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July 17, 2026

Lisa Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Dear Secretary Barton,

Public Citizen files the following written submission in response to U.S. International Trade Commission investigation No. 332-610, "Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector."

Sincerely,

Peter Maybarduk
Public Citizen Access to Medicines Director

**Public Citizen Written Submission re: Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector**
Investigation No. 332-610

Public Citizen is a national nonprofit consumer advocacy organization based in Washington DC with over one million members and supporters nationwide. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

Our comment contextualizes key factors that contribute to pharmaceutical research, development, and production and emphasizes that consumer interests in the readily available supply of safe and affordable medicines are implicated by this investigation and related policy proposals.

**1. Maintaining the availability of and access to medicines should be a central consideration in any government action that targets pharmaceuticals.**

China makes significant contributions to global pharmaceutical supply chains and pharmaceutical availability. Hindering these without careful attention to consequences and adequate, timely alternatives could have damaging effects for consumers and health, including millions of Americans.

Chronic drug shortages and the interruptions to care that they bring, are a pressing concern for patients in the United States and globally.[1] While the causes of shortages are complex and often non-transparent, research finds that predictive factors include a decline in suppliers and manufacturing issues.[2] One-third of unique APIs produced for the U.S. market rely on a single facility and another 30% rely on two or three facilities, indicating supply chain vulnerabilities and a lack of redundant supply.[3]

In the wake of the COVID-19 pandemic and persistent drug shortages, it is appropriate that the United States and many other countries view pharmaceutical production as a national concern. At the same time, it would be counterproductive and likely harmful to pursue policy proposals that could disrupt already limited sources of supply for essential medicines and their components. Policymakers should address overconcentration by focusing their attention on improving supply chain resilience and diversifying supply sources. Here, there are several important considerations.

Incomplete data severely limit assessment of the drivers of drug shortages and supply chain vulnerabilities.[4] As such, there is a need for greater visibility and investment in the necessary data infrastructure to better understand vulnerabilities and match policy responses accordingly.

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[1] ASPE, Impact of Drug Shortages on Consumer Costs (May 2023), https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf; ASPE, Impact of Drug Shortages on Patients in the United States: A Case Study of Three Drugs (Apr. 2024), https://www.ncbi.nlm.nih.gov/books/NBK608930/

[2] Barber, Written statement, U.S. Senate Committee on Armed Services, Subcommittee on Personnel Hearing: The Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals (Apr. 30, 2024), at 3, https://www.armed-services.senate.gov/imo/media/doc/barber_statement.pdf

[3] Socal et al., Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients, Health Affairs (2023), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.01120

[4] Barber, Written statement, U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health Legislative Proposals to Prevent and Respond to Generic Drug Shortages (Sept. 2023), https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/evo-media-document/melissa-barber_witness-testimony_09.14.23.pdf

Diversifying supply sources will require strategic and long-term approaches that include public funding and incentives to make relocation more cost-effective and sustainable. Relevant tools to achieve this include loans, grants, and cost-sharing for critical medical infrastructure to offset capital investment; investments in advanced manufacturing processes to improve efficiency; and a regulatory environment that facilitates qualification while simultaneously maintaining standards that promote quality, transparency, and resilience.[5] Investments should prioritize developing capacity to meet the United States' most critical supply needs by targeting medicines based on assessments of clinical importance and number of suppliers. The U.S. government has produced lists of essential medicines deemed particularly important.[6]

Additionally, federal legislation and burgeoning state initiatives suggest that public pharmaceutical options offer a promising way to help prevent shortages.[7] Publicly accountable manufacturing and distribution of medicines can help rebuild U.S. manufacturing capacity for essential medicines and address the market problems that drive manufacturing overseas.[8]

While increased domestic capacity is important, it would not be feasible or cost-effective to produce all U.S. medicines domestically. Moreover, relying on a single or a few suppliers, or a single geographic region, for a drug or component is inherently risky, whether those suppliers are based in the U.S. or another country. As such, addressing supply chain vulnerabilities requires efforts that support timely, affordable, quality-assured medicine production from capable facilities worldwide. The U.S. government has shown interest in supporting this aim, including in past foreign assistance initiatives to purchase African-made HIV tests and antiretroviral treatments for use in global health programs and U.S. International Development Finance Corporation investments in efforts to build pharmaceutical manufacturing capacity in other countries.[9] At the same time, maximalist intellectual property policies can

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[5] Barber, Written statement, U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health Legislative Proposals to Prevent and Respond to Generic Drug Shortages (Sept. 2023), https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/evo-media-document/melissa-barber_witness-testimony_09.14.23.pdf; Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

[6] Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, FDA (May 2022), https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs; Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

[7] The Affordable Drug Manufacturing Act, https://www.congress.gov/bill/118th-congress/senate-bill/3398/text; Brown and Morten, Public pharma is the best solution to the ongoing problem of drug shortages, Stat News (Aug. 9, 2023) https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/; National Defense Authorization Act for Fiscal Year 2025, Sec. 739. Plan To Improve Access By Members Of The Armed Forces To Safe, High-Quality Pharmaceuticals.

[8] Sahil Agrawal et al, Drug Dealing: Making Public Pharma Work, Wash. U. L. Rev. (2025), https://wustllawreview.org/2025/09/03/drug-dealing-making-public-pharma-work/; Dana Brown & Christopher Morten, Public pharma is the best solution to the ongoing problem of drug shortages, STAT News (Aug. 9, 2026), https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/

[9] U.S. Department of State, PEPFAR sets bold manufacturing targets for Africa (Dec. 13, 2022), https://2021-2025.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/; The U.S. International Development Finance Corporation, Healthcare, https://www.dfc.gov/our-work/healthcare (accessed July 14, 2026); International Finance Corporation, IFC, Proparco, DEG, and DFC Support Aspen to Strengthen Africa's Pharmaceutical Sector (Sept. 3, 2024),

hinder efforts to grow global manufacturing capabilities.[10] The U.S. government should support flexible intellectual property rules and a more open technology transfer environment to encourage capacity expansion in geographically diverse locations.

By targeting policies to identify and address vulnerabilities and enable useful global capacity, the U.S. can help address overconcentration and mitigate public health risks from potential supply chain disruptions.

**2. Government support for research and production often contributes to efforts to build and sustain pharmaceutical capacity; this kind of support helps address public priorities, including in the United States.**

A study examining biopharmaceutical innovation and industrial development in South Korea, Singapore, and Taiwan highlighted the use of government policies including "public investment in biomedical hubs, research funding and research and development (R&D) tax credits."[11] Another noted that government policies including those that "invested in an educated labor force, public R&D, tariff protection, and subsidized credit to support domestic firms" featured in efforts to build productive capacity in several countries.[12] The U.S. employs many of the same types of policies that attract scientific talent, support R&D and production, and provide tax and other incentives to companies.[13]

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https://www.ifc.org/en/pressroom/2024/ifc-proparco-deg-and-dfc-support-aspen-to-strengthen-africas-pha; The U.S. International Development Finance Corporation, DFC Board Approves $2.5 Billion in New Strategic Investments Advancing Infrastructure, Energy, and Supply Chain Security (June 3, 2026), https://www.dfc.gov/media/press-releases/dfc-board-approves-25-billion-new-strategic-investments-advancing (noting the DFC's interest in investments that strengthen supply chains).

[10] Shelly Malhotra et al., PLOS Glob. Public Health, Novel approaches to enable equitable access to monoclonal antibodies in low- and middle-income countries (2024), https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0003418; Mustafizur Rahman et al., Policy Space for Building Production Capabilities in the Pharmaceuticals Sector in Low- and Middle-Income Countries (2021), https://www.bu.edu/gdp/files/2021/09/GEGI_WP_051_FIN.pdf

[11] Chee-Ruey Hsieh, Hans Lofgren, Biopharmaceutical innovation and industrial developments in South Korea, Singapore and Taiwan, Aust Health Rev (2009), https://connectsci.au/ah/article-abstract/33/2/245/71444/Biopharmaceutical-innovation-and-industrial?redirectedFrom=fulltext

[12] Mustafizur Rahman et al., Policy Space for Building Production Capabilities in the Pharmaceuticals Sector in Low- and Middle-Income Countries (2021), https://www.bu.edu/gdp/files/2021/09/GEGI_WP_051_FIN.pdf

[13] Congressional Research Service, The Federal Research and Development (R&D) Tax Credit (Feb. 6, 2026), https://www.congress.gov/crs-product/R48848 (describing the R&D tax credit); Congressional Research Service, The Orphan Drug Act: Legal Overview and Policy Considerations (March 5, 2024), https://www.congress.gov/crs_external_products/IF/PDF/IF12605/IF12605.2.pdf ("Drug manufacturers or sponsors may apply to obtain an orphan-drug designation for drugs in development at any time before the drug receives FDA approval. If granted, designation enables a manufacturer to access various forms of financial assistance for drug research and development, including tax credits for clinical testing costs, grant funding to cover research expenses, and a waiver of the FDA's prescription drug user fee if the manufacturer submits an application for FDA approval of the drug"); BARDA Ventures, https://drive.hhs.gov/ventures.html; GAO, HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks (2023), https://www.gao.gov/assets/gao-23-105713.pdf (describing manufacturing development programs); GAO, Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges (2021), https://www.gao.gov/products/gao-21-319 (Operation Warp Speed (OWS)—a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD)—aimed to help accelerate the development of a COVID-19 vaccine.).

Public funding for biomedical research, for example, is a critically important part of the pharmaceutical value chain. The United States, via the National Institutes of Health (NIH), is the world's largest public funder of biomedical innovation.[14] NIH provides significant support for basic research, which often produces the foundational discoveries upon which drug development is based, as well as support for applied research later on in the development process. As a result, NIH funding contributes to almost every drug that reaches the U.S. market.[15]

Concerningly, the Trump Administration has taken several actions that endanger public support for biomedical research. The Administration has proposed deep cuts to the NIH budget, terminated or disrupted hundreds of millions of dollars' worth of funding for research projects, and awarded thousands fewer grants than in previous years.[1617] The Office of Management and Budget recently proposed a new rule that would fundamentally restructure federal grant governance, including by requiring alignment with Administration priorities and approval by political appointees.[18] The proposal and related actions have received widespread opposition from scientists, the wider public,[19] and the pharmaceutical industry over concerns about the negative impacts on research in the United States.[20]

Despite significant public contributions, taxpayer-funded discoveries are often given to private companies that then seek windfall profits at the expense of patients. Public Citizen supports attaching conditions to publicly funded research agreements to address this unbalanced arrangement. The United States has started taking helpful steps in this area through policies that embed access considerations in certain NIH and health security agreements.[21] The U.S. can build on these efforts and urge other countries, including

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[14] NIH, Grants & Funding, https://www.nih.gov/grants-funding

[15] Ekaterina Galkina Cleary, Matthew J. Jackson, & Fred D. Ledley, Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019, Institute for New Economic Thinking (2020), https://www.ineteconomics.org/uploads/papers/WP_133-Cleary-et-al-Govt-innovation.pdf; Rahul K Nayak, Jerry Avorn, & Aaron S Kesselheim, Public sector financial support for late stage discovery of new drugs in the United States: cohort study, BMJ (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC6812612/

[16] Megan Molteni and Anil Oza, NIH would get $5 billion cut under Trump's 2027 budget, but Congress unlikely to go along, STAT News (April 3, 2026), https://www.statnews.com/2026/04/03/trump-budget-nih-5-billion-cut-in-2027/

[17] Congressional Research Service, NIH Grants Policy Under the Second Trump Administration (April 17, 2026), https://www.congress.gov/crs-product/IF13131; Jocelyn Kaiser, NIH likely to award fewer grants as it races to spend 2026 budget, Science (June 29, 2026), https://www.science.org/content/article/nih-likely-award-fewer-grants-it-races-spend-2026-budget

[18] https://www.federalregister.gov/documents/2026/05/29/2026-10817/regulation-for-federal-financial-assistance

[19] Anil Oza & J. Emory Parker, Flood of comments on White House grantmaking overhaul is largely negative, analysis shows, STAT News (July 15, 2026), https://www.statnews.com/2026/07/15/trump-omb-grant-funding-proposal-comments-95-percent-opposed/ (of the 52,322 public comments comments submitted in response to the rule, about 95% were in opposition and just 1% supported the proposed changes).

[20] Caitlin Owens, Trump's federal grant overhaul plan draws strong pushback, Axios (July 9, 2026), https://www.axios.com/2026/07/09/omb-grant-overhaul-pushback ("The proposed changes to research funding decisions could introduce a level of unpredictability that would weaken the scientific ecosystem," a spokesperson for the Pharmaceutical Research and Manufacturers of America (PhRMA) told Axios. A spokesperson for the Biotechnology Innovation Organization (BIO) voiced similar concerns, stating, "[r]esearch funding decisions must be guided by scientific merit, public health needs, and the potential to advance human knowledge. At a time when China is investing aggressively in biomedical research, the United States must be strengthening the pillars of our scientific and technological leadership.")

[21] NIH, About the IRP Access Planning Policy, https://www.techtransfer.nih.gov/policy/access-policy/about; HHS, HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies (Sept. 8,

China, to implement transparent and accountable policies that ensure the public gets a fair return on its investment in the form of guaranteed affordable pricing and broad access to technologies that result from public support.

Regarding pharmaceutical pricing and reimbursement policies, we urge the Commission and policymakers to focus their assessments on evaluating whether such policies actually disadvantage foreign companies compared to domestic companies. That is, policies that apply equally to foreign and domestic suppliers should not be considered unfair, even if they happen to disproportionately affect U.S. companies. In our experience, pharmaceutical companies' claims about countries' "unfair" pricing disciplines are often used to obscure the drugmakers' own monopoly pricing practices (such as setting unjustifiably high and non-transparent prices), which hurt consumers in the United States and abroad, and to avoid domestic accountability for rising drug costs.

**3. New and broader sources of research and innovation benefit patients in the U.S. and abroad.**

Two often cited concerns about China's biopharmaceutical research capacity — the increasing number of clinical trials performed in the country and the increase in out-licensing activity — may overstate the risk to the United States, potentially obscuring helpful policy options and the benefits of greater innovative capacity to patients.

While China is hosting a growing number of trials (more in total than the United States),[22] this appears to be a poor metric for understanding potential impacts on the United States. U.S. FDA regulations set out quality and patient representation guidelines for applicants relying on foreign clinical trial data.[23] The U.S. FDA has rejected several applications that relied solely on data from a single (non-U.S.) country, indicating the data were not generalizable to the U.S. population and citing the need for multi-regional clinical trials.[24] Moreover, most new drug and biologic applications approved by the FDA rely on pivotal clinical trials that include U.S. participants (in 2025, for example, only two novel FDA-approved drugs relied on pivotal trials that included no U.S. participants [accounting for 4.3% of the total approved NDAs and BLAs that year]).[25]

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2023), https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2024-01-02T03:56:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2023%2F09%2F08%2Fhhs-announces-details-partnership-regeneron-develop-life-saving-monoclonal-antibodies.html&timestamp=2024-01-02T03:43:14Z

[22] World Health Organization, Number of clinical trials by year, country, WHO region and income group (1999-2025), https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group

[23] Elizabeth George et al., Regulatory landscape with U.S. patient requirements and Clinical Trial Diversity expectations, Contemp Clin Trials Commun. (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11417185/

[24] *Id*.

[25] U.S. FDA, Drug Trials Snapshots Summary Report (2025), https://www.fda.gov/media/193285/download?attachment (showing 2025 FDA data); IQVIA, Global Approaches To Drug Development: When Ex-US Clinical Data Can Support US Drug Approvals (2018), https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/global-approaches-to-drug-development.pdf (showing 30 out of 176 new drug and biologic approvals between 2013–17 were based on pivotal clinical trial data with <10% U.S. patients).

We note this not to deter this investigation or legislators from attempting to assess issues related to the running of clinical trials abroad, but to urge careful evaluation of policy proposals for their ability to address perceived challenges and their potential impacts on patients. In our view, for example, U.S. collaboration with regulators in other countries, coupled with adequate FDA inspection and enforcement capacity can help identify potential issues and provide oversight to ensure global trials meet robust ethics and safety standards. Similarly, to the extent that policy proposals favor speeding up regulatory processes in the United States, policymakers should ensure that such efforts do not come at the expense of patients (for example, the U.S. FDA should not sacrifice high-quality safety and efficacy data in favor of accelerated approvals for their own sake).

Increasing out-licensing activity from China indicates progress in producing innovative products with global applications. In general, the addition of new sources of innovation is a good thing, particularly when steps are taken to ensure safe and effective medicines are made broadly accessible.

The development of new medicines can improve care and treatment options available to patients in the U.S. and globally. Several Chinese-made drugs have been first-in-class medicines (targeting novel mechanisms of action) or have been shown to represent therapeutic improvements over existing treatments.[26] During the COVID-19 pandemic, governments and companies raced to develop effective vaccines, which would, by necessity, require rapid manufacturing and broad distribution. Despite immense global need, companies that manufactured some of the earliest approved vaccines overwhelmingly prioritized sales to the U.S. and other high-income countries (66.84% of Pfizer/BioNTech doses and 79.59% of Moderna doses).[27] Notably, nearly half of the more than one million U.S. COVID deaths were due to virus variants. Many of these may have been preventable, including through more rapid and equitable access to medical tools abroad helping curb variant development and transmission.[28] Diverse innovative capacity can also help address needs that traditionally market-dominant actors have failed to prioritize. For example, an Indian manufacturer recently received FDA approval for a new antibiotic medication designed to address hard-to-treat bacterial infections, at a time when the antibiotic research pipeline is shrinking.[29]

We appreciate the opportunity to comment. Thank you.

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[26] Kerstin N. Vokinger et al., The Rise of Drug Innovation in China — Implications for Patient Access in the United States and Globally, N Engl J Med. 393;9 (Sept. 4, 2025), https://www.nejm.org/doi/pdf/10.1056/NEJMp2505821 (citing: Chen Z, Zhong H, Hu H, Kong F, Liang W, Li G. Chinese innovative drug R&D trends in 2024. Nat Rev Drug Discov 2024; 23:810-1).

[27] Adrián Alonso Ruiz et al., Which roads lead to access? A global landscape of six COVID-19 vaccine innovation models, Glob. Health (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC10964709/

[28] https://www.medrxiv.org/content/10.1101/2022.05.31.22275835v1

[29] Rajeshwari Sinha, Novel antibiotic Zaynich brings relief to the drought in antibiotic innovation, Down to Earth (June 2, 2026), https://www.downtoearth.org.in/health/novel-antibiotic-zaynich-brings-relief-to-the-drought-in-antibiotic-innovation ; Access to Medicine Foundation, Antibiotic Innovation Shrinks as Drug-Resistant Infections Rise Globally, says New Report (March 23, 2026), https://accesstomedicinefoundation.org/in-the-media/antibiotic-innovation-shrinks-as-drug-resistant-infections-rise-globally-says-new-report