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Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development

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Chairman Griffith, Ranking Member DeGette, and distinguished Members of the Subcommittee, thank you for this opportunity to testify on the role of the U.S. Food and Drug Administration (FDA) in advancing U.S. drug development and America's leadership in biomedical innovation.

I am the Bloomberg Chair in Global Health at the Council on Foreign Relations (CFR). My expertise is in the international trade and regulation of pharmaceuticals, biotechnology, and other medical technologies, and I have been studying the globalization of clinical trials for about 15 years. I recently co-led a year-long CFR analysis with biopharmaceutical specialists, China scholars, and industrial policy experts to identify the true scope of U.S. pharmaceutical dependence on China and to recommend policies to reduce it.[1]

My testimony builds on that analysis and is divided into three parts.

First, I begin with describing how U.S. dependence on China expanded to first-in-human trials and drug development generally—largely by China running the same playbook it deployed on generic medicines and their ingredients.

Next, I explain the potential implications of dependence on China for U.S. biosecurity, public health, and patients. Herein lies a central tension: China has become genuinely innovative in expediting biopharmaceutical development, and some of the medicines emerging from its system may have significant benefits for U.S. patients. At the same time,

this emerging dependence on China, a strategic competitor, for drug development undermines U.S. economic and biosecurity interests and is resulting in a level of clinical trial activity in China that FDA cannot effectively oversee and, thus, in data on which U.S. patients and healthcare providers may not be able to fully rely.

Third, I conclude with a specific set of recommendations for how Congress can support the FDA in advancing timely development of safe and effective drug development while still preserving America's leadership in biomedical innovation and needed safeguards for patients and trial subjects.

The Origins of U.S. Dependence on China for First-in-Human Trials

Over the last decade, China has surged up the innovation ladder to become a major force in biomedical innovation, largely by running the same playbook it used on generic pharmaceutical products and their ingredients.

U.S. laws and policies adopted to lower domestic drug costs opened the door to cheap generic imports. However, production moved to China specifically because it offered weaker environmental and regulatory standards than those rising in the U.S., discounted water and power inputs, and, as more pharmaceutical ingredients and key starting materials became sourced there, enormous economies of scale.[2] The results were measurable and rapid. As recently as 2008, nearly all U.S.-administered amoxicillin was domestically manufactured.[3] Now 92 percent of the key ingredients for the U.S. supply of amoxicillin, the most prescribed antibiotic in America, come from China.[4]

Conducive U.S. laws and regulations similarly opened the door to clinical studies being conducted abroad. In 2008, FDA regulations were amended to permit the submission of data from foreign clinical studies not conducted under a U.S. Investigational New Drug (IND) application, provided those studies are conducted in accordance with good clinical practices (GCP)—including independent ethics review—and that the FDA can validate the data through an on-site inspection if the agency deems it necessary.[5] Developers, already seeking ways to reduce high clinical trial costs and recruit large, treatment-naïve patient populations, jumped on the chance to go abroad for early-stage studies.[6]

China, and a handful of other countries, have benefited most from this globalization of clinical trials by offering a pathway for drug sponsors to conduct first-in-human trials that are faster and less burdensome than the U.S. IND process but can still be used to support an U.S. IND later. To attract these trials, China cracked down on falsified data, and undertook a step-by-step regulatory overhaul.[7] In 2015, China allowed foreign companies to conduct multiregional clinical trials within its borders. In 2017, China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, adopting global GCP guidelines for its clinical trials. Starting in 2018, the National Medical Products Administration (NMPA), China's national drug regulator, adopted reforms that cut its IND approval process from years to months, and then to weeks.[8]

These reforms in China were reinforced by a dense contract research and data manufacturing organization (CRDMO) ecosystem, greater use of investigator-initiated trials, and disease-specialized hospitals capable of enrolling hundreds of patients at a single site. Made-in-China-2025 designated biopharmaceuticals as a strategic sector Beijing intended to dominate, providing the financing and political mandate for everything that followed: tax holidays, low-interest loans, land discounts, dedicated biotech hubs, and "a scientific-ethics system with Chinese characteristics" that reportedly permited animal and gene-editing experiments off-limits in the West.[9,10,11]

The ability to conduct first-in-human trials more quickly and at lower costs enables small biotech firms to generate data on human safety and pharmacokinetics—how a drug is processed in the body—to determine which compounds hit their biological targets, refine them and show therapeutic promise, leapfrog competitors, and attract licensing deals. Large treatment-naive patient populations, low costs, and fast regulatory approval have made China extremely attractive for first-in-human trials—a competitive advantage over U.S. biotech firms conducting their early-stage research entirely under the slower U.S. IND process. Early-stage trials in China are three to five times faster than in the U.S. and at one-third to one-half of the cost.[12,13] Accordingly, China's share of global clinical trial starts rose from one percent in 2009 to roughly 30 percent in 2024.[14]

Managing risks to U.S. biosecurity, public health, and patient safety

There are three categories of risk that will emerge from the U.S. ceding its global leadership in clinical research, biopharmaceutical innovation, and domestic manufacturing capacity to China.

First, China could create economic, strategic, and political leverage over the U.S. directly by choking off supplies of an innovative medicine or countermeasure developed and manufactured in China on which U.S. patients have come to rely.[15] Beijing has already demonstrated a willingness across rare-earth elements, critical minerals, and agricultural products to weaponize its control of critical supply chains for diplomatic, trade, and geopolitical leverage. There are reasons to believe the U.S. biopharmaceutical supply chain could be next. "China is the world's largest exporter of vitamins and antibiotic raw materials," Chinese economist Li Daokui stated in a March 2019 general meeting of the Chinese People's Political Consultative Conference, a top PRC political advisory body. "Once the export is reduced, the medical systems of some developed countries will not work."[16] China imposed export controls on dual-use products shipped to Japan, including those used in pharmaceutical manufacturing, after remarks by Japan's prime minister on Taiwan.[17] Chinese producers flooded the market with below-cost exports in order to cripple the API and KSM suppliers that India's government had been seeking to establish for domestic resilience.[18]

There would be plenty of targets for such leverage. The United States imports numerous essential generic injectable drugs directly from China, including broad-spectrum hospital antibiotics, an immunosuppressant critical for preventing organ transplant rejections, and an acute heart failure agent.[19] CAR T-cell therapy, a breakthrough cancer immunotherapy, was first approved in the United States, but clinical trials for that therapy in China now outnumber those anywhere in the world.[20] Chinese firms hold thirty-two of fifty-five monoclonal antibody programs globally —a $380 billion product class deployed in cancer immunotherapy, autoimmune treatment, and in antiviral therapies against biological and pandemic threats.[21,22] Between 2021 and 2024, the number of novel drugs in development by Chinese companies nearly doubled, rising to almost 4,400.[23] The National Security Commission on Emerging Biotechnology projects that China will represent roughly one-third of U.S. FDA approvals by 2040.[24]

Second, the competitive erosion of U.S. capacity for innovative pharmaceutical discovery and development to China undermines U.S. economic security, public health, and the capability to produce, in a timely way, the effective countermeasures and cancer medicines on which many Americans depend. A Biotechnology Innovation Organization survey found that 79 percent of pharmaceutical companies use WuXi or other Chinese CRDMOs, reflecting accumulated know-how and client relationships that cannot be quickly unwound.[25] U.S. development of effective COVID-19 vaccines occurred in a matter of months, thanks to innovative trial designs; clinical trial networks; the

active support of the FDA; and financing and coordination from the National Institutes of Health and the Department of War.[26] Ensuring that same U.S. capacity exists in the next crisis requires robust and sustained support in peacetime.

Third, there are practical limits to the FDA's ability to inspect research conducted abroad — especially for pre-IND trials in China —making it difficult to conclude that patients and clinical trial subjects are receiving the protections and assurances that FDA regulations were meant to provide.

Existing FDA regulations are designed to ensure that foreign data used to support an IND are reliable, predicated on appropriate human subject protections, and subject to FDA on-site and remote inspections. Yet, one recent study found that just 20 of the 2,732 eligible GCP inspections that FDA conducted between January 1st, 2016 and July 20th, 2023 occurred in China, while 93 percent (2,541) of the GCP inspections occurred in the United States. FDA conducted fewer GCP inspections of Chinese trials than of those in Japan or Europe.[27] Another study found only 45 FDA inspections on trials conducted in China between January 1, 2009 and July 20, 2023.[28]

FDA purports to prioritize inspections based on risk, but it conducts fewer GCP inspections than it did in 2017 and finds violations at an even lower rate.[29] A recent GAO report found that FDA also inspects few institutional review boards and had not conducted a risk-based assessment to determine whether it is conducting an adequate number. It remains unclear how many inspections, if any, FDA has conducted of IRBs or CROs operating abroad.

Since many first-in-human trials conducted in China are performed under a Chinese clinical trial application alone and without a U.S. IND, FDA learns about these trials when, and if, the sponsor later submits the resulting data to support an IND application. Of course, the data at that point have already been collected, the subjects have already received the treatment, and any health risks or ethical failures to human or animal subjects are no longer reversible.[30]

FDA can and should look for opportunities to strengthen its GCP oversight, but the current gap between U.S. oversight of domestic and Chinese trials is so large that it is difficult to avoid concluding that the best chance for greater FDA oversight would be for more first-in-human trials to be conducted domestically. In the meantime FDA's Oncologic Drugs Advisory Committee recently rejected the use of single-country foreign data—from China—to support an application for marketing approval.[31]

Advancing Timely U.S. Drug Development and American Leadership in Biomedical Innovation

China is at risk of systemically displacing U.S. leadership across the innovatiive biopharmaceutical value chain — discovery, clinical development, and manufacturing. This competitive erosion is not simply the result of market conditions but rather the product of decades of coordinated Chinese state investment. It will require an equal, coordinated and sustained U.S. response, including from the FDA.

That FDA response should begin with making the U.S. biomedical sector more competitive. Whereas China's regulatory process does not sufficiently uphold patient safeguards, FDA could attract trials by streamlining its early-stage clinical development process without compromising patient safety or delaying access to medicines.

A U.S. approach should adopt operational features of other nations' well-regulated models without sacrificing speed, patient safety or the scientific integrity of the trial. Congress and the FDA should also consider authorizing a narrow, expedited clinical trial notification pathway for well-characterized drug platforms or lower-incremental-risk early first-in-human studies, such as Australia has pioneered. Australia also offers a national single-application and tracking infrastructure (National One Stop Shop) as well as standardized operating procedures—streamlining timelines while preserving transparency governance through mandatory IRB approval and drug regulatory inspection and backstop powers. Norway's NorTrials program serves as a public-private national entry point linking industry sponsors with hospitals, feasibility support, central ethics committees, and funded clinical-trial centers.[32] Investing in university and hospital trial sites, as Norway has, could boost U.S. capacity while ensuring the distribution of those sites supports the scientific objectives of a diverse trial subject population that can draw from rural areas as well.[33] The recently released Operational Trialblazer has elements of these approaches that deserve further refining and implementing, but fails fully to address inadequate FDA staffing, inconsistency, and unpredictability as a bottleneck in the review process.[34]

Second, FDA can reduce dependence on Chinese contract biomanufacturers without cutting off supplies to U.S. patients. Reducing the regulatory and commercial uncertainty that firms face when switching from legacy processes to potenially cheaper, advanced biopharmaceutical technologies and artificial intelligence-driven process innovations can help. FDA should reduce this friction by providing model comparability protocols for assessing new technologies and expedited review of post-approval manufacturing changes. FDA should also be prepared to more readily authorize temporary importation of essential medicines from well-regulated allied markets. Although that is already permitted, FDA only does so as a last resort after months or even years of delay.[35] The agency should proactively identify and assess foreign sources for essential medicines where China holds a concentrated market dominance.

Finally, Congress needs to continue to invest in the enabling environment that the U.S. government has created to support a thriving biomedical industry, including federal health agencies, such as FDA, NIH, and ARPA-H, that are intended to align U.S. public health priorities with innovation and patient access.[36] Rehiring has begun at FDA, but staffing at the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are still down from the start of FY2025 by 18 percent and 16 percent, respectively.[37] Adding a user fee to enhance the number and quality of inspections of research sites for IND submission with foreign clinical data would help boost FDA GCP inspection capacity. An analagous user fee instituted to fund inspection of foreign manufacturing plants helped identfy breaches of good manufacturing practices. Improving FDA review for cell and gene therapies by strengthening staffing stability, retaining scientific and clinical expertise, and improving transparency would add speed, predictability and reasonableness to the review process and boost US biophamarcceutical innovation.

The U.S. dependence on China for essential medicines has also moved beyond generic drug manufacturing into the innovation pipeline itself. Every licensing agreement signed with a Chinese biotech firm transfers commercial rights, process knowledge, clinical data, and development expertise that cannot be recovered through downstream U.S. manufacturing policy alone. The same dynamic that hollowed out small-molecule API manufacturing is now playing out in biologics and synthetic biology, but it is taking place at an earlier stage where intervention would be more effective and is more urgent. The time to act is now.

I thank the Subcommittee for its attention and leadership in elevating U.S. drug development and biomedical innovation as a national priority. I stand ready to answer your questions and to assist anyway I can.

Notes

[1] Bollyky TJ, Doshi R, Kosloff O, Yadav, P, and Every E. *The Pharma Choke Point: How to Reduce U.S. Dependence on Chinese Pharmaceutical and Biotechnology Supply Chains*. Council on Foreign Relations, June 2026, https://www.cfr.org/reports/the-pharma-choke-point.
[2] Thomas J. Bollyky, Chloe Searchinger, and Prashant Yadav, "America's Pill Problem: Tariffs Won't Fix the Country's Dangerous Dependence on Foreign Medicines," Foreign Affairs, October 20, 2025, http://foreignaffairs.com/united-states/americas-pill-problem.
[3] Patrick Cashman, "Written Testimony of Patrick Cashman, President, USAntibiotics," testimony before the U.S. Senate Special Committee on Aging, hearing: "Made in America: Restoring Trust in Our Medicines," November 19, 2025, http://aging.senate.gov/imo/media/doc/54f2de22-d91a-d0f2-e680-172077039edd/Testimony_Cashman%2011.19.25.pdf.
[4] Bollyky et al, *The Pharma Choke Point*.
[5] 21 CFR 312.120.
[6] Fabio A. Thiers et al., Trends in the Globalization of Clinical Trials, Nature Review Drug Discovery (2007).
[7] Yanzhong Huang, "A Biopharmaceutical Superpower: China's Rise, Its Limits, and What Comes Next," *Horizons* (Center for International Relations and Sustainable Development, April 2026), http://cirsd.org/horizon-article/a-biopharmaceutical-superpower-chinas-rise-its-limits-and-what-comes-next.
[8] Jerry Chapman, "An Inside Look at China's Regulatory and Drug Approval Processes," Redica Systems, June 10, 2021, https://www.redica.com/resources/post/an-inside-look-at-chinas-regulatory-and-drug-approval-processes.
[9] Adolfo Arranz, "Betting Big on Biotech," *South China Morning Post*, October 9, 2018, https://multimedia.scmp.com/news/china/article/2167415/china-2025-biotech/index html.
[10] Center for Security and Emerging Technology, "Opinions on Strengthening the Governance of Science and Technology Ethics" (translation of 关于加强科技伦理治理的意见), April 2, 2025, https://cset.georgetown.edu/publication/china-science-ethics-opinions/.
[11] Jeroen Groenewegen-Lau, testimony before the U.S.-China Economic and Security Review Commission, "Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security," June 5, 2025, https://www.uscc.gov/sites/default/files/2025-06/Jeroen_Groenewegen-Lau_Testimony.pdf.
[12] Huang, "A Biopharmaceutical Superpower".
[13] Scott Gottlieb. How to stop the shift of drug discovery from the U.S. to China. *STAT*. May 6, 2025. https://www.statnews.com/2025/05/06/how-to-stop-the-shift-of-drug-discovery-from-the-u-s-to-china/
[14] IQVIA Institute for Human Data Science. Rethinking Clinical Trial Country Prioritization. Published online July 2024. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/rethinking-clinical-trial-country-prioritization
[15] Eleanor Olcott, Haohsiang Ko, and William Sandlund, *[article title needed],* Financial Times, [date needed], https://www.ft.com/content/c0a1b15b-84ee-4549-85eb-ed3341112ce5.
16. Ken Dilanian and Brenda Breslauer, "U.S. Officials Worried About Chinese Control of American Drug Supply," NBC News, October 18, 2019, http://nbcnews.com/health/health-care/u-s-officials-worried-about-chinese-control-american-drug-supply-n1052376.
17. "China Tightens Export Controls of Japan-Bound Dual-Use Items Amid Security Tensions." People's Daily Online (*Global Times*), January 7, 2026, http://en.people.cn/n3/2026/0107/c90000-20411016.html.
18. Ambika Sharma, "China's Price War Hits Indian Active Pharmaceutical Ingredients Industry," *The Tribune*, September 12, 2025, http://tribuneindia.com/news/himachal/chinas-price-war-hits-indian-active-pharmaceutical-ingredients-industry.
[19] Bollyky et al. *The Pharma Choke Point*.
[20] Isabel Briz Hernández, Yuki Ishihara, and Dong Dong, "Beyond the State: First-Person Ethics and the Governance of Targeted Therapies in China," *Social Science & Medicine* (2026), https://doi.org/10.1016/j.socscimed.2026.119484.
[21] KPMG AG, *The Biologics Manufacturing Rivalries: A Strategic Trilogy—Episode I: A New Geopolitical Order: The Rise of the Biomanufacturing Empire* (Zurich: KPMG AG, July 2025), http://assets.kpmg.com/content/dam/kpmgsites/ch/pdf/the-biologics-manufacturing-wars.pdf.coredownload.inline.pdf.
[22] Bollyky et al. *The Pharma Choke Point*.
[23] Chen Z, Zhong H, Hu H, Kong F, Liang W, and Li G, "Chinese Innovative Drug R&D Trends in 2024," *Nature Reviews Drug Discovery* 23 (2024): 810–811, https://doi.org/10.1038/d41573-024-00120-5.
[24] National Security Commission on Emerging Biotechnology, The Future of U.S.-China Biotechnology Competition at 4 (Dec. 2025), https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf.
[25] Biotechnology Innovation Organization, "BIO Survey Reveals Dependence on Chinese Biomanufacturing," *Good Day BIO*, May 9, 2024, http://bio.org/gooddaybio-archive/bio-survey-reveals-dependence-chinese-biomanufacturing
[26] Chad P. Bown and Thomas J. Bollyky, "How COVID-19 Vaccine Supply Chains Emerged in the Midst of a Pandemic," *The World Economy* 45, no. 2 (Feb. 2022): 468–522, http://doi.org/10.1111/twec.13183.

[27] Courtney McGuire, Jenn W. Sellers, and Laurie Muldowney, "A 7-Year Analysis of the U.S. FDA Good Clinical Practice Inspection Outcomes for Marketing Applications," *Therapeutic Innovation & Regulatory Science* 2025 https://link.springer.com/content/pdf/10.1007/s43441-025-00835-6.pdf.
[28] Huiyao Huang, Yiru Hou, Hong Fang, Ling Xu, Yue Yu, Huifang Zhang, Jing Zhang, Yu Tang, Gongtao Lan, Wenbao Zhang, and Ning Li, "Unveiling Quality of Clinical Trial in China: From Concern to Confirmation," PMC11110953, https://pmc.ncbi nlm nih.gov/articles/PMC11110953/.
[29] McGuire et al., "A 7-Year Analysis of the U.S. FDA Good Clinical Practice Inspection Outcomes."
[30] Lowell Schiller, testimony before the United States Senate Committee on Health, Education, Labor, and Pensions, "The Future of Biotech: Maintaining U.S. Competitiveness and Delivering Lifesaving Cures to Patients," October 29, 2025, https://www.help.senate.gov/imo/media/doc/77287bdb-084f-c84c-7a93-3624e7471c2a/Schiller%20Testimony.pdf.
[31] Kerry Dooley Young, "FDA Panel Rejects Sintilimab Clinical Trial Data From China," *Medscape*, February 11, 2022, https://www.medscape.com/viewarticle/968320.
[32] Bollyky et al. *The Pharma Choke Point*.
[33] Bollyky et al. *The Pharma Choke Point*.
[34] U.S. Dep't of Health & Human Servs., Operation TrialBlazer (June 2026); U.S. Dep't of Health & Human Servs., Press Release, HHS Launches Unprecedented Department-Wide Effort to Restore American Leadership in Clinical Trials (June 22, 2026).
[35] Thomas J. Bollyky, Sarosh N. Nagar, Chloe Searchinger, and Aaron S. Kesselheim, "The Role of Importation in Remediating U.S. Generic Drug Shortages," *New England Journal of Medicine* 392, no. 4 (January 23, 2025): 315–318, http://nejm.org/doi/abs/10.1056/NEJMp2413253.
[36] Thomas J. Bollyky, "A U.S. Industrial Policy for Global Health," *Health Affairs* 42, no. 8 (Aug. 7, 2023), http://doi.org/10.1377/hlthaff.2023.00641.
[37] https://www fda.gov/industry/fda-user-fee-programs/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data-fy-2023