



# The Future of U.S.–China Biotechnology Competition

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# The Current State of U.S.-China Biotechnology Competition

Imagine a world where the cutting edge of biopharmaceutical innovation no longer runs through San Francisco or Boston, but through Beijing and Shanghai. Where everyone from new startups to established multinational drugmakers prefers to position their research and development (R&D) pipeline in China over anywhere else in the world. In that scenario, high-skilled biotechnology jobs would migrate abroad, first-in-class therapies would reach Chinese patients first, and global supply chains for critical medicines would become increasingly shaped—and potentially constrained—by Beijing's regulatory and strategic priorities.

Although the United States has historically led in biotechnology, over the past 20 years China has systematically built a vertically integrated biotechnology ecosystem that is now in prime position to challenge U.S. leadership. In April 2025, the Commission came to a sobering conclusion: U.S. policymakers have a three-year window to retain, or in some cases regain, biotechnology leadership or risk ceding profound military, geopolitical, and economic advantages to China.

Since the publication of that assessment, the trajectory the Commission identified has continued—and in several respects intensified. Emerging evidence indicates that China is now surpassing

the United States in certain domains of biopharmaceutical innovation, marking a new inflection point in this great-power competition. Specifically, China is moving beyond copycat generic medicine manufacturing and is now driving a significant share of global biopharmaceutical innovation.<sup>1</sup> If the United States loses its primacy in biopharmaceutical innovation, it risks weakening the financial and intellectual engine that drives broader biotechnology leadership—undermining not only healthcare competitiveness but also strategic capabilities in agriculture, energy, and defense.

China's new competitive posture is propelled by strategy and policies implemented on top of a foundation of non-market practices and brute force economics. With this paper, the Commission will continue its analysis of the state of U.S.-China competition in biotechnology, documenting both the empirical evidence of China's emerging lead and the policy and investment mechanisms driving it. While the Commission previously identified a three-year window for decisive action, new evidence indicates that this window is closing far faster than anticipated, underscoring the urgency for an accelerated U.S. policy response.

<sup>\*</sup> Here, "brute force economics" refers to a set of policies designed to increase China's dominance in strategically important sectors, including biotechnology.

# China is Demonstrating That it Can Out-Innovate the U.S. in Biopharma

For much of the past few decades, China's biopharmaceutical industry was characterized by its fast-following nature and large-scale manufacturing—that is, replicating proven therapies, producing generic medicines at scale, and supplying lower-margin inputs into global pharmaceutical supply chains. The leading edge of biopharmaceutical innovation was predominantly driven by U.S. and European firms, as evidenced by new drug introductions.<sup>3</sup>

Over the past five years, however, the biopharmaceutical competitive landscape has shifted dramatically. China is no longer just following. In key areas, China is competing head-to-head with the United States and in some cases, pulling ahead. There is a recent trend of large multinational pharmaceutical firms turning to China for innovative drugs and paying millions, if not billions, of U.S. dollars to license the intellectual property (IP). These licensing deals involve a company obtaining the rights to develop, manufacture, or commercialize a drug from another company (often a smaller biotechnology firm) in exchange for upfront payments, milestone fees, and royalties on sales.

In 2022, only 5% of licensing deals with at least \$50 million in upfront payments went to Chinese companies. In just the first quarter of 2025, Chinese companies accounted for 42% of licensing deals over \$50 million.<sup>4</sup> In just three years, China's biopharmaceutical industry rose from near irrelevance to dominance. This massive increase in IP licensing deals is clear evidence that Chinese firms are generating globally competitive domestic biopharmaceutical innovation. Moreover, success in even a fraction of these candidates will result in considerable U.S. capital flowing into Chinese biopharmaceutical firms that could fuel compounding growth in other areas of biotechnology.

This overall innovation trend is set to accelerate, with Chinese drugs projected to account for 35% of U.S. Food and Drug Administration (FDA) approvals by 2040.<sup>5</sup> We no longer have to imagine a world in which China outperforms the United States in biopharmaceutical innovation. That world is already emerging.

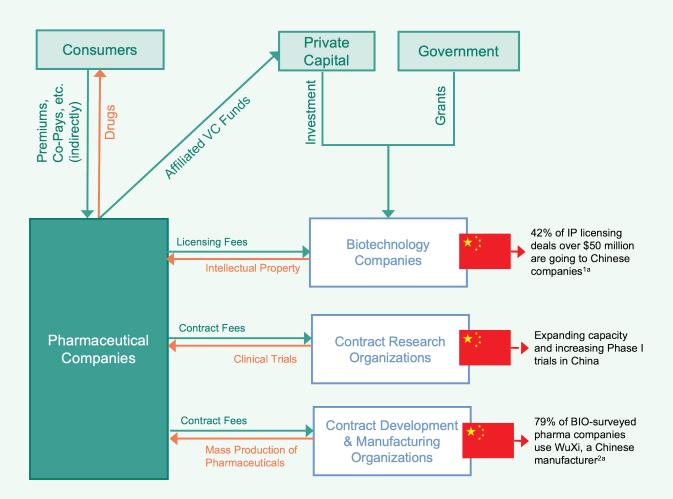


U.S. policymakers have a three-year window to retain, or in some cases regain, biotechnology leadership or risk ceding profound military, geopolitical, and economic advantages to China.

#### Figure 1.

## China is Capturing the Biopharmaceutical Value Chain

Building on a pre-existing advantage in biomanufacturing, Chinese firms are moving up the value chain in biopharmaceutical drug development, as evidenced by increasing clinical trial capacity and IP generation for multinational firms.



# China's Strategy to Usurp U.S. Biotechnology Leadership

China's ascension in biopharmaceutical innovation is due, in part, to deliberate government policies. Reforms to the nation's clinical trial system, the establishment of government guidance investment funds, and stronger coordination between early-stage research and commercial-scale manufacturing have accelerated China's emergence in

biotechnology. Moreover, these efforts build on the unfair advantages China has obtained from years of well-documented nonmarket practices and brute force economics.\*,6 In this paper, the Commission examines the specific policies that have positioned Chinese biotechnology firms to be globally competitive.

### A Warning for the Future

If the United States cedes biopharmaceutical innovation to China, the U.S. biotechnology industry will never look the same. Biopharmaceuticals represent the most profitable segment of the biotechnology industry, with high-profit-margin therapies that are overwhelmingly financed through the U.S. healthcare market. Those profits, generated predominantly by American consumers, create the reinvestment capacity that fuels basic science, venture capital (VC) activity, and the next generation of biotechnology startups.

This cycle creates a flywheel effect: revenues from breakthrough drugs sustain research infrastructure, attract top global talent, and underwrite future innovation in adjacent domains such as agricultural biotechnology, gene editing, and biomanufacturing. Surrendering this cycle to China would facilitate the decline of U.S. biotechnology leadership and provide unrivaled advantages to a foreign adversary.





China's overhaul of its clinical trial and drug regulatory system is central to its strategy to outpace the United States in biopharmaceutical innovation. Through targeted reforms to the nation's clinical trial processes, China has enabled biopharmaceutical companies to conduct faster and cheaper early-stage clinical trials. This, in turn, allows startups that perform their trials in China to obtain a strategic advantage over competing firms by reaching proof-of-concept earlier and thereby attract investor interest to scale and out-license other drugs. In addition to these reforms, China has built a regulatory landscape that further incentivizes domestic biopharmaceutical innovation that can compete on the global stage.

This paper outlines how the Chinese Communist Party (CCP) has re-engineered its regulatory landscape to accelerate domestic biopharmaceutical innovation, as well as the broader implications for U.S.-China biotechnology competition.

In a time when U.S. biotechnology startups are struggling, these regulatory reforms are propelling Chinese startups ahead of U.S. competitors toward investments, out-licensing deals with major pharmaceutical companies, and global success.<sup>9</sup>

## How China's Clinical Trial Reforms Have Fostered Innovation

Over the past decade, China has transformed its clinical trial regulations, shifting from one of the slowest approval systems in the world to one of the fastest, with reforms also improving quality and alignment with international standards. Historically, long approval backlogs and rigid requirements discouraged investment in innovative drug development in China. Beginning in 2015, the State Council launched comprehensive reforms to clear these bottlenecks and accelerate the development pipeline.

One of the most important changes was the introduction of an "implied approval" system for investigational new drug (IND) applications in 2018. Under this system, clinical trials can begin if China's National Medical Products Administration does not raise objections within a certain period, replacing the old, open-ended approval timelines that often stretched beyond a year.<sup>12</sup> In addition to China's efforts to streamline IND applications, the use of investigator-initiated trials (IITs)—trials initiated by clinical researchers for scientific research—has expanded in China to provide early safety and efficacy data and proof-of-concept for cutting-edge biopharmaceuticals.<sup>13</sup> Due to these regulatory shifts, the number of clinical trials launched in China has increased year after year.14

To further harmonize with international standards, China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017, of which the U.S. FDA was a founding member. These efforts have enabled the integration of Chinese sites into multi-regional clinical trials (MRCTs) at earlier stages, cutting redundancy and allowing Chinese patients earlier access to experimental therapies. In adherence to international standards set by ICH, China also began accepting foreign clinical trial data for new drug registrations when scientifically justified.

China's efforts to streamline and harmonize its clinical trial system have bolstered the nation's drug innovation ecosystem to be globally competitive with the United States. Compared to the United States, conducting clinical trials costs significantly less and launching Phase 1 clinical trials is far simpler and faster in China. Moreover, the expanded use of IITs, with numerous research institutions and large hospitals in China actively engaged, is providing early safety and efficacy data while avoiding the additional regulatory constraints of industry-sponsored trials (ISTs) in the country.

Due to China's improved clinical trial system, Chinese startups possess an inherent advantage in attracting investments and intellectual property licensing interest. Although, in theory, non-Chinese firms can also take advantage of China's faster and cheaper early-stage clinical trial processes, this is not reflected in reality. Only 14.3% of clinical trials in China were conducted by multinational firms in 2024; most of the trials were launched by domestic companies.<sup>20</sup> Although the percentage of clinical trials conducted by multinational firms has been increasing since 2019, China's clinical trial reforms are still mostly benefiting Chinese companies, as these firms are using results from early-stage trials as proof-of-concept for investors to scale up and out-license the drug.21

The evidence is in the numbers. Last year, China surpassed the United States in drug clinical trials, marking a turning point in the global race for biopharmaceutical innovation. In 2024, China listed more than 7,100 clinical trials in the World Health Organization's International Clinical Trials Registry Platform. The United States listed about 6,000 trials.<sup>22</sup> This rise in clinical trial activity corresponds to a rise of biopharmaceutical out-licensing. In the first half of 2025 alone, U.S. pharmaceutical companies signed licensing deals worth roughly \$18.3 billion from China-based companies.<sup>23</sup>

# How China Compounds Regulatory Reforms to Accelerate Domestic Innovation

In addition to reforms to clinical trial processes, in 2015, China's State Council amended definitions of innovative drugs and introduced reforms to accelerate the review and approval of innovative drugs to market, thus incentivizing domestic biopharmaceutical innovation. The definition of innovative drugs was amended from "drugs not previously introduced to the Chinese market" to "drugs not yet introduced to the global market."24 In doing so, China incentivized domestic entities to develop biopharmaceutical products that can compete globally.<sup>25</sup> Moreover, a special review system was implemented to expedite the approval of innovative drugs.<sup>26</sup> As a result, from 2019 to 2023, the number of approved innovative drugs by China's National Medical Products Administration (NMPA) increased from 20 to 66.27

Recent changes to China's marketing policies have alleviated the regulatory barriers between biopharmaceutical discovery and manufacturing and will accelerate the impact of China's clinical trial reforms on domestic biopharmaceutical innovation. China's 2019 Drug Administration Law rolled out the nationwide Marketing Authorization Holder (MAH) system, decoupling marketing authorization from factory ownership.<sup>28</sup> By allowing R&D-focused companies to outsource manufacturing to qualified contract facilities, MAH lowered capital intensity and let Chinese biopharmaceutical firms specialize in discovery, clinical development, and partnering—capabilities essential to compete with global peers.<sup>29</sup>

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# China's Rise Threatens U.S. Competitiveness

China's recent regulatory reforms have reshaped its role in global drug development by cutting timelines and costs while bolstering domestic innovation. U.S. investors are taking notice. For example, in a March 2025 biopharma market update report by investment banking company Stifel, investors noted that China's biopharmaceutical ecosystem is increasingly innovative and a "buyers market," given the scale of available pipeline.30 With a conducive regulatory environment in place, current trendlines point to China becoming the leading source of new drug discovery within the next decade. If it does, the U.S. startup and clinical-stage biopharmaceutical ecosystem that has historically supplied the pipelines of major pharmaceutical companies will be cannibalized by Chinese firms.<sup>31</sup> Ceding this vast preclinical and clinical-stage infrastructure and human capital to China would diminish U.S. capabilities in early drug development and create a growing strategic dependency on Chinese-originated innovation, leaving U.S. biopharmaceutical progress more vulnerable to the geopolitical objectives of the CCP.

The Commission has also heard from stakeholders who expressed concern that performing clinical trials in China may not only erode our domestic trial infrastructure but increase U.S. firms' exposure to IP theft, data leakage, or copycat activity. One stakeholder expressed that for every innovative U.S. biotechnology firm, there is a "shadow" Chinese firm working to replicate its work at a lower cost. Commission staff could not independently verify these assertions, but they may warrant further study by the Government Accountability Office (GAO) or FDA Inspector General.

The shift in biopharmaceutical competitiveness lends even more urgency to the need for U.S. policymakers to revisit and reconsider strategic reforms to biopharmaceutical regulation. Should the United States cede its global leadership in biopharmaceuticals, the nation will lose the engine that underpins broader U.S. competitiveness in biotechnology.



For hard technologies, such as biotechnology, the pathway to commercialization can be expensive and time-consuming. Overly complicated regulatory processes, limited pre-commercial scale infrastructure, and an uncertain market increase risk for private sector investments in biotechnology. Emerging biotechnologies are not moving efficiently from lab to market, and without targeted policy catalysts to de-risk private capital, the commercial market will not produce a biotechnology sector that addresses broad U.S. national security needs.

The Chinese government, by contrast, has adopted innovation policies that channel capital into biotechnology as a strategic industry and address key barriers that impede the transition of early-stage technologies into commercial products. While these policies are generally viewed as fair and legitimate, they operate alongside—and are reinforced by—China's long-standing predatory

nonmarket practices and brute force economic tactics. Since April 2025, the Commission has continued to hear from U.S. stakeholders, especially biotechnology founders and investors, about unabated IP theft, copycat activity, and artificially low prices that allow Chinese companies to undercut their U.S. competitors. Together, these approaches allow China to exploit U.S. market failures and accelerate its progress in this critical technology sector.

Using 3SBio as a case study, this paper analyzes China's policy tools, demonstrates how they generate sustained advantages for Chinese biopharmaceutical companies, and outlines the implications for U.S.—China competition in advanced biomanufacturing. The cumulative analysis shows how China's state-designed financing architecture and commercialization strategies are widening the innovation gap, underscoring the urgency of U.S. policy intervention.



China has made biotechnology and biomanufacturing a strategic priority for the past 20 years, dedicating a variety of industrial policy tools toward scaling this critical industry.<sup>32</sup> China's approach to industrial policy is also evolving as Beijing experiments with new financing mechanisms that combine "market operations and government steerage."33 For example, as early as 2002, China leveraged public-private VC funds known as government guidance funds (GGFs) to provide patient capital for the scale-up of emerging technologies like biotechnology, which can have longer time horizons for return on investment (ROI).34 Over the past decade, these government guidance funds have channeled almost \$1 trillion into strategic technology industries, with government investments attracting additional investments from private VC and compounding their impact.35

By 2020, Chinese officials had established over 1,500 GGFs, with a registered target size of \$1.55 trillion.<sup>36</sup> Some GGFs explicitly invest in biotechnology, such as the Shanghai Biomedicine M&A Fund, while other funds broadly invest in strategic emerging industries, such as the National Fund for Technology Transfer and Commercialization.<sup>37</sup>



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Since at least 2016, the CCP has pursued a policy of technology-driven development, viewing technological progress as fundamental to economic prosperity. Key to this effort, the CCP has pursued policies that connect a technology from invention to commercialization, also known as the "innovation chain." China has been building an innovation-driven system by focusing resources not just on research and development (R&D), but on fortifying supply chains and fostering the broader ecosystems needed to carry new technologies from the lab to market.

China has established innovation clusters that physically co-locate research institutes, regulatory authorities, and industrial-scale manufacturing

within the same geographic area. This co-location catalyzes collaboration across laboratory research, pilot testing, and mass production. According to the U.S.-China Economic and Security Review Commission's (USCC) 2025 report, "Chinese scientists and lab technicians appear increasingly convinced that innovation accelerates when R&D and production are co-located [in biotechnology]."<sup>41</sup>

The Commission has also heard from stakeholders that Chinese government policies incentivize the rapid construction of manufacturing facilities through measures such as expedited permitting and accelerated depreciation tax policies of fixed assets.

#### Case Study

## How 3SBio Became a Globally Competitive Biopharmaceutical Company

In July 2025, 3SBio marked a major milestone for China's biopharmaceutical industry by clinching one of the largest biopharmaceutical licensing deals ever for a single drug. ASCEB staff examined the innovation policies behind 3SBio's success and found that 3SBio benefited from public-private capital flows that supported the company's scaling and expansion. Moreover, the company's location in Shenyang offered strategic advantages by co-locating early-stage research with supply chain inputs and manufacturing.



#### Case Study Continued

### How Coordinated State and Market Capital Propelled 3SBio

3SBio provides an illustrative case study on how China propels innovation in biotechnology with mutually reinforcing channels of state-directed and private investment. First, the company received direct government support that subsidized facilities, equipment, and other infrastructure, thereby lowering the cost of capital investment. 3SBio's 2020 annual statement notes that the company received government grants to support the purchases of property, facilities, and equipment in recognition of its "contribution to the development of the local pharmaceutical industry."43 According to local reporting in 2024 on public investments in technology innovation in Liaoning, 3SBio is explicitly named as a leading biopharmaceutical company with substantial production capacity, with the implication that the company is a recipient of provincial support.44

At the same time, 3SBio was involved in the establishment of the provincial-level biotechnology GGF and appears to have had privileged access to public-private capital pools that could be used to lower the financing risk for emerging projects, channel additional investment into the company's local ecosystem, and align the company's growth trajectory with provincial industry policy. Both 3SBio and its subsidiary have established investment funds and private equity infrastructure, not just as investors (limited partners, or LPs) but also as fund managers (general partners, or GPs). 45,46 In 2017, 3SBio's subsidiary also contributed a large portion of investment to the biotechnology-specific GGF, established by the Liaoning **Provincial Development and Reform Commission** with additional funding from the provincial-level GGF.<sup>47</sup> The same commission then announced that 3SBio's subsidiary was selected as a recipient for investment in 2018 for a construction project.<sup>48</sup> Although official reporting does not explicitly link the subsidiary's role in founding the GGF to its subsequent selection for funding, the timing suggests a privileged position in securing provincial support and investments.

### How Shenyang's Innovation Ecosystem Fostered 3SBio

3SBio's success also reflects the strategic advantages of its location in Shenyang. The city has become a model for how local governments operationalize China's "innovation chain" strategy and translate early-stage research into commercial success. Local officials have prioritized biopharmaceuticals as a strategic industry, channeling resources into both laboratory construction and manufacturing capacity via state-backed financing mechanisms in order to connect research with production capacity inside a single region.<sup>49</sup> In fact, in local reporting, Shenyang has implemented a "chain leader system" for biopharmaceuticals, a strategy of industrial development that connects early-stage research with supply chain management and manufacturing in order to effectively move biotechnology innovations from lab to market.<sup>50</sup> Located in Shenyang's highly productive Economic and Technology Development Zone, 3SBio was able to scale up its operations, navigate regulatory processes, and begin mass production within a highly coordinated regional innovation ecosystem.51





# The Innovation Gap Will Widen Without U.S. Policy Action

China's innovation policies are effectively accelerating its biotechnology industry and positioning the nation to surpass the United States. China is combining public investments with mechanisms that mobilize private capital to accelerate commercial readiness in emerging biotechnologies. Moreover, with targeted innovation policies that link research, pilot-scale capabilities, and manufacturing within single regions, China is ensuring its biotechnology companies can overcome key commercialization barriers.

These ideas are not new. In fact, the Commision proposed a suite of policy recommendations to address these very issues in the United States in its <u>April 2025 report</u>. The alarming success of 3SBio and other Chinese biopharmaceutical firms are heightening the urgency for U.S. policy action now. Success at the biopharmaceutical

frontier fuels the talent, financing, and technical know-how that spill over into other biotechnology verticals.

In what the USCC describes as "interlocking innovation flywheels," China's innovation gains in the biopharmaceutical sector will soon reverberate across its pre-existing investments in biomanufacturing. With recent announcements by China's Ministry of Industry and Information Technology (MIIT) and National Development and Reform Commission (NDRC) to significantly expand the nation's pilot-scale biomanufacturing capacity, China's innovation trajectory in biotechnology could soon outpace the United States. Unless the U.S. government adopts the necessary policies to catalyze its own domestic biotechnology industry, China's competitive edge in biopharmaceuticals may soon expand into an unsurmountable lead.

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