# THE NEW BIOTECH COLD WAR

U.S. Medicine Can't Afford to Fall Behind China





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# The New Biotech Cold War: U.S. Medicine Can't Afford to Fall Behind China

# **Key Points**

- China has overtaken the U.S. in clinical trial volume: In 2024, China registered 7,100 clinical trials vs. about 6,000 in the U.S. [16], and now accounts for about 39% of global Phase I-IV trial starts [17].
- **Trial quality concerns persist**: FDA rejections of drugs like surufatinib and sintilimab underscore flaws in China-only trials [19] [20], including outdated comparators, weak oversight, and homogeneous patient clinical trial populations that do not adequately reflect the genetic background of patients in the U.S. [23].
- **China's R&D spending is surging**: In 2024, China invested ¥3.6 trillion (about \$500B), 2.68% of GDP in total R&D spending, surpassing the Euro area (2.3%) and rapidly approaching the U.S. (3.6%) [25] [26]. China's biopharma R&D spending alone climbed to about \$15 billion by 2023.
- **Biotech patenting and research leadership**: China's biotech PCT filings rose from 119 in 2010 to 1,918 in 2023 [29], and 7 of the world's top 10 research institutions in Nature Index 2024 are now Chinese [28]; Harvard is the only U.S. entry.
- **China is shifting from copycat to innovator**: By 2025, about 40% of global licensing deals involve Chinese-origin drugs [33] a sharp rise from low single digits just five years ago.
- **China's state-driven edge:** Heavy subsidies, tax breaks, and state loans [2] paired with lax labor and safety regulations [5] and weak environmental enforcement [6] give Chinese biotech firms an artificial cost advantage over U.S. firms.

America's biotechnology sector has long been a pillar of national strength, driving breakthroughs in precision medicine, cutting-edge cancer treatments, and advanced genetic therapies. That edge, however, is no longer guaranteed. Over the past 20 years, U.S. biotech has followed a familiar pattern: manufacturing moved offshore, and with it much of the technological innovation. Clinical trials migrated to cheaper, under-regulated environments. Research funding and talent shifted east. And now China is producing not only the world's generics but also first-inclass therapies.

This is no accident. Beijing deliberately treated biotech as strategic infrastructure, pairing subsidies, tax breaks, and industrial loans with lax regulation to speed up development. The result: China now leads in clinical trial volume, dominates active pharmaceutical ingredient (API) production, and is exporting novel therapies—by value in the first half of 2025, about 32% of global pharmaceutical out-licensing deals involved China-origin assets [40].

The Trump administration has begun to recognize these risks and is weighing unprecedented regulatory steps. A draft executive order circulating in September 2025 would impose sweeping restrictions on U.S. firms licensing Chinese-developed medicines [44]. Proposals under discussion include tougher FDA scrutiny of China-generated trial data, mandatory disclosure of foreign clinical sourcing, potential CFIUS review of biotech licensing deals, and procurement preferences for U.S.-made drugs paired with tax incentives to reshore production. This underscores that biotech is no longer treated as a neutral marketplace — it is strategic terrain where regulatory policy will determine whether the U.S. regains control of its medicine supply or cedes the field to Beijing.

If Washington continues to treat biotech like "just another industry," America risks waking up to a world where its medicines are not only made, but increasingly invented, somewhere else. America's entire health system, economic competitiveness, and national security are at risk.

# **How We Got Here: China's Rapid Ascent in Biotechnology**

China's biotech dominance didn't appear overnight. It has been the product of a deliberate, step-by-step strategy—beginning with low-cost pharmaceutical manufacturing, then expanding into clinical trials, research, and talent development. Understanding this chronology is key to seeing how America's current dependence took shape and why it now poses such a strategic risk.

## **Manufacturing Moves Offshore**

In the 1990s and early 2000s, U.S. and European drugmakers began shifting production of APIs and generics to China [1]. The rationale was straightforward: lower labor costs, cheaper inputs, and fewer regulatory hurdles.

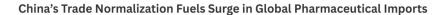
Beijing has long treated pharma and biotech as strategic sectors. Under Made in China 2025, for example, the government uses direct subsidies, tax breaks, state-backed loans, and export tax rebates to build domestic capacity [2]. Export rebates for pharmaceutical products were raised in the early 2000s as part of broader export promotion policy [3]. China has also designated biotechnology as a priority industry under its 13th Five-Year Plan [4].

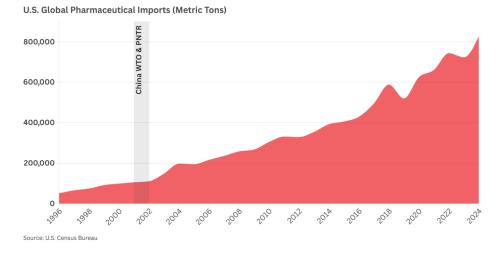
At the same time, labor law enforcement in China has historically been weak, with long hours, low wages, and poor compliance common in factories despite formal legal protections [5]. China's industry has also long benefited from lax environmental enforcement, with pollution controls often under-applied and inconsistently enforced across provinces [6].

Intellectual property protections were similarly under-enforced, allowing practices like reverse-engineering and trade-secret leakage to proliferate in the generics and pharmaceutical-adjacent sectors [7]. By reverse-engineering Western processes with little consequence, Chinese firms gained capabilities that allowed their domestic R&D environment to catch up quickly to the U.S.

Beijing's state-driven industrial policies, coupled with its willingness to cut corners on safety, labor, and environmental standards, manufactured an artificial cost advantage that multinationals eagerly exploited. As shown in Figure 1, after China's WTO entry and trade normalization, U.S. pharmaceutical imports skyrocketed, as global supply chains became increasingly anchored in China.

Figure 1:





This import dependence reflects Beijing's grip on the base of the pharmaceutical supply chain — active pharmaceutical ingredients (APIs). China now controls 80-90% of global API production for many essential medicines, such as antibiotics [8].

As of 2025, China has over 1,600 pharmaceutical manufacturers generating more than \$183 billion in revenue [9]. In critical categories, U.S. production disappeared altogether. For example, the last U.S. penicillin fermentation plant shut down in 2004 after Chinese producers flooded the market with low-cost products, leaving the United States dependent on overseas sources [10]. Today, China manufactures nearly all of the world's supply of penicillin G, controlling the key starting material needed for many antibiotics [11].

The risks soon became visible. In 2017, an explosion at a single Chinese antibiotic factory caused worldwide shortages of piperacillin-tazobactam, forcing hospitals to ration a last-resort drug [12]. In 2018, carcinogenic impurities (NDMA) were discovered in blood pressure drugs made by Zhejiang Huahai, triggering sweeping recalls across the U.S. and Europe [13].

And while some argue that reliance on India diversifies supply, India itself imports 70% or more of its APIs from China [14]—meaning U.S. buyers are often still indirectly dependent on Beijing.

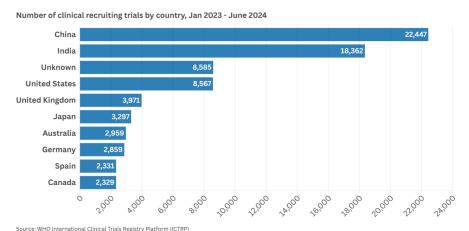
#### **Clinical Trials Follow Production**

Once China built scale in manufacturing, clinical trials naturally followed. In the mid-2010s, Beijing restructured its National Medical Products Administration (NMPA) to clear a massive backlog and nominally align with international standards. But in practice, China's system remained far looser, cheaper, and faster than that of the FDA or EMA.

Chinese biotech firms have raced from launch to first-in-human testing on timelines far shorter than would ever be feasible in the U.S. [15]. By 2024, China logged over 7,100 registered clinical trials, surpassing the U.S. tally of around 6,000 [16]. China also now accounts for about 39% of all global Phase I-IV clinical trial starts [17] — a dramatic rise over the past decade. Moreover, as shown in Figure 2, both China and India far outpace the United States in clinical recruiting trials over the past two years [18].

Figure 2:





However, this breakneck pace often prioritizes speed over rigor. Regulators in the U.S. have repeatedly flagged the shortcomings of Chinaonly data: the FDA rejected applications for drugs like surufatinib and sintilimab [19] [20], citing trial designs that failed to meet international standards of care or include representative patient populations.

Studies show that China's speed often comes at the cost of quality. Trials there have been found to suffer from weak ethical oversight, inconsistent registration, and problems with how consent and data are handled. Reviews also point to deeper issues: poor design of studies (such as weak randomization or outdated methods), selective reporting of results, and spotty monitoring of safety problems. Investigator-initiated trials are especially prone to these shortcomings. Quality also varies widely across regions and hospitals—leading experts to conclude that, despite reforms in the 2010s, China's clinical trial system still falls well short of U.S. and European standards [21] [22].

Many trials also enrolled only homogeneous Han Chinese populations, limiting generalizability, and often relied on outdated or inappropriate control arms that would not be permitted in U.S. studies [23].

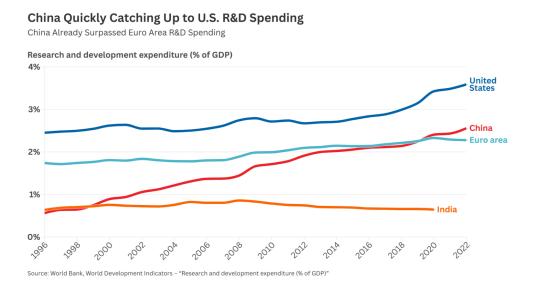
Despite these flaws, the perception persists that China is the fastest place to generate clinical evidence. U.S. and European companies increasingly treat China as a "first stop" proving ground, generating preliminary data under looser standards before attempting to replicate studies in the West. This practice raises risks: speed may come at the expense of safety, and reliance on low-quality trials threatens to lower the bar for global innovation if not checked by regulators.

# **Research and Discovery Shift**

Clinical research momentum attracted greater investment. Beijing made biotech a key priority as part of *Made in China 2025* [24], resulting in billions of industrial investments and subsidies. In 2024, national R&D spending reached ¥3.6 trillion (around \$500B), or 2.68% of GDP [25]—massive by any measure. China's biopharma R&D spending alone climbed to about \$15 billion by 2023 [39].

As shown in Figure 3, in 2022, Chinese R&D spending as a % of GDP (2.6%) already surpassed that of the Euro area (2.3%), and is quickly catching up to the United States (3.6%) [26].

Figure 3:



Private investment in Chinese biotech has also surged: in 2023, 69 biotech firms raised a combined \$20.61 billion [27]. The average funding round for Chinese companies was nearly triple that of U.S. firms — a reflection of both investor enthusiasm for China's rapid-but-loosely regulated biotech sector and Beijing's push to turn massive R&D spending into commercial breakthroughs.

Output followed input. According to the 2024 Nature Index Research Leaders data, China holds 7 of the top 10 global research institutions (including Zhejiang, Tsinghua, PKU, etc.), with Harvard being the only U.S. institution in that top 10 tier [28].

#### Table 1:

Rank	Institution	Country
1	Chinese Academy of Sciences (CAS)	China
2	Harvard University	United States of America
3	University of Science and Technology of China (USTC)	China
4	Max Planck Society	Germany
5	University of Chinese Academy of Sciences (UCAS)	China
6	Peking University (PKU)	China
7	Nanjing University (NJU)	China
8	French National Centre for Scientific Research (CNRS)	France
9	Tsinghua University	China
10	Zhejiang University (ZJU)	China

Source: Springer Nature Index, Research Leaders 2024: Leading Institutions

China's biotech patent output has also exploded: biotech-PCT filings rose from about 119 in 2010 to 1,918 by 2023, reflecting a many-fold increase in patenting in life sciences and medtech [29].

Meanwhile, NIH funding has been essentially flat for two decades when adjusted for inflation. By 2024 the NIH budget was about 7% below the 2003 peak [30], even as research costs and the U.S. population kept rising. Many university labs faced flat or declining funding, just as China was showering resources on its own.

Human capital has also been critical. Thousands of "sea turtles"—Chinese nationals trained in U.S. and European labs—have returned to China with generous startup packages, free lab space, and access to domestic venture capital [31] [32]. Shanghai, Shenzhen, and Beijing now host biotech clusters with talent and infrastructure rivaling Boston or San Diego.

# **From Copycat to First Mover**

For years, Chinese firms were known mainly for copycats and biosimilars. That era is ending. Increasingly, China is producing first-in-class therapies.

In 2025, nearly 40% of licensing deals worldwide involved Chinese-origin drugs, up from low single digits five years earlier [33]. U.S. and European companies are now "shopping" in China for promising compounds.

One striking example is ivonescimab, a cancer drug developed by the Chinese company Akeso. Touted as a major challenger to Merck's Keytruda, it was approved guickly in China after a trial conducted only with Chinese patients appeared to show better results [34].

A U.S. firm, Summit Therapeutics, soon licensed the drug for global rights. But when tested more broadly, the benefits were much stronger in Chinese patients than in Western ones, with some groups outside China showing little to no clear improvement [35]. This outcome reflects the flaws built into China's clinical trial system — reliance on uniform patient groups, outdated comparators, and speed prioritized over rigor — and raises serious doubts about whether such headline 'breakthroughs' can truly deliver for patients worldwide.

### **Current Picture: U.S. vs. China in Biotech (2025)**

China has turned speed, subsidies, and scale into a global biotech challenge. The U.S. still leads in innovation platforms, but is increasingly exposed on manufacturing, trials, and supply chain resilience.

#### **Innovation**

- **U.S. Strengths:** Still leads in foundational platforms (CRISPR, mRNA, cell therapies). Boston, Bay Area remain global hubs with unmatched venture capital and talent density.
- **China's Advances:** Now dominates global clinical trial volume (7,100 vs. about 6,000 U.S. in 2024) and accounts for around 39% of global trial starts. Nearly 40% of global licensing deals now involve Chinese-origin drugs.

#### **Manufacturing**

- U.S. Weakness: Domestic API and antibiotic production has collapsed (last penicillin plant closed in 2004).
- China's Edge: World's largest API supplier; over 70% of India's API imports come from China, meaning even "Indian" generics often depend on Beijing.

#### **Supply Risks**

• **Evidence:** 2017 explosion at a Chinese plant caused global shortages of piperacillin-tazobactam; 2018 NDMA contamination at Zhejiang Huahai triggered recalls of blood pressure meds. Continuing shortages of essential medicines, such as oncology injectables [36], show ongoing fragility disrupting chemotherapy regimens in U.S. hospitals and raising mortality risks.

#### **Regulatory Arbitrage**

 China's Speed: Startups can push to first-in-human far faster than in the U.S. But speed often comes from looser oversight, homogeneous patient cohorts, and outdated comparators. FDA rejections of drugs like surufatinib and sintilimab show the risks of relying on China-only data.

#### **Non-Market Distortions**

- China: Heavily subsidizes biotech with tax breaks, state-backed loans, and procurement preferences.
- U.S.: Firms face higher compliance costs and a distorted domestic market where PBMs, GPOs, and wholesalers capture margins
  instead of manufacturers.

# **Why It Matters**

China's dominance in biotech is not just an economic challenge — it threatens U.S. patients, raises prices, weakens national security, and risks shifting global innovation leadership to Beijing. The costs of inaction will be felt across every level of America's health system and economy.

#### **Public Health**

Shortages of antibiotics, cancer drugs, and blood pressure meds have already forced rationing in U.S. hospitals [41].

#### **Prices**

 Fragile supply chains = price spikes. Even decades-old generics soared when Puerto Rico's plants were hit by Hurricane Maria in 2017 [42], or when a 2016 factory explosion in China crippled global supplies of the antibiotic piperacillin-tazobactam, forcing rationing and treatment delays worldwide [43].

#### **National Security**

Pharmaceuticals are now strategic infrastructure. The Pentagon warns that dependence on China is a liability [37]; China previously
curtailed exports of essential medical goods during COVID-19 [38], raising concern it could use supply chains as strategic leverage.

#### **Innovation Leadership**

 Reliance on Chinese-origin compounds risks hollowing out U.S. biotech hubs like Kendall Square in Cambridge, Mass. Capital and talent could shift to Shanghai's Zhangjiang cluster.

# **Policy Agenda: Rebuilding U.S. Biotech**

China has treated biotech as strategic infrastructure, using subsidies, loose standards, and scale to build global dominance, while the U.S. let its production and research base erode. This dependence now threatens patients, prices, and national security.

Reversing course will take more than half-measures: America must rebuild manufacturing, enforce high trial standards, reinvest in research and talent, fix a distorted distribution system, and counter unfair competition. Only then can we secure medicine supply, protect patients, and ensure future cures are discovered and made in the United States.

#### I) Industrial Policy for Manufacturing

- Biopharma 'CHIPS' Act: Modeled on the semiconductor program, providing tax credits, concessional loans, and grants to build and
  modernize U.S. facilities for APIs, biologics, and sterile injectables, prioritizing resilient continuous-manufacturing plants.
- PILLS Act: Create direct incentives for U.S.-made generics and APIs, including tax offsets and federal purchasing preferences, to restore economic viability against subsidized Chinese competitors.
- Defense Production Act: Designate essential medicines and APIs as part of the defense industrial base, enabling priority contracts and rapid expansion of production during emergencies.
- Procurement Power: Direct federal purchasers (VA, DoD, HHS, Medicare) to preferentially source from U.S. producers or <u>trusted</u> regulatory partners, using long-term contracts to guarantee demand and justify new domestic investment.

#### II) Trials Without Shortcuts

- **FDA Resourcing:** Expand inspection capacity for foreign trial sites and manufacturing facilities; hire additional reviewers to oversee compliance abroad and modernize systems to shorten startup times.
- Adaptive Oversight: Use advanced analytics and real-world evidence to flag irregularities in overseas trials and improve riskbased targeting of inspections.
- Multi-Regional Standards: Mandate diverse cohorts and up-to-date comparators in all foreign data packages, and require
  enhanced verification of site quality and data integrity before approval.

#### III) Reinvest in Research and Talent

- Expand Grants: Reverse NIH stagnation by raising budgets in real terms and targeting more funds to early-stage research. This
  ensures university labs and independent investigators can pursue long-term discovery without being crowded out by short grant
  cycles and flat budgets.
- Support Startups: Direct a share of federal R&D dollars to research-focused biotech startups, not only to universities and large
  institutions. Provide matching grants, loan guarantees, and translational research funds to help early-stage firms bridge the gap
  between academic breakthroughs and market-ready therapies.
- Attract and Retain Global Talent: Keep U.S.-trained PhDs and postdocs in America with competitive fellowships, permanent
  research opportunities, and world-class lab infrastructure. Where appropriate, selectively recruit top foreign PhD researchers in
  biotech so the most advanced discoveries are made in the U.S., not abroad

#### **IV)** Trade and Competition Rules

- **National-Security Backstop:** Prepare Section 232-style actions for APIs and medicines that pose strategic risks due to shortages in U.S. production .
- Transparency: Mandate clear country-of-origin labeling for all pharmaceuticals and require FDA disclosure of API and
  intermediate sourcing. This will let hospitals, patients, and policymakers see where vulnerabilities lie and make informed
  purchasing decisions.

#### V) Fix the Middleman Problem

- **Cap Markups:** Limit Pharmacy Benefit Manager (PBM), wholesaler, and group purchasing organization (GPO) markups to 10% in federal programs. This prevents intermediaries from extracting excessive rents that raise costs without adding resilience.
- Antitrust Enforcement: Direct the FTC and Department of Justice to investigate how extreme concentration among PBMs and
  wholesalers allows them to dictate terms and extract artificial markups across the supply chain. Break up exclusionary
  contracting practices and restore competitive access so smaller U.S. manufacturers can supply hospitals and pharmacies without
  being shut out by dominant intermediaries.
- **Long-Term Contracts:** Use the Defense Production Act and federal purchasing power to establish multi-year, volume-certain contracts for critical generics. Stable demand signals reduce the risk for firms investing in U.S.-based facilities.

#### VI) Ethics and Data Security

- Smart Use of Foreign Data: Accept foreign trial data only if it is multi-regional, uses modern comparators, and passes independent verification of site quality and patient diversity. This protects against low-quality China-only studies being used as shortcuts to approval.
- Protect Patient Material: Prohibit the export of U.S. patient cells, genomic data, or biological samples to adversary countries
  without consent and traceability. Establish criminal penalties for unauthorized transfers, and strengthen federal oversight of
  partnerships involving sensitive biological material.

# What Success Looks Like by 2030

- Parity in clinical trial volume with China.
- Two or more non-Chinese suppliers for every essential API.
- U.S. trial startup times reduced by 6-12 months.
- Rising share of first-in-class licensing deals originating in the U.S.

Congress and agencies can track progress by requiring:

- Annual FDA reports on API source concentration.
- NIH budget benchmarks tied to inflation and global competition.

- GAO audits of federal procurement exposure to China.
- Public dashboards of shortages and supply resilience.

#### **Conclusion**

China has declared biotech a battlefield of the twenty-first century and has armed itself with subsidies, speed, and state power. The United States, by contrast, has treated medicine as just another commodity and is paying the price in dependence, shortages, and declining leadership. If we fail to act, the cures of tomorrow will not be invented or manufactured in Boston or San Diego, but in Beijing and Shanghai — and American patients, workers, and national security will all be hostage to a rival power.

But this outcome is not inevitable. With clear policy, bold investment, and the political will to rebuild, America can restore its biotech strength, secure its medicine supply, and remain the world's engine of medical innovation. The choice is urgent, and the stakes are nothing less than health, prosperity, and sovereignty.

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