this new list had also not yet been published.

Once a stable supply of the most critical medicines and ingredients is secured, the next phase of onshoring should include other important medications that have foreign dependence for any stage of production, which is to say, most pharmaceuticals. Patients should not have to risk losing access to medicines that are important to their health due to poorly designed supply chains unable to withstand foreseeable geopolitical, epidemic, or natural disaster threats.

POLICY-DRIVEN OFFSHORING AND DOMESTIC CONSOLIDATION

The systematic hollowing out of American pharmaceutical manufacturing capacity resulted from deliberate policy choices — including corporate-friendly trade and foreign investment policies as well as the resulting hyper-globalization — that prioritized short-term cost reduction over long-term resilience and national security.

Starting in the 1970s, a significant portion of America's drug manufacturing sector relocated from the continental United States to Puerto Rico, driven by attractive tax benefits and research incentives.[43] During the 1980s, pharmaceutical production expanded in Europe, similarly spurred by tax and re-

42 See 5.

43 See "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program" at 15.

search incentives.[44] By the end of the 1980s, drug manufacturing was expanding in developing nations, particularly in India and China, due in large part to industrial policies explained in more detail below.[45]

To make matters worse, similar philosophical and political underpinnings resulted in a lack of domestic competition policy enforcement thanks to the misguided "consumer welfare" standard, which facilitated merger mania in every part of the pharmaceutical market.[46] As a result, our economy is organized to serve a production model focused almost exclusively on economic efficiency and reliant on long, brittle global supply chains and production of medicine in too few countries — often by too few firms.[47]

Trade Policies Designed to Maximize Corporate Profits Incentivized Offshoring

Trade policy for decades encouraged corporations to move production overseas in a never-ending race to exploit the cheapest labor and lowest environmental standards and to concentrate production geographically. China, in particular, has consolidated large shares of production for APIs and many generic medicines using persistent mercantilist practices.[48] The United States is unable to make or reliably acquire many critical medicines and their inputs because of the mass outsourcing of U.S. industrial capacity since the mid-1990s and the intensive global concentration of production with little redundancy.[49]

In 1995, large U.S. and European pharmaceutical corporations pushed for the 1947 General Agreement on Tariffs and Trade (GATT) to be replaced by the World Trade Organization (WTO), a global commerce agency with new rules obliging countries to enforce extended intellectual property monopolies.[50] While the GATT covered only traditional trade matters, such as tariffs and quotas related to trade in goods over borders, the WTO enforced a dozen new agreements that required countries to change their domestic laws and policies.[51] One of these, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), required WTO member countries to provide 20-year monopoly patents for medicines, medical devices, and more.[52]

Except for the least-developed countries, which had an extended phase-in period, the new policy required WTO member nations to guarantee extended intellectual property monopoly rights in their

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44 Frank Barry and Adele Bergin, "Offshoring, Inward Investment and Export Performance in Ireland," Economic and Social Research Institute, February 2012, https://www.esri.ie/system/files?file=media%2Ffile-uploads%2F2015-07%2FOPEA81.pdf; Michael Burstall, "European Policies Influencing Pharmaceutical Innovation," The Changing Economics of Medical Technology, 1991, https://www.ncbi.nlm.nih.gov/books/NBK234307/.

45 See "The Role of China in the Global Generic Drug API Market" at 22.

46 Krista Brown et al., "The Courage to Learn," American Economic Liberties Project, January 2021, https://www.economicliberties.us/wp-content/uploads/2021/01/Courage-to-Learn-Final.pdf.

47 See 5 and 32; Lori Wallach, Written Testimony on "COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges," Sept. 21, 2020, https://www.citizen.org/wp-content/uploads/Public-Citizen-Written-Testimony-Covid-and-trade-with-Add-Submission.pdf.

48 "List of Chronic Global Trade Deficit and Surplus Countries 2024," Rethink Trade, July 2025, https://rethinktrade.org/wp-content/uploads/2025/07/TRADE-BALANCE-CATEGORIES_UPDATED.pdf.

49 See 32.

50 Charan Devereaux et al., Case Studies in US Trade Negotiation, Vol. 1, pp. 52-65, Institute for International Economics, September 2006, https://www.piie.com/publications/chapters_preview/392/03iie3624.pdf.

51 "Agreement on Trade-Related Aspects of Intellectual Property Rights," World Trade Organization, accessed Oct. 17, 2025, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

52 See above; Suma Athreye et al., "Twenty-five years since TRIPS: Patent policy and international business," Journal of International Business Policy, Oct. 12, 2020, https://pmc.ncbi.nlm.nih.gov/articles/PMC7549422.

domestic laws, with failure to do so subject to trade sanctions.[53] This policy shift not only allowed the industry to raise prices for medicines worldwide but also provided IP monopoly protections in low-wage countries that facilitated offshoring of production to these venues.[54], [55]

Over time, protected by these WTO intellectual property monopoly guarantees and incentivized by trade pacts' failure to require compliance with any labor or environmental standards as a condition of gaining access to another market, pharmaceutical firms began offshoring their manufacturing to countries with low environmental and worker standards.[56] This shift accelerated in 2000, when the U.S. Congress approved China's admission to the WTO.[57] At that point, with low-tariff or duty-free access back into the U.S. market guaranteed, U.S.-based pharmaceutical firms and the chemical manufacturers that supplied many APIs were focused on offshoring production to China, where there are no independent unions, low wages, and weak environmental protections.[58] The lack of environmental standards is notable, as many medicines' components are effectively food-grade chemicals. Under the WTO's rules, these chemicals could be produced while dumping toxins and without containing industrial emissions and then sent back for sale in countries where domestic producers must operate under rules and incur expenses to ensure production does not threaten the public.

China's emergence as a pharmaceutical industry powerhouse required several decades of development. The country implemented a deliberate industrial strategy that emphasized the production of KSMs, intermediates, and APIs.[59] The government provided considerable investment to support the pharmaceutical industry through subsidies, tax breaks, and low-cost loans to construct infrastructure and increase production capabilities.[60]

As with many industries, the Chinese government's strategic plans involved taking over the pharmaceutical sector with anti-competitive practices, including through pumping and dumping, i.e., heavily subsidizing pharmaceutical manufacturing, gaining market share, and then flooding the market with cheap products.[61] Beginning in the early 2000s, Chinese companies fixed the price of vitamin C, with much of the world dependent on China for this essential vitamin.[62] Similarly, in 2004, Chinese companies formed a cartel and flooded the generic market with cheap penicillin, driving alternative sources

53 See above; "Responding to least developed countries' special needs in intellectual property," World Trade Organization, updated Oct. 16, 2023, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

54 Lori Wallach, Testimony on "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedures, 2021 Report," U.S. International Trade Commission, Oct. 2, 2020, https://www.citizen.org/wp-content/uploads/Public-Citizen-Written-Testimony-FTAs-under-TPA-with-Add.-Submission.pdf.

55 Domestic patent changes also played a role in shipping American industries — and jobs — overseas. Among many statutory and doctrinal changes that impacted industry business models, some were explicitly trade-related. For example, the Patent Act was amended in 1988 and 1996 to make the importation of a product made by a patented process an act of infringement and an exclusive right. This likely reassured corporations that if a product they had manufactured offshore was pirated by their subcontractors or other manufacturers abroad, they would still have the exclusive ability to import that product for sale in the U.S. In other words, it made offshoring less risky. See Troy Petersen, "US Infringement Liability for Foreign Sellers of Infringing Products," Duke Law & Technology Review, 2003, https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1101&context=dltr.

56 "Hyperglobalization Undermines Response to COVID-19 Crisis," Public Citizen, Feb. 10, 2021, https://www.citizen.org/article/goods-needed-to-combat-covid-19-hyper-globalization-undermines-response/.

57 "Background Information on China's Accession to the World Trade Organization," Office of the United States Trade Representative, Dec. 11, 2001, https://ustr.gov/archive/Document_Library/Fact_Sheets/2001/Background_Information_on_China's_Accession_to_the_World_Trade_Organization.html.

58 See "Statement on Designing a Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities," p. 10, at 1.

59 See "2019 Annual Report to Congress, Chapter 3 Section 3 - Growing U.S. Reliance on China's Biotech and Pharmaceutical Products" at 4.

60 See "2019 Annual Report to Congress, Chapter 3 Section 3 - Growing U.S. Reliance on China's Biotech and Pharmaceutical Products" at 4.

61 Janardan Prasad Singh and Rosemary Gibson, China Rx: Exposing the Risks of America's Dependence on China for Medicine, pp. 70-81, 2021.

62 Bruce Sokler and Robert Kidwell, "Second Circuit: 'C' is for Comity; Price Fixing Judgment Against Chinese Vitamin C Sellers Reversed," Mintz, Sept. 27, 2016, https://www.mintz.com/insights-center/viewpoints/2016-09-27-second-circuit-c-comity-price-fixing-judgment-against-chinese; Lucy Terry, "Unpacking the Global Supply Chain of Vitamin C: Challenges, Trends, and Future Outlook," ChemAnalyst, Aug. 18, 2025, https://www.chemanalyst.com/NewsAndDeals/NewsDetails/unpacking-the-global-supply-chain-of-vitamin-c-challenges-trends-and-future-outlook-38599.

in the U.S., Europe, and India out of business.[63] China's "Made in China 2025" initiative, announced in May 2015, established objectives to become a worldwide pharmaceutical leader by expanding production capacity and bolstering domestic API manufacturers.[64]

Financialization Weakened Manufacturing

Financialization refers to the increasing dominance of financial motives, financial markets, financial actors, and financial institutions in the operation of domestic and international economies. This process — promoted by both domestic financial deregulation and by WTO and other trade-pact rules designed to limit regulation of capital flows and financial services — has fundamentally transformed the American economy since the 1980s, representing a shift from industrial capitalism toward what some scholars call finance-led capitalism.[65] This transformation has created systematic barriers to domestic manufacturing, diverting capital away from productive activities toward financial engineering and short-term profit maximization.[66]

Although the wide-ranging reforms needed to combat financialization are beyond the scope of this paper, the ways in which it has undermined domestic manufacturing are important to highlight: the elevation of shareholder primacy over long-term industrial strategy, the massive growth of stock buybacks that crowd out productive investment, the rise of private equity's extractive approach to manufacturing companies, and the broader shift from an economy focused on making things to one focused on making money from money.[67] Rising stock prices essentially have become the foundation of the U.S. economic model, funding important things like retirement and education, which creates systemic opposition to manufacturing that might reduce financial returns.[68] Now, America's dominant exports are the products of this financialized economy,[69] such as derivatives and other investment instruments, rather than physical goods (including APIs and finished drugs).

Tax Policy Incentivized Offshoring

U.S. tax policy actively incentivized pharmaceutical companies to move production overseas, compounding the effects of trade policy changes and financialization.

In 1976, Congress enacted Section 936 of the tax code, which exempted profits from U.S. companies from federal income tax under certain conditions if the company was based in Puerto Rico or other U.S. territories.[70] This was designed to encourage business investment in Puerto Rico, the Virgin

63 Rosemary Gibson, "Safeguarding Pharmaceutical Supply Chains in a Global Economy," U.S. House Committee on Energy and Commerce Subcommittee on Health, Oct. 30, 2019, https://docs.house.gov/meetings/IF/IF14/20191030/110718/HHRG-116-IF14-Wstate-GibsonR-20191030.pdf.

64 See "The Role of China in the Global Generic Drug API Market" at 22. For more information on the Chinese API industry, see also "China's Active Pharmaceutical Ingredient (API) Manufacturing System" at 34.

65 Thomas Palley, "Financialization: What It Is and Why It Matters," The Levy Economics Institute of Bard College, December 2007, https://www.levyinstitute.org/pubs/wp_525.pdf.

66 Michael Collins, "How Financialization Is Starving Manufacturing," Industry Week, Sept. 21, 2018, https://www.industryweek.com/the-economy/article/22026385/how-financialization-is-starving-manufacturing.

67 See above; Ruth Strachan and Sebastian Shehadi, "Who killed US manufacturing?," Investment Monitor, May 12, 2021, https://www.investmentmonitor.ai/manufacturing/who-killed-us-manufacturing/; Will Dobbs-Allsopp, Lenore Palladino, and Reed Shaw, "Saving Industrial Policy from Shareholder Primacy," The Law and Political Economy Project, Dec. 18, 2022, https://lpeproject.org/blog/saving-industrial-policy-from-shareholder-primacy/.

68 Matt Stoller, "Monopoly Round-Up: Tariffs, Abundance and Why America Can't Build," BIG, March 30, 2025, https://www.thebignewsletter.com/p/monopoly-round-up-tariffs-abundance.

69 See above.

70 "Puerto Rico and Section 936: A Taxing Lesson from History," Citizens for Tax Justice, Aug. 9, 2016, https://ctj.org/puerto-rico-and-section-936-a-taxing-lesson-from-history/.

Islands, and other U.S. "possessions," but it was also a major corporate tax loophole, which promoted companies shifting profits around.[71] However, one outcome of Section 936 was that many U.S. pharmaceutical firms shifted production to Puerto Rico to get a zero tax rate. Puerto Rico became a hub of considerable pharmaceutical production — until 2006, when Section 936 was phased out.[72] Within a few years, the island had lost 40% of its manufacturing jobs as the pharmaceutical industry, no longer lured with tax breaks, sought lower-wage production venues. The 936 phase-out coincided with China's massive surge in investment in pharmaceutical production, exacerbating offshoring of pharmaceutical manufacturing from the United States.[73]

More recently, provisions in the 2017 Tax Cuts and Jobs Act (TCJA) not only let Big Pharma get away with paying little or no U.S. taxes but also incentivized offshoring of the production of generic and branded drug manufacturing. Brad Setser of the Council on Foreign Relations has even suggested that the TCJA should be renamed the "(Pharmaceutical) Tax Cuts and (Irish) Jobs Act."[74] The TCJA established three key tax rates: the 21% standard U.S. corporate rate, the 13.125% reduced rate for foreign-derived intangible income (FDII), and the 10.5% global minimum on intangible income (GILTI).[75]

Since pharmaceutical profits derive primarily from intellectual property (intangibles) rather than manufacturing costs, companies chose to pay the 10.5% GILTI rate by producing offshore rather than paying the 21% U.S. rate. "Getting out of the headline tax rate basically required producing abroad," explains Setser.[76] This is because Subpart F of the U.S. tax code disfavors firms that manufacture in the United States and sell domestically, while claiming that the tax home of the relevant IP is abroad.[77] "That's why U.S imports soared after the TCJA (more than doubling between 2017 and 2024) and are now nearly a percentage point of U.S. GDP," Setser says.[78] U.S. companies have made major investments in manufacturing abroad because of incentives created by the TCJA.[79]

71 See above.

72 See 70.

73 Brad Setser, "The Irish Shock to U.S. Manufacturing?," Council on Foreign Relations, May 15, 2020, https://www.cfr.org/blog/irish-shock-us-manufacturing.

74 Brad Setser, "American Pharmaceutical Companies Still Aren't Paying Tax in the U.S.," Council on Foreign Relations, March 14, 2025, https://www.cfr.org/blog/american-pharmaceutical-companies-still-arent-paying-tax-us.

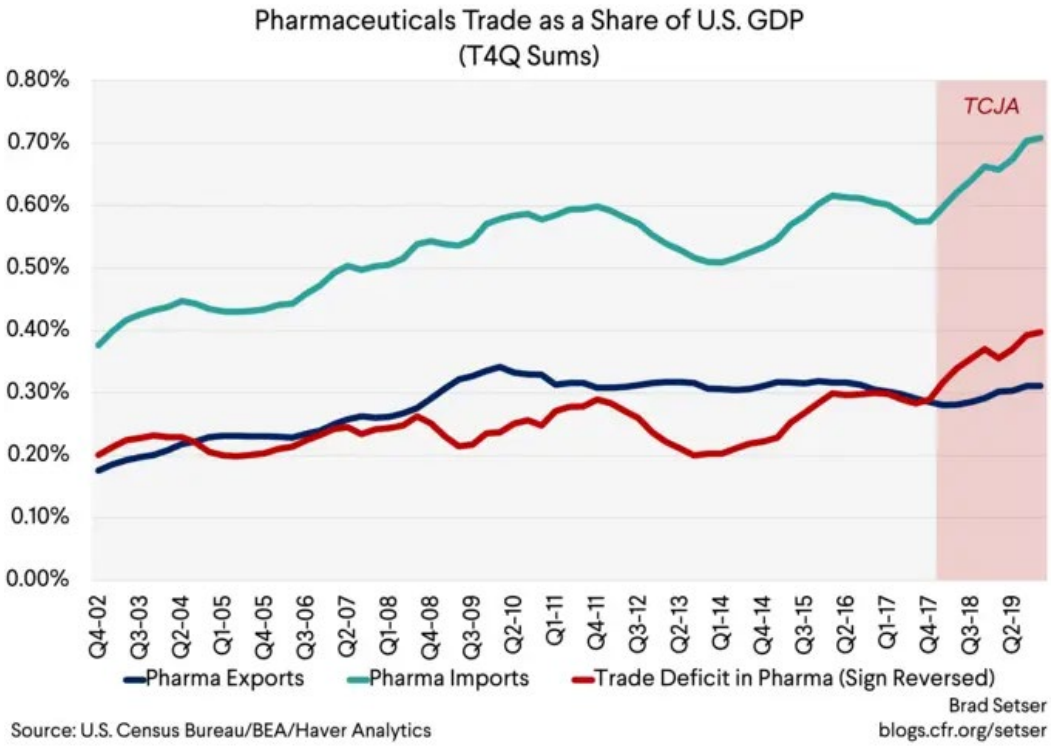
75 See above.

76 See 74.

77 See 74

78 See 74.

79 See 74.



Consolidation Embrittled Domestic Supply Chains

That foreign subsidies and other unfair trade practices have distorted pharmaceutical competition globally is well understood.[80] What is far less understood is how anti-competitive practices and market structures right here at home — enabled by weak competition policy and enforcement — have fueled drug shortages and undermined the resilience of America's pharmaceutical supply chains by incentivizing the consolidation of drug manufacturers and middlemen.

>>> Timeline: Making Medicines in America Again

80 See 2.

DRUG MANUFACTURERS

Prescription drug manufacturers develop and make prescription drugs and then distribute them to wholesalers and, less often, directly to providers and consumers.[81]

In the late 20th century, Congress passed two laws that transformed the generic drug industry. The 1962 Federal Foods, Drug, and Cosmetic Act tied regulatory approval for new drugs to proof of efficacy, often through clinical trials, which many generic manufacturers were unwilling or unable to afford to conduct.[82] The 1984 Drug Price Competition and Patent Term Restoration, or Hatch-Waxman, Act sought to balance incentives for innovation by providing temporary patent monopolies to brand-name manufacturers with access to lower-cost options by streamlining the generic approval process.[83] Although the Hatch-Waxman Act initially led to increased spending on drug research and development as well as generic manufacturing, it failed to account for other domestic and foreign policy changes that were already starting to embrittle the U.S. prescription drug supply chain.[84]

For instance, by the late 1980s, deregulation had prompted an uptick in mergers, as major drug manufacturers "with expiring drug patents sought to make up for their revenue losses by acquiring other profitable drugs."[85] Without vigorous antitrust enforcement, the merged entities also developed a suite of anti-competitive strategies to abuse their government-granted monopolies and thwart generic market entry, driving up drug costs.[86]

Around the same time as international trade policies increasingly incentivized the offshoring of U.S. manufacturing capacity and the Chinese government poured money into an industrial policy designed to speedily grow a world-class pharma manufacturing sector, drug manufacturers underwent another merger wave in the 1990s, "join[ing] forces to reach more potential markets" and avoid patent cliffs.[87] This consolidation continued, spurred again in 2010, when the Obama administration lowered the threshold for federal antitrust review.[88] Altogether, between 1995 and 2015 — the same time period when production largely shifted to China and India — the 60 biggest drug manufacturers merged to just 10.[89]

Merger mania by both branded and generic pharmaceutical manufacturers contributed to fragile drug

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81 "Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," Kaiser Family Foundation, March 2005, https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

82 "Generic Drug Shortages and How a Race to the Bottom in Price has Upended 30 years of Hatch-Waxman," Coalition for a Prosperous America, Oct. 20, 2021, https://prosperousamerica.org/wp-content/uploads/2021/10/Generic-Drug-Shortages-and-How-a-Race-to-the-Bottom-in-Price-has-Upended-30-years-of-Hatch-Waxman.pdf.

83 "The Costs of Pharma Cheating," American Economic Liberties Project and Initiative for Medicines, Access, & Knowledge, May 2023, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

84 See above.

85 Robin Feldman, "Drug companies keep merging. Why that's bad for consumers and innovation." The Washington Post, April 6, 2021, https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/.

86 See 83.

87 See 85; "Comment Re: 'Foreign Nations Freeloading on American Financed Innovation," American Economic Liberties Project, June 27, 2025, https://comments.ustr.gov/s/commentdetails?rid=DM4CJ3HYXD.

88 See 83.

89 Robin Feldman et al., "Pharmaceutical Mergers: Do We Have the Right Cure?," Columbia Science and Technology Law Review, Oct. 15, 2025, https://download.ssrn.com/2025/11/3/5605910.pdf; David Alvaro and Emilie Branch, "M&A: Fundamental to Pharmacy Industry Growth," Pharma's Almanac, March 20, 2020, https://www.pharmasalmanac.com/articles/manda-fundamental-to-pharma-industry-growth; Jaimy Lee, "Drug manufacturers have spent a record $342 billion on M&A in 2019," MarketWatch, Dec. 10, 2019, https://www.marketwatch.com/story/drugmakers-have-spent-a-record-342-billion-on-ma-in-2019-2019-12-09; Marilyn Singleton, "Book Review: China Rx: Exposing the Risks of America's Dependence on China for Medicine," Association of American Physicians and Surgeons, June 8, 2019, https://aapsonline.org/book-review-china-rx-exposing-the-risks-of-americas-dependence-on-china-for-medicine/.

supply chains, with relatively few large firms dominating many categories of medicines.[90] A report analyzing pharmaceutical M&A trends from 2010 to 2023 found that there were 3,006 pharmaceutical M&As during this period.[91] In the course of rolling up the competition, drugmakers shut down the production capacity of the firms they acquired.[92] The report found that M&As are associated with an increase in the risk of drug shortages: "Generic drugs in particular were significantly more likely to go into shortage within the two years after an M&A than were similar non-M&A drugs."[93]

At the same time, drug industry middlemen also consolidated, putting more downward price pressure — in the form of rebates and exclusive contracts — on generic drug manufacturers, as discussed below.[94] These manufacturers, in turn, further consolidated, discontinued production of unprofitable drugs, underinvested in factories, or closed.[95] In conjunction with offshoring, these market trends have resulted in "the importation of poor quality, unsafe" products, constant shortages of life-saving medications, and "widespread price manipulation" despite steady consumer demand.[96]

90 Marc-André Gagnon and Karena Volesky, "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016," Globalization and Health, Aug. 22, 2017, https://doi.org/10.1186/s12992-017-0285-x.

91 "Mergers and Acquisitions (M&As) in Pharmaceutical Markets: Associations with Market Concentration, Prices, Drug Quantity Sold, and Shortages," Eastern Research Group, Inc., and the Center for Integration of Science and Industry at Bentley University, Jan. 8, 2025, https://aspe.hhs.gov/sites/default/files/documents/ec5de77c72cff3abf802b5e9c6cc8ae4/aspe-pharma-ma-report.pdf.

92 See above.

93 See 91.

94 See 5.

95 See 5.

96 See 5; Nick Iacovella and Jon Toomey, "America's Other Health Care Crisis: Generic Medicine Supply Chains," American Affairs, spring 2022, https://americanaffairsjournal.org/2022/02/americas-other-health-care-crisis-generic-medicine-supply-chains/.

THE MYLAN-UPJOHN MERGER

The Mylan-Upjohn merger, which created the world's largest generic pharmaceutical company, illustrates how M&A contributes to brittle supply chains. In July 2019, Pfizer, a leading biopharmaceutical manufacturer, announced that its subsidiary Upjohn — the portion of its business devoted to generic medicines and off-patent-but-branded drugs — would combine with Mylan NV, another pharmaceutical company that specializes in generics, in a $12 billion deal. The merger would form a new entity called Viatris, which would become the world's largest generic pharmaceutical firm, in control of nearly 3,000 drug products.[97]

The FTC filed a complaint in October 2020, alleging that the proposed merger would hinder current or future competition in the market for 10 generic drugs used to treat a variety of symptoms and illnesses.[98] The FTC majority voted 3-2 to file the case but also voted simultaneously to accept a settlement approving the merger so long as Viatris divested its rights and assets related to seven of its generic drugs to Prasco, a competing firm.[99] Commissioner Christine Wilson published an accompanying statement, hailing the divestments as "comprehensive remedies to address the potential anticompetitive effects" of the merger, citing similar solutions reached after the FTC complaints against the mergers of pharma companies Bristol-Myers Squibb-Celgene and AbbVie-Allergan.[100]

The FTC's minority commissioners voted against both the complaint and the settlement for their overly narrow scope. Commissioner Rohit Chopra, in a dissenting statement, argued that mandating a few divestitures was not sufficient to ensure competition in the market for generic drugs.[101] "Both Pfizer and Mylan have been accused of collusion in the generic drug business. We must assess whether this merger will enhance their ability to conspire and collude," he wrote.[102]

In November 2020, the FTC approved the merger, and it subsequently closed. Just one month later, Viatris announced its intention to close, downsize, or divest up to 15 manufacturing facilities.[103] One of the facilities it would shutter was America's largest generic drug manufacturing plant, in Morgantown, West Virginia, laying off nearly 1,500 American workers and outsourcing their jobs to India.

As the plant's closing date neared, in July 2021, Viatris stalled negotiations to sell the facility, citing "confidential" discussions with alternative buyers that might have kept the facility in operation.[104] Advocates urged the government to invoke the Defense Production Act to stop closure of the plant,[105] but the Biden administration failed to do so. In March 2022, West Virginia University purchased the facility for $1.[106] Instead of resuming production of generic drugs, the university plans to convert the site into a nursing school.[107]

97 "Mylan and Upjohn, a Division of Pfizer, to Combine, Creating a New Champion for Global Health Uniquely Positioned to Fulfill the World's Need for Medicine," Pfizer, July 29, 2019, https://www.pfizer.com/news/press-release/press-release-detail/mylan_and_upjohn_a_division_of_pfizer_to_combine_creating_a_new_champion_for_global_health_uniquely_positioned_to_fulfill_the_world_s_need_for_medicine.

98 Complaint, In the Matter of Pfizer Inc. et al., Docket No. C-4727, Oct. 30, 2020, https://www.ftc.gov/system/files/documents/cases/c47271910182pfizermylancomplaint.pdf.

99 "FTC Imposes Conditions on Combination of Pfizer Inc.'s Upjohn and Mylan N.V.," Federal Trade Commission, Oct. 30, 2020, https://www.ftc.gov/news-events/news/press-releases/2020/10/ftc-imposes-conditions-combination-pfizer-incs-upjohn-mylan-nv.

100 "Statement of Commissioner Christine S. Wilson In the Matter of Pfizer Inc. / Mylan N.V.," Federal Trade Commission, Oct. 30, 2020, https://www.ftc.gov/system/files/documents/public_statements/1582394/191_0182_pfizer-mylan_cw_statement.pdf.

101 "Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter In the Matter of Pfizer Inc. / Mylan N.V.," Federal Trade Commission, Oct. 30, 2020, https://www.ftc.gov/system/files/documents/public_statements/1582382/191_0182_pfizer-mylan_-_dissenting_statement_of_commrs_chopra_and_slaughter_1.pdf.

102 See above.

103 Fraiser Kansteiner, "Pfizer-Mylan combo Viatris to slash up to 9,000 jobs, shutter manufacturing plants in global cost-cutting drive," Fierce Pharma, Dec. 11, 2020, https://www.fiercepharma.com/manufacturing/viatris-could-cut-up-to-9-000-global-manufacturing-jobs-as-it-plows-ahead-lb-saving.

104 Laura Flanders, "Closing the Largest Generic Drug Plant in the US Is a Sick Joke," The Nation, July 23, 2021, https://www.thenation.com/article/politics/mylan-plant-closing-manchin/; see also Douglas Sou, "With the Mylan Plant closing, Morgantown wonders what's next," Mountain State Spotlight, May 26, 2021, https://mountainstatespotlight.org/2021/05/26/mylan-plant-morgantown-wv-closure-job-loss/.

105 Dana Brown, "The US is about to lose its largest generic pharmaceutical plant. It doesn't have to." Democracy Collaborative: The Next System Project, July 26, 2021, https://thenextsystem.org/learn/stories/us-about-lose-its-largest-generic-pharmaceutical-plant-it-doesnt-have.

106 "WVU envisions bright future for former Mylan Chestnut Ridge property in Morgantown," West Virginia University, March 31, 2022, https://wvutoday.wvu.edu/stories/2022/03/31/wvu-envisions-bright-future-for-former-mylan-chestnut-ridge-property-in-morgantown.

107 David Beard, "Take a tour of WVU Medicine's planned Center for Nursing Education at the former Mylan Plant," The Dominion Post, March 30, 2024, https://www.dominionpost.com/2024/03/30/take-a-tour-of-wvu-medicines-planned-center-for-nursing-education-at-the-former-mylan-plant/.

GPOS

GPOs are buying cartels for hospitals and other health care providers.[108] Dating to the early 20th century, they grew in number following the creation of Medicare and Medicaid in 1965, when hospital executives sought to reduce spending on medical supplies, including generic drugs.[109] By the 1980s, there were hundreds of GPOs around the country, and nearly every hospital contracted with at least one.[110]

This changed in 1987, when Congress enacted the Medicare and Medicaid Patient Program Protection Act, creating a safe harbor exempting GPOs from a federal anti-kickback law — and revolutionizing their business model.[111] Where GPOs had previously earned money from hospital membership dues, holding them accountable to their customers, they now could accept rebates — typically calculated as a percentage of their total purchase amount — from manufacturers, incentivizing them to prefer higher-cost medical supplies and generic drugs.[112]

Deregulation and the rollback of antitrust enforcement was a bipartisan effort that continued under successive administrations, leading to more industry consolidation.[113] By the 1990s, just six GPOs controlled roughly 80% of the market.[114] Today, this concentration is even more extreme, with the "Big Three" — Vizient, Premier, and HealthTrust Purchasing Group — controlling roughly 90%.[115] Their market power gives them significant leverage in negotiations with manufacturers, which they use to demand anti-competitive contract terms and untenably low prices, exacerbating manufacturer consolidation and its attendant harms, including constant drug shortages.

GPO contracting practices create a high level of business uncertainty because they typically do not guarantee that a specific volume of drugs will be purchased at a set price.[116] Some contracts currently include "low-price clauses" that allow GPOs to cancel a contract if a different manufacturer is willing to supply the same product or bundle of products for a lower price.[117] Such uncertainty makes it risky for manufacturers to invest in buffer stock, expand production, upgrade facilities, or innovate to advanced manufacturing methods.

DRUG WHOLESALERS

Wholesale drug distributors deliver medical supplies to pharmacies, hospitals, and other health care providers, fulfilling the terms of GPO contracts.[118]

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108 "A Primer on Group Purchasing Organizations: Questions and Answers," Healthcare Supply Chain Association, accessed Aug. 1, 2025, https://www.hiscionline.org/sites/supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf.

109 See above.

110 See 108.

111 Phillip L. Zweig, "White Paper: A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers," Physicians Against Drug Shortages, Feb. 15, 2021, https://nebula.wsimg.com/cd1702b03dd5bdcbf25da39704c-4045c?AccessKeyId=62BC662C928C06F7384C&dispos%20ition=0&alloworigin=1.

112 See 5.

113 Letter to the Federal Trade Commission requesting a study of group purchasing organizations, American Economic Liberties Project, Nov. 22, 2022, https://www.economicliberties.us/wp-content/uploads/2022/11/2022-11-22-AELP-FTC-6B-GPO-Letter-Final.pdf.

114 See 5.

115 Bill Whitaker, "Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs," 60 Minutes, May 22, 2022, https://www.cbsnews.com/news/generic-drugs-pharmaceutical-companies-60-minutes-2022-05-22/; Adam Fein, "The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down," Drug Channels, Oct. 2, 2019, https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html; see 5.

116 See 2.

117 See 2, p. 226.

118 See 5.

Like GPOs, they began to consolidate in the late 1960s.[119] Between 1975 and 2000, they dwindled in number from more than 200 to fewer than 50, with the then-Big Four — AmeriSource Health, McKesson, Cardinal Health, and Bergen Brunswig — controlling almost 80% of the market.[120] Although the Clinton FTC blocked two proposed mergers — AmeriSource Health with McKesson, and Cardinal Health with Bergen Brunswig — citing antitrust concerns, the Bush FTC later approved a $2.3 billion merger between AmeriSource Health and Bergen Brunswig, resulting in AmerisourceBergen (now Cencora) and "entrench[ing] an oligopoly of near-equals."[121]

That oligopoly continues today, with just three wholesalers — McKesson, Cencora, and Cardinal Health — controlling 98% of the market. These groups' monopsony power allows them to drive prices below competitive levels, leading to reduced output, drug shortages, and market exits by generic drug manufacturers.[122]

Worsening the problem, each drug wholesaler operates a generic sourcing joint venture with a major U.S. chain pharmacy that further consolidates generic purchasing power.[123] These buying groups now control nearly 80% of the generic drug purchases in the retail market.

PBMs

PBMs manage prescription drug benefits for health plan sponsors, including private insurers, government programs, employers, and unions. For a markup, they negotiate on behalf of their clients with manufacturers and pharmacies, giving them outsized pricing power.[124]

Insurers began forming PBMs in the 1960s to manage their new pharmacy benefits.[125]

Like manufacturers, GPOs, and wholesalers, independent PBMs then merged with each other. Starting in the early 1990s, PBMs also began merging with manufacturers, prompting the Clinton administration to challenge these acquisitions and issue consent agreements; ultimately, manufacturers — including Eli Lilly, Merck, and SmithKline Beechman (now GlaxoSmithKline) — unwound these transactions.[126]

In 1999, the Clinton administration also expanded the anti-kickback safe harbor for GPOs to PBMs, thereby "decriminalizing" post-sale rebates paid to them by manufacturers.[127] PBMs were no longer incentivized to lower prices for the health plan sponsor clients; instead, they now sought higher rebates from manufacturers, which corresponded with higher drug list prices, and eschewed cheaper generics. Later, PBMs began excluding drugs from their formularies to further increase rebates, a practice that

119 "Regarding the Federal Trade Commission (FTC) and U.S. Department of Health and Human Services (HHS) Solicitation of Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages," Hercules Pharmaceuticals, May 30, 2024, https://downloads.regulations.gov/FTC-2024-0018-6403/attachment_1.pdf.

120 See 81 and above.

121 See 119.

122 See 119; "AAM Submits Comments to HHS and FTC on the Impact of GPOs and Wholesalers on Access to Generic Medicines," Association for Accessible Medicines, May 30, 2024, https://accessiblemeds.org/resources/press-releases/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages/; Adam Fein, "Meet The Power Buyers Driving Generic Drug Deflation," Drug Channels, Feb. 1, 2018, https://www.drugchannels.net/2018/02/meet-power-buyers-driving-generic-drug.html.

123 See "AAM Submits Comments to HHS and FTC on the Impact of GPOs and Wholesalers on Access to Generic Medicines" above.

124 See 7.

125 Dylan Scott, "The mysterious middlemen being blamed for America's sky-high drug prices," Vox, May 10, 2023, https://www.vox.com/2023/5/10/23709448/what-are-pbms-pharmacy-benefit-managers-bernie-sanders.

126 Denise Myshko, "Beyond the Big Three and How We Got Here," Managed Healthcare Executive, Dec. 14, 2022, https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-and-how-we-got-here; see, e.g., Trefis Team, "Insurance Companies Start To Bring PBM In-house: CVS Health's PBM Business Could Be Under Threat," Forbes, Dec. 15, 2015, https://www.forbes.com/sites/greatspeculations/2015/07/28/insurance-companies-start-to-bring-pbm-in-house-cvs-healths-pbm-business-could-be-under-threat/.

127 See 111.

has since taken off.[128]

Starting in the 2000s, PBMs merged first with chain pharmacies and then with "the health insurers from which they were spawned."[129] Altogether, between 2000 and 2021, 39 PBMs consolidated under the "Big Three" — CVS Caremark, Cigna Group's Express Scripts, and UnitedHealth Group's Optum Rx — which account for nearly 80% of all prescription drug claims. This market power, combined with their vertically integrated business model, gives them outsized leverage in price negotiations with manufacturers, plan sponsors, and independent pharmacies, leading to higher costs, worse quality of care, and pharmacy closures.[130]

Like GPOs and wholesalers, PBMs create barriers to generic drug manufacturers' access to markets in several ways. First, they exclude lower-priced generics from insurance formularies when branded alternatives generate higher rebates.[131] Second, they place certain generic drugs in lower formulary tiers that require prior authorization or higher patient copays.[132] Third, PBMs stall inclusion of new generic drugs on formularies to extract concessions from manufacturers.[133] Last, they limit patient access to pharmacies that stock certain generic alternatives.[134]

Most recently, the Big Three have begun to reintegrate with manufacturers by establishing offshore private labeling entities that distribute drugs under new brand names.[135] This arrangement creates several new potential revenue streams, including "assurance of supply … and bargaining leverage in negotiations with [generic manufacturers]."[136]

128 Adam Fein, "The Big Three PBMs' 2024 Formulary Exclusions: Biosimilar Humira Battles, CVS Health's Weird Strategy, and the Insulin Shakeup," Drug Channels Institute, Jan. 9, 2024, https://www.drugchannels.net/2024/01/the-big-three-pbms-2024-formulary.html.

129 See 125.

130 This represents a significant change from 2003, when seven PBMs accounted for roughly the same share of prescription drug claims. See 125.

131 "FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices," Federal Trade Commission, Sept. 20, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices; see also 7, pp. 66-70.

132 See 7, p. 10, 67.

133 "The Role of Pharmacy Benefit Managers in Prescription Drug Markets," p. 4, U.S. House Committee on Oversight and Accountability, July 2024, https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

134 See above.

135 See 7.

136 See 7.

COMPETITION POLICIES TO RESTRUCTURE PHARMACEUTICAL MARKETS AND REIN IN ANTI-COMPETITIVE MIDDLEMEN

Successful pharmaceutical onshoring requires addressing the anti-competitive market structures that have made domestic manufacturing financially unviable or the necessary industrial and trade policy reforms, discussed below, will not succeed. All three types of consolidated middlemen use their market power to extract value from the pharmaceutical supply chain while forcing generic manufacturers into a "race to the bottom" on pricing. Indeed, Vizient, the largest GPO, was among the corporate interests lobbying the U.S. Trade Representative to grant exceptions to tariffs on China for medical supplies.[137]

When manufacturers are forced to exit markets due to unsustainable economics, the remaining suppliers often lack sufficient capacity to meet total market demand, leading to shortages that can persist for months or years.[138] And because of the GPOs' anti-competitive contract terms, hospital members are prohibited from seeking out alternative suppliers even in instances of shortage, squashing demand.[139]

Building U.S. capacity for manufacturing essential generic drugs and their ingredients will require correcting the market structures that create these unsustainable economics. Such reform is essential for a functional generic pharmaceutical market that durably sustains investment and promotes innovation in the longer term. Generic drug manufacturers' margins are razor thin as is, using cheap foreign imports of APIs, KSMs, and intermediates.[140] Ultimately generic drug makers must have the financial ability to purchase higher quality, more secure, domestically produced inputs, or to invest in end-to-end manufacturing methods themselves.

Our policy recommendations for addressing anti-competitive market structures[141] include:

CONGRESSIONAL ACTION

» **Eliminate the Anti-Kickback Safe Harbor.** Congress should repeal the GPO and PBM safe harbors in the anti-kickback statute, which allow middlemen to exploit kickbacks and rebates that

137 Letter from Vizient Vice President of Public Policy & Government Relations Shoshana Krilow to U.S. Trade Representative Robert Lighthizer, Vizient, Dec. 22, 2020, https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20201222_letter_urging_tariff_exclusions_extension.pdf.

138 "Drug Shortages: Causes & Solutions," Association for Accessible Medicines, June 22, 2023, https://accessiblemeds.org/wp-content/uploads/2024/11/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

139 See 111.

140 Traditional generic manufacturers' profit margins can average as low as 2%, leading to drug shortages and bankruptcies. John Evans, "What Profit Margin Can You Expect in 2025?," PhamaBusinessHub, accessed Oct. 20, 2025, https://pharmabusinesshub.com/what-profit-margins-can-you-expect-in-2025/; "Drug Manufacturers – Specialty & Generic," Stock Analysis, accessed Oct. 20, 2025, https://stockanalysis.com/stocks/industry/drug-manufacturers-specialty-and-generic/; "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States," U.S. Department of Health and Human Services, Jan. 26, 2024, https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf; Jessica Glenza, "Generic drugs in the US are too cheap to be sustainable, experts say," The Guardian, Jan. 18, 2024, https://www.theguardian.com/science/2024/jan/18/us-generic-drugs-prices-causing-shortage; "Short Supply: The Health and National Security Risks of Drug Shortages," U.S. Senate Committee on Homeland Security and Governmental Affairs, March 2023, https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf; Dan Gorenstein, "Why pharma companies are bowing out of generics," Marketplace, Aug. 2, 2017, https://www.marketplace.org/story/2017/08/02/drug-prices-why-pharma-companies-are-bowing-out-generics.

141 Policy recommendations regarding industrial policy are addressed in the next section.

would otherwise constitute a felony offense. The statute prohibits payments to induce the referral of any business reimbursed by federal health programs like Medicare. The safe harbors protect GPO and PBM percentage-based administrative fees, even when these fees are used to finance exclusive or "pay-to-play" contracts that restrict competition.

» **Prohibit Anti-Competitive Contracts.** Congress should rein in pharmaceutical middlemen's use of unfair terms — including most-favored nation clauses that require manufacturers not to give a more favorable price to any other buyer and failure-to-supply penalties that shift all risk to the manufacturer while providing no volume guarantees — in their contracts with manufacturers, providers, and insurers.[142]

» **Require GPOs and Wholesalers to Multi-Source Contracts.** GPOs and drug wholesalers should be required to multi-source contracts that are over a certain size. Their practices of providing large, near-exclusive contracts to manufacturers, consolidating the market and creating fragile bottlenecks, is detrimental to onshoring goals.

» **Break Up Dominant Middlemen.** The bargaining power of the three biggest monopolistic GPOs and drug wholesalers over manufacturers puts undue downward pressure on price. Their sheer size creates an untenable bargaining position for manufacturers. Reducing the bargaining disparity would help generic drug manufacturers to viably onshore manufacturing, invest in buffer stock, and invest in advanced manufacturing technologies. The Association for Accessible Medicines, a trade group representing generic and biosimilar manufacturers, has proposed that any market share higher than 20% should be presumed to establish monopsony power.[143]

» **Ban Vertical Integration.** Borrowing from the New Deal-era banking reform, Congress should pass a "Glass-Steagall Act" for health care to structurally separate payers from providers.[144] Specifically, Congress should bar insurance companies, PBMs, and wholesalers from owning pharmacies and medical providers. Doing so would rein in the outsized bargaining power of vertically integrated middlemen. An October 2025 working paper estimates that divestiture of vertically integrated pharmacies would reduce drug prices by 7.3%.[145]

» **Require Transparency.** Although transparency alone cannot restructure markets to be more competitive, it can expose how promised savings flow to middlemen instead of patients, spurring middlemen reform. Congress should update transparency laws to:

    » Require public reporting of every GPO's vendor-fee schedule and pass-through arrangements.

    » Mandate public reporting of wholesaler fee schedules, contract terms, and pass-through arrangements. This includes requiring disclosure of exclusive arrangements and administrative fees.

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142 Somewhat like these clauses, President Trump's most-favored nation drug-pricing policy — outlined in a May 2025 executive order — seeks to compel manufacturers to sell their drugs to U.S. patients at the lowest price available abroad. See "Delivering Most-Favored Nation Prescription Drug Pricing to American Patients," The White House, May 12, 2025, https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/.

143 Letter to FTC Chair Lina Khan and HHS Secretary Xavier Becerra Re: Request for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages, May 30, 2024, https://docs.house.gov/meetings/GO/GO00/20240723/117540/HHRG-118-GO00-20240723-SD018.pdf.

144 The 1933 Banking, or Glass-Steagall, Act structurally separated commercial and investment banks in response to the Great Depression.

145 Eric Yde, "Vertical Integration and Regulated Profits in Pharmacy Benefit Markets," working paper, Oct. 14, 2025, https://www.dropbox.com/scl/fi/bgwfw0axy7sw9pozed60q/Yde_JMP.pdf?rlkey=me357af25eauyjgvx873y7xgn&e=1&st=zzmv0ark&dl=0.

    - Bring vertical PBM consolidation and corporate ownership into the sunlight.

- **Prohibit Patent Abuse.** Brand-name drug manufacturers engage in myriad forms of patent abuse to deter generic competition, further threatening generic manufacturers' viability. To ensure and promote generic market entry, Congress must prohibit patent thickets, product hopping, and junk Orange Book patent listings.

- **Increase Funding for Federal Antitrust Enforcers.** Congress should also dramatically increase funding and resources for federal antitrust enforcers so that they can adequately police the pharmaceutical industry and tighten laws around pharmaceutical patent eligibility.

STATE AND FEDERAL ANTITRUST ENFORCEMENT

- **FTC Should Use Its 6(b) Authority.** The FTC should complete its investigations into PBMs, GPOs, and wholesalers, and file additional lawsuits related to their rebating practices.

- **FTC Should Enforce Section 2(c) of the Robinson-Patman Act.** The provision bans kickbacks and other side payments by a seller either to a buyer or some intermediary acting on their behalf.146 In short, it would prohibit the kickbacks on which pharmaceutical middlemen have come to rely as a source of revenue, and which would be illegal under the federal anti-kickback statute were it not for safe harbors.147

- **Enforce Antitrust Laws Against Anti-Competitive Practices by Middlemen.** State and federal antitrust enforcers should investigate dominant GPOs, drug wholesalers, and PBMs for likely Sherman Act Section 2 violations, by virtue of their monopsony power and exclusionary contracting practices, including both exclusive dealing and tying.148

- **Strengthen Merger Enforcement.** To prevent market structures from becoming even more consolidated, antitrust enforcers should strengthen enforcement against mergers that add to dominant middlemen monopsony power, reduce domestic manufacturing capacity, or vertically integrate the pharmaceutical sector. Aggressive merger enforcement is needed to ensure that essential medicines and their ingredients are made by multiple manufacturers in multiple locations, and to stave off shortages and supply chain fragility.

HHS REGULATORY ACTION

- **Regulate Middlemen's Anti-Competitive Business Practices.** Pending congressional action, HHS' Office of the Inspector General should re-engage in rulemaking to repeal the anti-kickback safe harbor[149] and update the conditions of participation in federal health care programs to prohibit

146 15 U.S. Code § 13(c).

147 See 111.

148 In 2023, the Department of Justice Antitrust Division and the Federal Trade Commission withdrew antitrust policy statements that took an "overly permissive" approach to enforcement in health care markets, citing "profound changes" to those markets in recent decades. "Justice Department Withdraws Outdated Enforcement Policy Statements," U.S. Department of Justice, Feb. 3, 2023, https://www.justice.gov/archives/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements; "Federal Trade Commission Withdraws Health Care Enforcement Policy Statements," Federal Trade Commission, July 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements.

149 42 C.F.R. § 1001.952(h).

middlemen's anti-competitive business practices.[150]

» **Facilitate Generic Market Entry.** Within HHS, the FDA should issue regulations to prohibit improper Orange Book patent listings[151] and update its approval process for generic drugs[152] to curtail product hopping, another form of patent abuse.

INDUSTRIAL POLICIES TO ONSHORE AND DECONCENTRATE MANUFACTURING

Simultaneously with restructuring pharmaceutical markets, policymakers have the unique opportunity to build America's pharmaceutical manufacturing base from the ground up with resilience and deconcentration as core design principles. Deconcentrated production, with intentionally targeted investment, can help restore economic opportunity to regions of the country that were hollowed out and depressed by decades of offshoring. Using a combination of smartly sequenced trade and industrial policies, the United States can replace the failed model with new policies and market structures explicitly designed to deliver thick and resilient supply chains for key medicines and their components.

Building domestic manufacturing capacity in the pharmaceutical supply chain will require a complex suite of industrial policies, including direct subsidies, tax benefits, grants, loans, or other incentives, the details of which are beyond the scope of this report. However, we discuss the elements of such a comprehensive program that might otherwise be overlooked by those not viewing onshoring through an antimonopoly lens, as well as the principles that must undergird program design to maximize resilience and deconcentrate corporate power in the pharmaceutical sector.

Policymakers should aim to establish distributed, regionalized production with geographic diversity and multi-sourcing to avoid single points of failure, and to develop regional capacity. As the major domestic medicine purchaser, the federal government should contract with multiple manufacturers and invest in the infrastructure and technology needed to create a distributed and redundant system that can withstand supply chain shocks created by domestic or foreign climate events and pandemics, as well as political crises in other countries.

As University of Minnesota Professor Stephen Schondelmeyer explained in his June 2025 testimony before Congress' U.S.-China Economic and Security Review Commission, the U.S. drug supply is "dependent" when any component required for a step in drug manufacturing is not available in a timely manner. Market concentration increases the risk of that dependence:

> *"[E]ven when there are several alternative API sources in the market, the risk of dependence and subsequent drug shortages would be expected to increase with the degree of concentration as measured by unit volume market share. For an API that has 10 active producers in the market with one of those producers holding a 50% market share, there would be more dependence and a higher risk of drug shortages than if all 10 active producers each held a 10% market share. If the one producer with a 50% market share is no longer able to produce, and the other nine producers are operating at an efficient level they*

150 42 C.F.R. § 482.1-498.103; "Written comments to FTC and HHS regarding drug shortages," American Economic Liberties Project, April 26, 2024, https://www.economicliberties.us/wp-content/uploads/2024/04/2024-04-26-AELP-Shortages-Comment.pdf.

151 21 U.S.C. §§ 355(b)(1)(A)(viii), 355(c)(2); 21 C.F.R. § 314.53(b)(1).

152 21 U.S.C. § 355.

may not have the capacity to meet the spike in demand from loss of supply for 50% of the market."[153]

To maximize resilience in the manufacturing base, government procurement and investment should create a deconcentrated network of small and medium enterprises (SMEs). Ideally, there would be at least five critical API manufacturers operating in different U.S. regions, ensuring security, distributed economic opportunity, and equitable access to medicine.

GOVERNMENT INVESTMENT IN ADVANCED MANUFACTURING TECHNOLOGIES

Federal and state governments should directly fund research and development and cost-effective methods for API production. Advanced manufacturing technologies allow for agile production in smaller plants, making it easier than ever to build a deconcentrated manufacturing base.[154] Conventional pharmaceutical manufacturing relies on batch production, which involves an inefficient, segmented approach characterized by considerable idle time between different phases of the process. In contrast, continuous manufacturing (CM) creates a 24/7 workflow, where production is streamlined and processing time significantly reduced.[155] CM technology can help facilitate resilient domestic manufacturing because it allows API, KSM, and finished drug production in smaller facilities, with an estimated cost savings of 30% to 50% less than traditional manufacturing methods.[156]

The advantages are considerable. CM technology can shrink manufacturing facility size by more than tenfold, resulting in decreased capital investment and operating expenses, and allowing for deployment in many different locations.[157] It improves drug quality through continuous monitoring and process control, minimizes material waste, and establishes a more responsive and adaptable manufacturing system that can be modified for various products within weeks instead of months.[158] CM and other advanced manufacturing technologies also allow quick pivots in production to respond to shortages and health crises, shorten transportation routes, and reduce dependence on complex logistics.[159]

The U.S. Biomedical Advanced Research and Development Authority (BARDA) has already begun to fund advanced manufacturing technologies, awarding a $812 million contract to the Phlow corporation to start building the Strategic Active Pharmaceutical Reserve (SAPIR) in May 2020.[160] Phlow proposed the SAPIR framework to the first Trump administration as part of a public-private partnership.[161] Phlow

153 See "Statement on Designing a Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities" at 1, p. 5.

154 Advanced manufacturing technologies "improve drug quality, address shortages of medicine, and speed time-to-market," according to the FDA. "Advanced Manufacturing," Food and Drug Administration, updated Feb. 13, 2024, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing.

155 "An FDA Self-Audit of Continuous Manufacturing for Drug Products," Food and Drug Administration, updated June 28, 2022, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-self-audit-continuous-manufacturing-drug-products; Meg Snyder," The Benefits of Continuous Manufacturing," Pharmaceutical Processing World, Dec. 28, 2016, https://www.pharmaceuticalprocessingworld.com/the-benefits-of-continuous-manufacturing/.

156 See 12, pp. 35-43 and 153.

157 "5 reasons to adopt continuous processing in pharmaceutical manufacturing," WSP, accessed Aug. 1, 2025, https://www.wsp.com/en-gb/insights/how-continuous-processing-can-optimise-pharmaceutical-manufacturing.

158 Sarah Lee, "The Future of Generic Drugs," Number Analytics, June 25, 2025, https://www.numberanalytics.com/blog/future-generic-drugs-development.

159 Cost Plus Drugs has built a state-of-the-art fill-and-finish facility in Dallas that uses advanced robotic and AI technology. This allows the company to quickly pivot production between drugs — sometimes within four hours — to address whatever medication is in shortage. See 12, pp. 24-34.

160 "New Pharma Company lands $354 Million Government Contract to Produce Coronavirus Drugs in the U.S.," Phlow, May 19, 2020, https://www.phlow-usa.com/new-pharma-company-lands-354-million-government-contract-to-produce-coronavirus-drugs-in-the-u-s-2/.

161 "Phlow Corp. Applauds Executive Action to Operationalize the Strategic Active Pharmaceutical Ingredient Reserve (SAPIR)," Phlow, Aug. 14, 2025, https://www.phlow-usa.com/phlow-corp-applauds-executive-action-to-operationalize-the-sapir/.

uses "flow" chemistry and other CM processes to help manufacture its APIs, with the goal of increasing quality, safety, and volume of medicine for a lower cost.[162] Working with several partners, Phlow began manufacturing KSMs, APIs, and finished dosage forms for more than a dozen critical medicines used to treat patients hospitalized with COVID.[163] As of June 2025, Phlow had eight essential APIs in development and had delivered more than 2 million finished medicines to the Reserve.[164]

However, this represents a minimal investment compared to what is needed. The $280 billion CHIPS Act demonstrates the scale of industrial policy required to restore American pharmaceutical manufacturing, as discussed below. Congress should also ensure continued funding for the Manufacturing Extension Partnership (MEP) National Network, a public-private partnership with centers in all 50 states and Puerto Rico to strengthen and empower small- and medium-sized manufacturers.

BUILDING REGIONAL NETWORKS OF SME MANUFACTURERS

A national network of small and medium enterprises (SMEs), manufacturers, and larger regional hubs would allow information-sharing regarding pandemics, natural disasters, and other crises that create drug shortages and threaten public health. When one part of the network is disrupted, the remaining parts fill gaps and meet needs. Government investment and procurement thus should prioritize SMEs distributed across multiple regions.

The CHIPS Act provides a valuable model for supporting distributed manufacturing networks. The Regional Innovation and Technology Hubs (Tech Hubs) Program designated 31 communities across 32 states and Puerto Rico as innovation centers, specifically aimed to (1) help small businesses access resources no matter where they are located, (2) create regional clusters of manufacturing that support SMEs, and (3) promote collaboration between businesses, academic institutions, and government.[165] Four of the designated Tech Hubs are in states with low population counts, and four include coal communities, ensuring diversity geographically and socioeconomically.[166] Although the Trump administration has rescinded some awards and rebooted the application process for Tech Hubs,[167] the model itself is worth emulating.

Policymakers could also learn from the Smaller War Plants Corporation (SWPC), a pioneering federal agency created during World War II to ensure that small businesses could participate in the American war production effort. Established by Congress in 1942, the SWPC represented the first comprehensive government initiative to support small business enterprises in the United States.[168]

The SWPC was formed under the general supervision of the War Production Board in response to

162 "New Pharma Company Lands $354 Million Government Contract to Produce Coronavirus Drugs in the U.S.," Phlow, May 19, 2020, https://www.phlow-usa.com/new-pharma-company-lands-354-million-government-contract-to-produce-coronavirus-drugs-in-the-u-s-2/.

163 See above.

164 "APIs and Finished Drug Products," Phlow, accessed Oct. 20, 2025, https://www.phlow-usa.com/product-portfolio/.

165 Mark Muro, Joseph Parilla, and Francesca Ioffreda, "New Tech Hub investments aim to unleash diverse regional tech clusters," Brookings, July 2, 2024, https://www.brookings.edu/articles/new-tech-hub-investments-aim-to-unleash-diverse-regional-tech-clusters/.

166 "Fact Sheet: Phase 1 Portfolio," U.S. Economic Development Corporation, Oct. 25, 2023, https://www.eda.gov/sites/default/files/2023-10/EDA_TECH_HUBS_Phase_1_Fact_Sheet.pdf.

167 "U.S. Department of Commerce Announces Relaunch of Tech Hubs Program," National Association of Development Organizations, May 21, 2025, https://www.nado.org/tech-hubs-relaunch/.

168 Jonathan Bean, "World War II and the "Crisis" of Small Business: The Smaller War Plants Corporation, 1942-1946," Cambridge University Press, Oct. 14, 2011, https://www.cambridge.org/core/journals/journal-of-policy-history/article/abs/world-war-ii-and-the-crisis-of-small-business-the-smaller-war-plants-corporation.

growing concerns that large corporations were monopolizing defense contracts, squeezing small manufacturers out of the war effort. Senator Joseph O'Mahoney warned at the time that "if we let little business go down in a total effort to defend democracy we shall let the very foundation of democracy perish."[169] Operating through 107 field offices nationwide, the SWPC helped small manufacturers obtain 54,000 contracts valued at over $6 billion.[170]

A new pharmaceutical-focused SWPC should coordinate government investment and procurement with SME manufacturers across America, while also providing technical assistance for navigating regulatory requirements and quality standards; contract facilitation between government agencies and manufacturers; and coordinate regionally to ensure geographic distribution of production capacity.[171]

WORKFORCE DEVELOPMENT AND TRAINING PROGRAMS

Regionally based advanced manufacturing technologies require skilled workers capable of operating sophisticated CM systems across America. Although the precise details of workforce development are beyond the scope of this paper, federal investment should involve collaborating with community colleges in regions throughout America to develop training programs for advanced manufacturing, creating apprenticeships that combine traditional classroom instruction with on-the-job training, training facilities connected to the manufacturing hubs to build expertise with advanced equipment, and partnering with high schools to help develop related career paths. These programs should be designed to provide good-paying, high-skilled jobs that support middle-class families, while contributing to national health security.[172]

GOVERNMENT PROCUREMENT TO GUARANTEE DEMAND

Simultaneously with investing in building deconcentrated manufacturing capacity and a skilled workforce, the U.S. government should guarantee demand for domestically made APIs, KSMs, intermediates, and finished drugs. Manufacturers of essential generic drugs and their ingredients need guaranteed long-term demand contracts with the government to ensure return on the needed investments for onshoring, including investing in new technologies and expanding capacity. Unlike branded drugs with patent protection and high margins, generic manufacturers operate with thin margins that cannot support the uncertainty and risk of building domestic capacity without assured markets.

Because the federal government is the largest purchaser of prescription drugs in America through multiple programs,[173] federal health care purchasing power — both direct purchasing and reimbursement for programs involving private insurers — can be leveraged to create steady demand that draws investment for domestic production.

169 See above.

170 See 168; C.W. Fowler, "The Legislative Origins of The Smaller War Plants Corporation," Smaller War Plants Corporation, 1945, accessed via the Internet Archive, https://archive.org/details/legislative-origins-swpc; Wendell Barnes, "What Government Efforts Are Being Made to Assist Small Business," Law and Contemporary Problems, 1959, https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2779&context=lcp.

171 "Smaller War Plants Corporation (A Government Agency) Will Help Veterans," Smaller War Plants Corporation, 1947, https://www.govinfo.gov/content/pkg/GOVPUB-P32_4800-728154285ec303e493e9b5c41ba04e21/pdf/GOVPUB-P32_4800-728154285ec303e493e9b5c41ba04e21.pdf.

172 See, e.g., "Workforce Development Planning Guide," CHIPS for America, March 27, 2023, https://www.nist.gov/system/files/documents/2025/09/09/CHIPS%20Workforce%20Development%20Planning%20Guide%20%281%29.pdf.

173 "Prescription Drugs," Congressional Budget Office, accessed Oct. 20, 2025, https://www.cbo.gov/topics/health-care/prescription-drugs.

» **Medicare Part D:** The largest prescription drug program, which serves over 65 million Americans.[174] Although Part D is administered by private insurers, it is regulated by the federal government.

» **Medicaid:** A joint federal-state program that covers low-income Americans.

» **TRICARE:** A health benefits program for military personnel, retirees, and families that is administered by the U.S. Department of Defense.

» **Veterans Affairs:** Health care facilities for military veterans.

» **Federal Employee Health Benefits Program (FEHB):** The program that administers health insurance plans for federal employees.

Combined, these programs represent billions of dollars in annual pharmaceutical purchasing power that could be leveraged to guarantee demand for domestically produced essential medicines and their ingredients. In 2023, Medicare Part D accounted for nearly $145 billion in drug spending,[175] Medicaid accounted for approximately $51 billion,[176] TRICARE accounted for approximately $8 billion,[177] Veterans Affairs spent $3.9 billion on pharmaceuticals and prosthetics combined,[178] and FEHB plans accounted for nearly $19 billion in prescription drug spending.[179]

TRICARE and Veterans Affairs already employ domestic procurement preferences, but waivers are too easily obtainable.[180] Congress should end such waivers as well as the broad Buy American trade-pact waivers for medicines so that only goods with domestic production at every stage, including APIs, KSMs, intermediates, and finished drug forms, can obtain domestic procurement preferences.

Government procurement through TRICARE and Veterans Affairs also should provide the demand certainty needed to justify domestic manufacturing investments, including by providing multi-year, multi-supplier contracts. Contracts should guarantee the purchase of specific quantities at predetermined prices over multi-year terms. And rather than single-sourcing contracts, government procurement should contract with multiple manufacturers per essential medicine and ingredient to ensure redundancy.

Medicare, Medicaid, and FEHB do not purchase medical supplies, including prescription drugs, but instead reimburse providers for them based on set fee schedules and other factors that do not take into account where the supplies are manufactured. However, the 2023 American Made Pharmaceutical Act would have required the Centers for Medicare and Medicaid Services (CMS) to conduct a pilot program that preferred drugs made in America by reducing patient cost-sharing requirements, favoring

174 Roosa Tikkanen et al., "International Health Care System Profiles: United States," The Commonwealth Fund, June 5, 2020, https://www.commonwealthfund.org/international-health-policy-center/countries/united-states.

175 Kristi Martin, "Medicare Drug Price Negotiations: All You Need to Know," The Commonwealth Fund, May 15, 2025, https://www.commonwealthfund.org/publications/explainer/2025/may/medicare-drug-price-negotiations-all-you-need-know.

176 Elizabeth Williams et al., "Recent Trends in Medicaid Outpatient Prescription Drugs and Spending," KFF, Oct. 11, 2024, https://www.kff.org/medicaid/recent-trends-in-medicaid-outpatient-prescription-drugs-and-spending.

177 "Defense Health Care: DOD Should Improve Monitoring of TRICARE Beneficiaries' Access to Prescription Drugs," Government Accountability Office, Feb. 13, 2025, https://www.gao.gov/products/gao-25-107187.

178 "The Causes and Conditions That Led to a $12 Billion Supplemental Funding Request," U.S. Department of Veterans Affairs Office of Inspector General, March 27, 2025, https://www.vaoig.gov/sites/default/files/reports/2025-05/vaoig-24-03127-66-final-locked.pdf.

179 "Drug Costs, Ineligible Enrollees Named as among Top Issues in FEHB," FEDWeek, Oct. 15, 2024, https://www.fedweek.com/issue-briefs/drug-costs-ineligible-enrollees-named-as-among-top-issues-in-fehb.

180 Lorraine Campos, "Department of Veteran Affairs Announces Shift in Trade Agreements Act Policy," Crowell, April 15, 2016, https://www.cmhealthlaw.com/2016/04/department-of-veterans-affairs-announces-shift-in-trade-agreements-act-policy/.

such drugs on formularies, and implementing bonus payments for compliance, among other tactics.[181] The API Innovation Center, a nonprofit organization focused on building a resilient pharmaceutical supply chain, has also proposed that Medicare prefer drugs made in America on its formularies.[182] Additionally, state Medicaid programs should use their authority to update their preferred drug lists with drugs made in America.[183] Similarly, Congress should require the Office of Personnel Management (OPM), which administers the FEHB program, to prefer drugs made in America for program beneficiaries.[184]

Strategic National Reserve Expansion

Beyond regular procurement, the government should expand the Strategic National Stockpile (SNS) to include finished drugs, APIs, and KSMs for critical medicines. The "Ensuring Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve" Executive Order, which aims to stockpile a six-month supply of APIs on an updated essential medicines list, is an important step to mitigating the risks associated with foreign dependence.[185] However, as of publication, the ASPR has yet to provide any progress updates. Additionally, given the United States' weakened manufacturing capacity, a strategic national reserve of both APIs and finished drugs is needed.[186]

One option is a "virtual stockpile" approach that increases the supply of essential drugs but keeps medicines and inputs from expiring by rotating stock that the manufacturer holds. HHS would pay manufacturers for inventory management and to produce and hold a specific quantity on behalf of the SNS.[187] This approach provides guaranteed demand for domestic manufacturers while maintaining fresh inventory through regular rotation.[188] HHS could then create mechanisms for pharmacies to purchase drugs in shortage directly from the Strategic National Stockpile, once it is fully stocked, instead of from wholesale drug distributors.

SUPPLY CHAIN TRANSPARENCY TO COORDINATE REGIONAL MANUFACTURER NETWORKS

Building a resilient domestic manufacturing base will require data transparency. To coordinate manufacturing needs, and for a full assessment of supply chain weaknesses and risks, the U.S. government must use data to ascertain what percentage of pharmaceuticals and pharmaceutical inputs are coming from which firms in which countries. A significant problem is a lack of mandatory reporting by producers on the sources of APIs and the facilities making finished medicines and APIs. The producers

181 "S.3311 - American Made Pharmaceuticals Act of 2023," Library of Congress, introduced Nov. 15, 2023, https://www.congress.gov/bill/118th-congress/senate-bill/3311.

182 See "Building a Resilient Domestic Drug Supply Chain: The Path to National Health Security" at 15.

183 "State Medicaid Preferred Drug Lists," KFF, July 1, 2019, https://www.kff.org/state-health-policy-data/state-indicator/medicaid-preferred-drug-lists/.

184 For instance, the BIOSECURE Act – which Congress passed in December 2025 – "aims to restrict public contracts and grants from going to foreign monopolists that control key segments of the API supply chains." See "China's Active Pharmaceutical Ingredient (API) Manufacturing System" at 34; Ada Cornell and Ryan Rosso, "Federal Employees Health Benefits (FEHB) Program: An Overview," Congressional Research Service, Feb. 3, 2016, https://www.congress.gov/crs-product/R43922#fn60.

185 See 5.

186 See "ASHP Shares Drug Supply Chain Recommendations with ASPR," American Society of Health-System Pharmacists, April 14, 2021, https://www.ashp.org/advocacy-and-issues/key-issues/drug-shortages/supply-chain-reccomendations; see also "S.2510 - RAPID Reserve Act," Library of Congress, introduced July 26, 2023, https://www.congress.gov/bill/118th-congress/senate-bill/2510.

187 See 2, p. 247.

188 See 2. Note that older drugs are either disposed of, given away, or sold. The U.S. Strategic National Stockpile tests its drugs for efficacy and keeps them for 12-24 months after their expiration dates, then disposes of them.

and distributors of all marketed prescription drug products in the United States must be required to report to the FDA the country of origin of both the API and finished drug for each drug product. This information, as noted above, should be made publicly available in summary form. The FDA and the Commerce Department should also require real-time reporting of inventories of APIs and finished dosage forms in the pipeline to create a comprehensive and up-to-date inventory of all essential medicines and inputs.

The bipartisan Mapping America's Pharmaceutical Supply (MAPS) Act was introduced in both the House[189] and Senate[190] in 2025 and aims to significantly improve the federal government's ability to secure, visualize, and manage domestic essential medicine supply chains. The Act directs HHS to maintain and publish a list of essential medicines, conduct risk assessments to identify vulnerabilities such as overreliance on foreign sources and cybersecurity threats, and map essential medicine supply chains from critical inputs to distribution.[191] Congress should pass the MAPS Act as an important step toward supply chain transparency.

PROCUREMENT AND INVESTMENT FUNDS SHOULD NOT FLOW TO BIG PHARMA

As mentioned above, a successful onshoring effort will require an array of industrial policy tools, the details of which are beyond the scope of this report. However, antimonopoly policies should inform policymakers' approaches to which companies receive the benefits of industrial policy programs for making medicines in America. Taxpayers should not subsidize already dominant pharmaceutical companies that have engaged in exclusionary conduct, anti-competitive acquisitions, or tax avoidance.

Excluding Antitrust Violators and Tax Dodgers from Government Contracts and Tax Breaks

American taxpayers should not subsidize corporations that have engaged in anti-competitive practices or offshored tax payment, both of which weaken supply chains and reduce manufacturing capacity.

Anti-competitive practices to keep lower-cost generic drugs and biosimilars off the market are rampant and should be stopped. AELP's May 2023 report with the Initiative for Medicines, Access, & Knowledge (I-MAK), The Costs of Pharma Cheating, estimated that U.S. patients and payers spent an additional $40.07 billion on pharmaceuticals in 2019 as a result of antitrust violations by the pharmaceutical industry.[192]

Additionally, antitrust enforcers at the Federal Trade Commission should work together with government agencies to set criteria for recipients of onshoring federal subsidies, investments, and procure-

189 "H.R.4191 - MAPS Act," Library of Congress, introduced June 26, 2025, https://www.congress.gov/bill/119th-congress/house-bill/4191.

190 "S.1784 - MAPS Act," Library of Congress, introduced May 15, 2025, https://www.congress.gov/bill/119th-congress/senate-bill/1784/related-bills.

191 See above.

192 The report identified 10 major categories of violations: horizontal collusion among competing manufacturers to restrict output, raise prices, or allocate markets; pay-for-delay agreements, where branded drug companies pay generic drug companies to stay off the market in order to preserve their monopoly power; patent abuse and evergreening to extend monopolies artificially and delay access to generics; product hopping, where branded companies make a small change to the branded drug and withdraw the original version, forcing patients onto the new version before the generic alternative to the original drug comes to market; sham citizen petitions that create fraudulent safety concerns to delay FDA approvals of generic competitors; abuse of the FDA's Risk Evaluation and Mitigation Strategy (REMS) program to prevent generic manufacturers from obtaining samples needed to create an equivalent product; exclusionary rebates paid to PBMs to lock out generic competitors from drug formularies; and anti-competitive acquisitions that eliminate potential competitors. See 83.

ment contracts. They should consider any past mergers where pharmaceutical companies shut down their competitors, any violations of the antitrust laws, and any future plans for acquisitions that may undermine competition or innovation.

Likewise, corporations that offshore tax payment should not qualify for taxpayer funds for onshoring. Brad Setser of the Council on Foreign Relations reports that most of the major U.S. pharmaceutical companies are paying zero U.S. corporate taxes or even reporting losses in 2024, despite making most of their profits in America.[193] For example, pharmaceutical company AbbVie structured its operations so that its intellectual property rights for its blockbuster drug Humira were owned by a subsidiary in Bermuda, even though the drug was made in Puerto Rico and 75% of its sales were in the United States. Only 1% of its income was reported in the U.S. for tax purposes in 2020, according to a Senate Finance Committee report.[194]

Big Pharma corporations are already pocketing giant sums from American patients, who pay the highest drug prices in the world. Even though the U.S. represented only 4.2% of the global population in 2024, it accounted for 40.1% of the global pharmaceutical spending that year (approximately $639 billion of $1.6 trillion).[195] American taxpayers should not further subsidize these corporations through industrial policy to promote onshoring.

The tax code also should be revised to disincentivize offshoring of manufacturing and tax avoidance. We endorse the following reforms proposed by Setser: (1) increasing the U.S. minimum tax, which would deny pharma corporations the ability to offshore profits earned in the U.S. by offshoring manufacturing; (2) limiting pharma corporations' ability to get tax breaks on research and development in the U.S. by offshoring intellectual property; and (3) taxing the profits on IP that are transferred from one part of a pharma company to another part of the same company.[196] Reforming the tax code would result in more domestic production of pharmaceuticals, writes Setser: "It would be a win-win-win: more U.S. tax revenue, more U.S. jobs, and a smaller U.S. trade deficit and thus less trade tension."[197]

Congress should set limits on stock buybacks and dividends as well as prohibit the flow of taxpayer dollars, such as for investment in manufacturing capacity or research and development, to companies that exceed such limits.[198] According to a report by Accountable, four Big Pharma companies — Johnson & Johnson, Bristol Myers Squibb, Novartis, and Novo Nordisk — spent more money on stock buybacks than they did on R&D in 2023.[199] Pending a congressional ban on stock buybacks, recipients of government funding and extended purchase procurement contracts should not be prohibited from any investor payments, but the total volume of stock buybacks and dividends should be tied on a sliding

193 See 74.

194 Chair Ron Wyden (D-OR), "Interim Report: Big Pharma Tax Avoidance," Senate Finance Committee, July 2022, https://www.finance.senate.gov/imo/media/doc/Pharma%20Tax%20Report.pdf.

195 "U.S. Pharmaceutical Market Size to Reach USD 1,093.79 Billion By 2033," Nova One Advisor, July 12, 2024, https://www.biospace.com/u-s-pharmaceutical-market-size-to-reach-usd-1-093-79-billion-by-2033.

196 See above.

197 See 73 and 74.

198 Stock buybacks, considered a form of illegal market manipulation, were largely illegal until the early 1980s. "The Dangers of Buybacks," FCLT Global, September 2020, https://www.fcltglobal.org/wp-content/uploads/The-Dangers-of-Buybacks-_FCLTGlobal.pdf. See, e.g., Todd Achilles, Erik Peinert, and Daniel Rangel, "Reshoring and Restoring: CHIPS Implementation for a Competitive Semiconductor Industry," p. 50, American Economic Liberties Project, Feb. 6, 2024, https://www.economicliberties.us/wp-content/uploads/2024/02/20240117-AELP-Ind-PolSeries-CHIPS-Paper_v4-1.pdf: "While the CHIPS Act prohibits CHIPS funding from being directly used for stock buybacks and dividends, money is fungible, and simple accounting maneuvers can substitute resources such that CHIPS funds could nonetheless facilitate such investor payouts."

199 "The Pharmaceutical Firms With Drugs On Medicare's Price Negotiation List Spent Only $95 Billion On Research And Development While Spending $162 Billion On Shareholder Handouts, Marketing, And Overhead In 2023—All While Industry Fights The Government's Attempts To Reign In Drug Prices," Accountable, May 2024, https://accountable.us/wp-content/uploads/2024/05/Pharmaceutical-Co.-Spending-vs.-RD.pdf.

scale to increases in investment in manufacturing equipment or R&D.[200]

For the onshoring of manufacturing of essential medicines and their ingredients to be successful, competition policy and enforcement must be used to combat exclusionary conduct by pharmaceutical manufacturers. Pending these reforms, pharmaceutical manufacturers that continue to engage in such misconduct should be disqualified from receiving taxpayer support for onshoring initiatives.

Although these practices are less prevalent with the low-cost, essential medicines to be prioritized for urgent domestic production, policymakers should aim to support expanding domestic manufacturing to additional important drugs in the longer term. Efforts to increase domestic manufacturing of pharmaceuticals and pharmaceutical ingredients will be thwarted if violators are allowed to eliminate competitors, and with them, capacity.

SEQUENCED TRADE REFORM

On Sept. 25, 2025, the Trump administration announced that as of Oct. 1, 2025, 100% tariffs would be imposed on branded, non-generic "pharmaceutical products," with an exception for firms breaking ground on new U.S. manufacturing plants.[201] But on Oct. 1, President Trump announced a pause on such tariffs.[202] Previously, the administration had announced plans to launch a process under Section 232 to impose "national security" tariffs to boost U.S. domestic medicine production capacity. On Sept. 26, the administration launched such an investigation for "medical consumables, equipment, and devices."[203]

Since then, the administration has announced one-off deals with brand-name drug manufacturers that grant multi-year tariff relief to companies that pledge to charge less for medicine and show evidence of some domestic production.[204] But written specifics of these details have never materialized beyond a fact sheet.[205] The uncertainty created by on-and-off-again tariff announcements undermines investors' willingness to risk development of new U.S. production facilities.

200 See, e.g., the sliding scale in "Reshoring and Restoring: CHIPS Implementation for a Competitive Semiconductor Industry" at 198, pp. 49-50.

201 Donald Trump, "Starting October 1st, 2025, we will be imposing a 100% Tariff on any branded or patented Pharmaceutical Product, unless a Company IS BUILDING their Pharmaceutical Manufacturing Plant in America. ..." Truth Social, Sept. 25, 2025, https://truthsocial.com/@realDonaldTrump/posts/115267512131958759.

202 Daniel Desrochers, "Trump delaying triple-digit pharma tariffs to negotiate drug price deals," Politico, Oct. 1, 2025, https://www.politico.com/news/2025/10/01/trump-delays-triple-digit-pharma-tariffs-to-negotiate-drug-price-deals-00590051.

203 "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices," Department of Commerce Bureau of Industry and Security, Sept. 26, 2025, https://www.federalregister.gov/documents/2025/09/26/2025-18729/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of.

204 "Delivering Most-Favored Prescription Drug Pricing to American Patients," The White House, May 12, 2025, https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/; Emma Freer, "Trump's order on drug prices isn't what is seems," MS NOW, May 13, 2025, https://www.ms.now/opinion/msnbc-opinion/trump-drug-price-executive-order-big-pharma-rcna206289.

205 "Fact Sheet: President Donald J. Trump Announces Major Development in Bringing Most-Favored-Nation Pricing to American Patients," The White House, Nov. 6, 2025, https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/.

Since then, the administration has announced one-off deals with brand-name drug manufacturers that grant multi-year tariff relief to companies that pledge to charge less for medicine and show evidence of some domestic production. But written specifics of these details have never materialized beyond a fact sheet.[206]

However, tariffs can play an important role as part of an effective policy to enhance U.S. production of medicine, APIs, and KSMs. But they will only have the desired effect on domestic production and the least impact on raising medicine prices and availability if they are predictable, targeted, and sequenced properly with industrial policies that create reliable demand for domestic products; tax, subsidy, and loan policies that incentivize new production capacity; and strong competition policies and antitrust enforcement.

In addition, the administration must formalize the U.S. Customs department practice of considering medicines that are made from an API to be a product of the API source country, even if the dosing and packaging occur elsewhere. This practice has been challenged in court, and administrative action is needed to make it official policy. Otherwise, medicines effectively made in China but processed into doses in the United States or a third country would qualify for industrial policies and trade reforms meant to incentivize on-, near-, and friend-shoring.

With respect to the strategic use of tariffs, announcing their effective date and a phase-in of rising rates well in advance as part of a broader industrial policy will promote investment in domestic production. However, while their phasing and targeting should be signaled from the start, tariffs should go into effect after implementing industrial policies to generate investment and demand for domestic goods.

Initial targeting should focus on categories of medicines deemed most essential to begin producing domestically and expand to additional categories over time. The finished doses, APIs, and KSMs for those medicines and the countries whose imports most undermine the goal of domestic production of targeted medicines, APIs, and KSMs should face the initial levies. (The goal is not U.S. medicine, API, and KSM autarky, but rather being able to make some share of critical categories of medicines and their components, and diversify the countries from which imports of medicines are sourced, both of which will enhance resilience.)

But even those targets should have tariffs phased in over time to provide opportunities for domestic production to ramp up and also to sequence tariffs on finished doses relative to API and relative to KSM.

If extremely high tariffs are imposed up front, all at once, and across all countries and types of medicines and their inputs, the shock on prices and access will be significant given how extremely dependent the United States is on imported medicines. Instead, a schedule of increasing tariff rates over time, starting with the priority categories of medicines, would indicate to investors and others interested in building U.S. production capacity that a domestic market for domestic-made medicines would grow over time. The tariff rates would be published with an increase over time — for instance, a rate jump in 18 months or once certain milestones are achieved — eventually growing to a rate high enough to keep out medicines from sources that are unfairly trading, monopolizing global markets, or otherwise deemed undesirable import sources.

206 "Fact Sheet: President Donald J. Trump Announces Major Development in Bringing Most-Favored-Nation Pricing to American Patients," The White House, Nov. 6, 2025, https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/.

CONCLUSION

Onshoring API, KSM, and essential drug manufacturing is an important and worthy goal that must be urgently pursued. Even as we diversify import sources of these critical goods, we must also be able to produce significant volumes of key medicines and their components domestically.

Success will require correcting pharmaceutical market failures caused by oligopolistic and monopsonistic market structures, horizontal and vertical consolidation, and anti-competitive conduct and contract terms. It will also require awarding government subsidies and procurement dollars to manufacturers of varying sizes across the country to build thick, resilient, regional supply chains that secure America's public health and national security. Strong governmental institutions will be required to coordinate investment, procurement, and supply chain tracking. Tariffs should be announced up front but phased in after efforts are underway to fix market structures and build deconcentrated domestic capacity and demand for domestic medicines. Patient access to essential medicine must not be compromised during the time it takes to rebuild U.S. domestic manufacturing of medicines and their component parts.

There is much to be gained by working toward resilient domestic manufacturing of essential medicines and their ingredients: better access to medicine, protection against life-threatening shortages, reduced prices by trimming the fat of extractive middlemen and rent-seeking by Big Pharma, improved national security, good jobs, better quality of medicine, and stimulated local economies. Manufacturers will thrive in a competitive and functioning market, without powerful, concentrated buyers and middlemen distorting the market. Fair contracting practices will reward manufacturers' innovations and use of higher-quality pharmaceuticals and pharmaceutical ingredients. For this vision to be realized, we must restructure pharmaceutical markets and intentionally design a deconcentrated pharmaceutical manufacturing base in America.

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