The American Economics Liberties Project and Rethink Trade thank the Department of Commerce for the opportunity to submit written comments related to its investigation under section 232 of the Trade Expansion Act (19 U.S.C. 1862) to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products. The Department is performing a vital service by investigating this critical issue.

The American Economic Liberties Project (AELP) is a nonpartisan, nonprofit research and advocacy organization dedicated to understanding and addressing the problem of concentrated economic power in the United States. Rethink Trade is a program of AELP. Its mission is to replace decades of trade policies captured by the largest multinational corporations with those that can deliver broader public interest outcomes that benefit American workers, farmers, consumers, and smaller businesses. This includes creation and support of good union jobs with workers empowered to earn decent wages, the public health and safety delivered by strong consumer and environmental standards, the security of resilient supply chains, the innovation and competition provided by fair markets, and the ability for those who will live with the results to decide the policies affecting their lives.

I. Introduction

Onshoring production of essential medicines, key starter materials (KSMs), and active pharmaceutical ingredients (APIs) is critically important for America's national security and public health. Strategic tariffs, designed to encourage the domestic manufacture of essential medicines and their inputs, are among the policy tools the government should consider to achieve this goal. Yet tariffs on pharmaceuticals will not only fail to promote the onshoring of most essential medicines and APIs but will create dangerous drug shortages and raise drug prices if they are not phased in methodically over time and paired with finely tuned competition, tax, procurement, and investment policies that are facilitated by strong government institutions.

The hollowing out of U.S. production capacity and the weakening of U.S. economic resilience is a national security threat that is undeniably linked to policies and practices that have left the United States largely dependent on other countries in general, and overly reliant on China in particular, for access to most essential medicines, KSMs, and APIs. Decades of hyper-globalization as implemented by a particular model of trade agreements and trade policies have undermined our independence and resilience. With our economy organized to serve a production model focused almost exclusively on efficiency and reliant on long, brittle global supply chains and production of medicine in too few countries – often by too few firms after decades of global consolidation – today America is vulnerable to untenable risks.

Decades of corporate-rigged trade policies have 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. Countries with mercantilist practices, especially China, have consolidated large shares of production for especially API and some generic medicines. The mass outsourcing of U.S. industrial capacity since the mid-1990s and the intensive global concentration of production with little redundancy now leaves the United States unable to make or reliably acquire many critical medicines and their inputs.

How did this happen? For decades, our economy and the rules of the global economy have been organized to serve a production model focused almost exclusively on efficiency at the cost of resiliency. Hundreds of corporate representatives who serve as official U.S. trade advisors pushed for trade and tax terms that rewarded relocating production overseas. Corporate-rigged trade rules and investment policies such as foreign investor protections and their investor-state dispute settlement enforcement made it easier and less risky to move production overseas to pay workers less. A lack of disciplines against currency misalignments and other mercantlist practices related wage suppression and massive subsidies undermined domestic firms trying to compete with imports.

To make matters worse, a lack of competition policy enforcement thanks to the misguided "consumer welfare" standard facilitated a merger mania that resulted in the elimination of redundant pharmaceutical production facilities. A few dominant firms sought to maximize efficiency by relying on thin, globalized supply chains with final production concentrated in a few locations. The mantra of just-in-time global supply chains maximizing efficiency has crashed into the reality that many governments and people now see: Obsession with efficiency has undermined resilience, reliable access, and public health.

What's needed is a thriving, competitive, resilient, and de-concentrated pharmaceutical manufacturing base in America that enables innovation, diversified risk, and shared prosperity. Resilient systems do not put all eggs in a few baskets but rather thrive through distributed resources. Resiliency requires redundancy and geographic diversification. This means we need more domestic makers at each stage of essential medicine production: KSMs, intermediate materials, APIs and finished medicines. Manufacturers should be located in different regions across America. And we must diversify globally, focusing on friend-shoring and near-shoring for capacity that is not met domestically. We need policies that dismantle oligopolistic market structures and combat exclusionary practices and anticompetitive consolidation, which by eliminating coopetition also eliminate redundancy, weaken supply chains, and destroy resilience.

Making KSMs, APIs and key medicines in America also can help restore economic opportunity to regions of the country that were hollowed out and depressed by decades of offshoring. Building a manufacturing base of the most critical medicines and their APIs in America will require a strategic sequencing of trade, competition, tax, procurement, and investment policies adapted to the complex realities of the current medicine and API production and distribution systems. Given the outsized market power of middlemen like

group purchasing organizations and pharmacy benefit managers, and their use of buyer power to flatten domestic generic manufacturers' profit margins, adopting tariffs on pharmaceutical inputs is likely to squeeze manufacturers further without providing a real opportunity to increase domestic production. These anticompetitive market structures, as well as anticompetitive acquisitions and contracts that reduce manufacturing capacity, must be addressed with competition policy in order for increasing domestic capacity to be feasible. And although existing U.S. manufacturing facilities are underutilized, with only about half of current generic production capabilities in use,[1] it will take several years and hundreds of millions of dollars to revive domestic manufacturing.[2] Remaking America's manufacturing is a worthy and important goal, but access to essential medicines and APIs must be preserved in the interim.

Protecting public health and national security will require both rebuilding domestic production and diversifying the sourcing of our imports. Simply moving from overreliance on China to overreliance on Vietnam or other distant and low-wage countries is not a solution. And, to meet these goals in a way that delivers good jobs to hardworking Americans, we must consider the rules that will elevate workers' wages and develop regional supply chains. We must explore what has not worked and how we can replace the failed model with new policies explicitly designed to deliver resilient supply chains and enhance our economic and national security.

II. Public Health and National Security at Risk

Climate disasters, geopolitical conflicts, and global pandemics necessitate stronger pharmaceutical supply chains and onshoring. Whether its 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 America. During the Covid-19 pandemic, our hospitals encountered devastating shortages of basic medical supplies needed to keep patients and hospital workers alive. But U.S. essential medicine shortages predated COVID and continue today.

Our 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 that threaten human life, on our shores. In fact, 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

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[1] *Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains: House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations,* 118th Cong. (2023) (testimony of Chairman Griffith). https://www.congress.gov/118/chrg/CHRG-118hhrg55967/CHRG-118hhrg55967.pdf.

[2] Rudman, Andrew I. and Haar, Jerry, "Strengthening US-Mexico Quality Pharmaceutical Supply Chains," Wilson Center, June 11, 2024 (estimates 5-10 years to set up a new manufacturing plant; cites projects costing $360 million to $812 million). https://www.wilsoncenter.org/article/strengthening-us-mexico-quality-pharmaceutical-supply-chains.

School at Washington University.[3] That includes the APIs needed to produce 97 percent of antivirals and 92 percent of antibiotics. 83% of the top 100 generic drugs have no U.S. source of API, reports the study.[4]

A startling share of API used worldwide originate in China, regardless of where finished medicines are produced. China manufactures over 2,000 API molecules and had more than 7,000 API manufacturers as of 2020, offering significant cost advantages compared to Western competitors.[5] China is also the dominant manufacturer of KSMs, the raw materials used in the production of API, and intermediates used in the manufacture of APIs.[6] China supplies a substantial portion of the intermediates required by other countries, including India, with about 70–85% of India's intermediates sourced from China. Globally, China supplies over 80% of APIs or their KSMs for essential drugs like antibiotics, fever reducers, painkillers, and diabetes medications.[7]

As a result, Americans' access to essential medicines is vulnerable to the geopolitical tactics of foreign governments, none more so than China. The Chinese government has demonstrated a willingness to cut off American access to vital resources – just last month, for example, it announced it would ban the export of critical minerals and magnets needed to make cars, planes, semiconductors, and military equipment.[8] If China were to ban or limit the export of crucial medicines and APIs similarly, the consequences would almost certainly be devastating.

The need to ensure not just more domestic manufacturing capacity but regionally diversified capacity is underscored by recent events. Even for medical supplies made in America, market concentration puts American's health at risk. For instance, when Hurricane Helene devastated a single North Carolina factory that makes 60% of the country's IV bags, one extreme weather incident in one region of the country created shortages nationwide.[9] These old ways must go.

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[3] Sardella, Anthony, "The U.S. Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US healthcare security," Center for Analytics and Business Insights, Olin Business School at Washington University, August 1, 2021, https://apicenter.org/wp-content/uploads/2024/07/The-US-Active-Pharmaceutical-Ingredient-Infrastructure.pdf.

[4] *Id.*

[5] "Indian API Industry: Reaching the Full Potential," KPMG and the Confederation of Indian Industry , 2020, https://www.cii.in/PublicationDetail.aspx?enc=8WtPUf8Nh6hH4VSx3f1m9WsCJHK9xxqz+uAO/6yie0Y71YAOu6zRjufengxfioBHdZmlRkhj64IdxNjT/mh94bOUGTPGZWN/tmx77sUzbFCqHhOxkeuIgmCJvlEvLf4y543QjSZXzXapfqDnR+nhvabbnOLine0RFdIBIuUNL2s=.

[6] DrugPatentWatch, "Sourcing the Key Starting Materials (KSMs) for pharmaceutical Active Pharmaceutical Ingredients," March 28, 2025, https://www.drugpatentwatch.com/blog/sourcing-the-key-starting-materials-ksms-for-pharmaceutical-active-pharmaceutical-ingredients-apis/.

[7] DrugPatentWatch, "The Role of China in the Global Generic Drug API Market," 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," August 14, 2019, Council on Foreign Relations Blog, https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

[8] Bradsher, Keith, "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.

[9] Leonard, Joseph, "Western North Carolina IV plant still shut down. Supply shortage 'affecting hospitals across the United States,'" WCNC Charlotte, October 13, 2024,

III. Unfair Competition Harms U.S. Manufacturing and Leads to Shortages

Drug shortages in America are an old and persistent problem. A decade before the COVID-19 crisis, the National Institutes of Health was already reporting growing shortages of commonly used medicines.[10] The Food and Drug Administration was reporting shortages in more than 100 essential drugs at the end of 2019.[11]

The COVID pandemic brought the problem of shortages into stark focus. 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 API, India produces many generic medicines sold worldwide and Italy produces a significant share of antibiotics. As reported in the New York Times: "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," quoting University of Minnesota's College of Pharmacy professor Stephen Schondelmeyer, whose work with the Resilient Drug Supply Project involves trying to map supply chains for key medicines used in the United States.[12]

That foreign subsidies and other unfair trade practices have distorted pharmaceutical competition globally is well understood. The practice of "pumping and dumping," in which countries heavily subsidize pharmaceutical manufacturing, gain market share and then flood the market with cheaper products to destroy competition, is an established tactic.[13] The U.S. government has recognized a need to comprehensively combat unfair foreign competition that erodes the resilience of U.S. pharmaceutical supply chains and manufacturing.[14]

What is far less understood is how anticompetitive practices and market structures right here at home in the U.S. have fueled drug shortages, weakened supply chains, and undermined resilience. Strong antitrust enforcement and competition policy that corrects market failures to restore a functioning market for pharmaceuticals must be part of America's onshoring plan – otherwise, attempts to revive U.S. manufacturing of KSMs, APIs, and essential medicines will fail.

Onshoring necessarily will require government investment, subsidies, and tax credits, but taxpayer dollars will be wasted if the anticompetitive practices that have helped create

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https://www.wcnc.com/article/news/local/hospitals-across-country-worry-over-iv-shortage/83-3374c97f-ef12-4f6c-af32-8419b12d34ab.

[10] C. Lee Ventola, "The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies", P T. 2011 Nov; 36(11): 740-742, 749-757, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/.

[11] U.S. Food & Drug Administration, "FDA Drug Shortages," https://dps.fda.gov/drugshortages.

[12] 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-shortages.html.

[13] Gibson, Rosemary and Singh, Janardan Prasad, *China Rx: Exposing the Risks of America's Dependence on China for Medicine* (Prometheus Books 2021), p.70-81.

[14] White House Report, "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," June 2021.

shortages are allowed to continue. Corporations that have violated the antitrust laws should not be rewarded for their role in weakening supply chains and reducing manufacturing capacity, nor should they be permitted to take taxpayers' money and run the U.S. right back into drug shortages and fragility. Rather than subsidizing already dominant pharmaceutical companies, and particularly those that engage in exclusionary conduct, anticompetitive acquisitions, or tax avoidance, a comprehensive plan to onshore manufacturing should prioritize small and medium sized regional manufacturers.

Competition Policy Regarding GPOs and PBMs is Needed for Domestic Manufacturing to Be Feasible

Onshoring pharmaceuticals and pharmaceutical ingredients requires using competition policy to address the anticompetitive practices of consolidated middlemen. One of the lesser-known causes of endemic drug shortages is the concentrated set of industry actors called group purchasing organizations (GPOs), with the three largest firms controlling 90% of the market.[15] GPOs negotiate procurement contracts for pharmaceuticals and medical supplies on behalf of hospitals and other health care providers, serving as industry middlemen who exert monopsony or "buyer power," on manufacturers. GPOs' incentives to single-source medical supply contracts to only the biggest corporations for the biggest kickbacks have created fragile supply chains, excluded competition, and thwarted innovation.[16] By demanding steep administrative fees and squeezing suppliers for low prices, GPOs have helped push medical manufacturing offshore. 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.[17]

GPO 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 using cheap foreign imports of APIs, KSMs, and intermediates. Ultimately generic drug makers must have the financial ability to purchase higher quality, more secure, domestically produced inputs at a higher cost or invest in end-to-end manufacturing methods.

Like GPOs, Pharmacy benefit managers (PBMs) are highly consolidated middlemen – the three largest control nearly 80% of the market – and engage in practices that contribute to fragility and reduce capacity. PBMs, which major insurance companies began to

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[15] 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/.

[16] For deeper context on GPOs and recommended reforms, see American Economic Liberties Letter to FTC, November 22, 2022, http://www.economicliberties.us/wp-content/uploads/2022/11/2022-11-22-AELP-FTC-6B-GPO-Letter-Final.pdf.

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

systematically acquire in the mid-2010s,[18] bargain over drug prices with pharmaceutical manufacturers, deciding everything from insurance coverage of certain drugs, prices, and the pharmacies that a patient is permitted to use.[19] PBMs continue to drive prices higher and reduce generic drug capacity by excluding coverage for lower-priced generics in favor of higher-priced branded drugs — and receive kickbacks for doing so.[20] For onshoring pharmaceuticals and pharmaceutical ingredients to be feasible, policymakers must evaluate and counter PBM practices that work against redundancy and resiliency.

Competition Policy and Enforcement Against Anticompetitive Mergers and Exclusionary Conduct Are Needed for Domestic Manufacturing to be Feasible

Another major contributor to fragile drug supply chains is that both branded and generic pharmaceutical firms have engaged in merger mania, such that relatively few large firms dominate many categories of medicines.[21] A report analyzing pharmaceutical M&A trends from 2010–2023 found that there were 3,006 pharmaceutical M&As in total during this period.[22] In the course of rolling up the competition, drugmakers shut down the production capacity of the firms they acquired. 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."[23]

Anticompetitive practices to keep lower-cost generic drugs and biosimilars off the market are also rampant. AELP's May 2023 report with the Initiative for Medicines, Access, & Knowledge (I-MAK), titled *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.[24] In seeking to reduce competition, these illegal acts eliminate market participants and thin out pharmaceutical supply chains.

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[18] *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/

[19] Zach Freed, "The Pharmacy Benefit Mafia: The Secret Health Care Monopolies Jacking Up Drug Prices and Abusing Patients and Pharmacists," American Economic Liberties Project, June 2022, http://www.economicliberties.us/wp-content/uploads/2022/06/2022-6-22-PBM-Quick-Take.pdf.

[20] U.S. Federal Trade Commission, "FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices," September 20, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices.

[21] Marc-André Gagnon & Karena D. Volesky, "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016", Global Health 13, 62 (2017). Available at: https://doi.org/10.1186/s12992-017-0285-x

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

[23] *Id*. at 40.

[24] American Economic Liberties Project and the Initiative for Medicines, Access, & Knowledge, "The Costs of Pharma Cheating," May 16, 2023. https://www.economicliberties.us/our-work/the-costs-of-pharma-cheating/.

In order for the domestic manufacturing of KSMs, APIs, and essential medicines to be feasible, competition policy must be used to combat anticompetitive mergers and exclusionary conduct by pharmaceutical manufacturers. Efforts to increase domestic manufacturing of pharmaceuticals and pharmaceutical ingredients will be thwarted if violators are allowed to pocket taxpayer dollars and then eliminate competitors, and with them, capacity. Antitrust enforcement against these practices must be robust to develop supply chains that are redundant and resilient and to promote competitive pharmaceutical markets that reward quality and innovation.

IV. National Security Requires Supply Chain Transparency

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. The Department of Commerce must obtain all available FDA data and require pharmaceutical market participants to fill in reporting gaps.

FDA data alone does not provide a full picture. The closest proximation is information on the geographic location of production facilities that the FDA has inspected, yet that data provides no insight into the volume or types of medicines or API being produced. And, with so many finished medicines being produced overseas, it is unclear that all API or finished medicines are even coming from FDA-approved facilities. A significant problem is a lack of mandatory reporting by producers on the sources of API and how many facilities they have making finished medicines and APIs.

The data required to be submitted do not enable the FDA to determine which drug product manufacturers are relying on a given API supplier, or how much of a manufacturer's API is being supplied by any given API supplier. Without knowing the volume of production in each facility in real-time, having a clear picture of the supply chain is not possible. The Commerce Department and the FDA should require frequent reporting by producers on the sources of API. The government should also require reporting of inventories of APIs and finished dosage forms in the pipeline in order to create a comprehensive and up-to-date inventory of all essential medicines and inputs.

Transparency would also help show quality measures. Currently generic drugs cannot differentiate or compete on quality, but Made in America metrics would help demonstrate quality and reward onshoring.

V. Conclusion

Creating American independence for API, KSM and essential drug manufacturing is an important and worthy goal that must be urgently pursued. Success will require correcting pharmaceutical market failures caused by anti-competitive conduct, oligopolistic market structures and horizontal and vertical consolidation, as well as ensuring that government subsidies and procurement dollars are awarded to only those companies that will help build thick, redundant, resilient, regional supply chains that secure America's public health and national security. Governmental investment is critical to build capacity, and patient

access to essential medicine must not be compromised during the time it takes to onshore and friend-shore manufacturing. Strong governmental institutions will be required to coordinate investment, procurement, and supply chain tracking.