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July 17, 2026

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

Dear Ms. Barton,

Thank you for the opportunity to provide a written submission in response to U.S. International Trade Commission Investigation Number 332-610, Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector. This submission from the Biotechnology Innovation Organization (BIO) does not contain confidential business information.

Please let us know if you have any questions regarding BIO's submission.

Sincerely,

/s/ Kelly M. Seagraves

Kelly M. Seagraves, PhD
Vice President, National Security and International Affairs
Biotechnology Innovation Organization

The Biotechnology Innovation Organization's comments on the U.S. International Trade Commission's investigation "Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector" (Inv. No. 332-610)

1. Introduction

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the U.S. International Trade Commission's (USITC) fact-finding investigation, "Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector," Investigation No. 332-610. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 35 other nations.

BIO views this investigation as an important opportunity to examine the factors that support global biotechnology leadership and to identify policy actions that will ensure the U.S. remains the world's leading destination for innovation. Through our comments BIO aims to help describe the current biotechnology competition landscape around innovative medicines, as well as steps the American ecosystem should take to remain competitive.

The U.S. has long been the global leader in biotechnology, driven by world-class research institutions, entrepreneurial companies, strong intellectual property (IP) protections, deep capital markets, and a science-based regulatory system. These strengths have enabled biotechnology companies to discover and develop groundbreaking therapies, create high-quality jobs, attract private investment, and improve the lives of patients around the world. As biotechnology becomes increasingly important to economic growth, public health, and national security, countries around the world are investing aggressively to expand their biotechnology capabilities. For example, China is investing at unprecedented speed and scale, with a coordinated national strategy to dominate biotechnology and biomanufacturing. The U.S. should not only assess the actions of competitors, but focus on strengthening the policies, infrastructure, and incentives that allow American innovators to discover, develop, manufacture, and deliver the next generation of medicines.

The U.S. possesses the scientific talent, innovative companies, academic institutions, and entrepreneurial culture necessary to lead the next generation of biotechnology breakthroughs. With targeted policy actions that support innovation, investment, manufacturing, workforce development, and regulatory efficiency, America can continue to set the global standard for biotechnology and deliver new therapies, economic growth, and health security for decades to come. BIO's comments largely focus on the steps policymakers can take to ensure the U.S. remains the global leader in biotechnology innovation, clinical development, manufacturing, and commercialization.

2. America's biotechnology ecosystem is a strategic competitive advantage

The U.S. biotechnology industry is one of the nation's greatest competitive strengths, comprising roughly 3,000 companies ranging from early-stage startups to global enterprises. Together, these organizations transform scientific discoveries into life-changing medicines and therapies, driving innovation across critical therapeutic areas. The industry is also a major contributor to economic growth, supporting millions of high-quality jobs across research, advanced manufacturing, supply chains, engineering, data science, and logistics. As the global biotechnology market continues to expand, U.S. companies remain the world's leading innovators and are well-positioned to drive the next generation of scientific breakthroughs.

American biotechnology leadership delivers significant benefits to patients, public health, and the economy. U.S. companies continue to develop novel therapies that address unmet medical needs, improve outcomes, and expand treatment options for patients facing serious diseases. The U.S. remains the preferred destination for biomedical innovation because of its world-class research institutions, strong IP protections, entrepreneurial culture, and science-based regulatory system. U.S. policies that support biotechnology innovation help ensure that breakthrough discoveries continue to be developed, manufactured, and commercialized in the United States.

A strong biotechnology ecosystem is also essential to America's national resilience and security. Domestic biotechnology capabilities support access to innovative medicines, strengthen preparedness for future public health challenges, bolster advanced manufacturing, and enhance supply chain resilience. Maintaining U.S. leadership will require policies that encourage innovation, modernize clinical development, strengthen domestic manufacturing, develop a highly skilled workforce, protect IP, and enable companies of all sizes to grow and compete in U.S. and global markets. Many of these issues can be addressed by domestic policymakers, and many may also benefit from coordination with trusted international partners to reduce global reliance on strategic competitors. By building on these strengths, policymakers can ensure that the next generation of therapies, investment, and high-quality jobs is created in the United States.

Sustaining U.S. leadership requires a comprehensive competitiveness agenda. The U.S. remains the global leader in biotechnology because of a unique combination of scientific excellence, entrepreneurial innovation, strong IP protections, investment capital, advanced research institutions, and a trusted regulatory system. As global competition intensifies, maintaining this leadership will require a coordinated policy agenda focused on strengthening the foundations of the American biotechnology ecosystem and ensuring markets are available to sell U.S. biotechnology innovations.

This submission notes recent comparative trends between China's biotech ecosystem relative to the U.S.', and also suggests how U.S. biotechnology competitiveness can be improved across three core areas:

- Regulatory excellence and clinical development. Policies that improve regulatory predictability, reduce unnecessary administrative burdens, accelerate clinical development, and support the adoption of innovative scientific approaches will strengthen America's position as the preferred destination for biomedical innovation.
- Domestic capacity, talent, and infrastructure. America's biotechnology leadership depends on a strong foundation of domestic manufacturing, skilled talent, modern infrastructure, and access to capital that enables innovative companies to develop and commercialize new therapies in the United States. Strategic investments in biomanufacturing capacity, workforce development, infrastructure, and innovation ecosystems will strengthen competitiveness, enhance supply chain resilience, and support long-term economic growth.
- IP and innovation protection: Strong IP protections are fundamental to biotechnology innovation. Policies that protect IP, strengthen technology transfer, safeguard trade secrets, and encourage long-term investment in research and development (R&D) are essential to maintaining U.S. leadership.

Together, these key areas provide the foundation for a biotechnology ecosystem that delivers breakthrough therapies, creates high-quality jobs, strengthens national security, and ensures that the next generation of biotechnology innovation is developed and manufactured in the U.S.

3. Recent trends that highlight shifts in China's biotech ecosystem relative to the U.S.

Providing even more impetus for U.S. action, China's biotechnology ecosystem has been innovating in medicines for years, gaining ground on the U.S. ecosystem. Historically, China's government provides advantages to its biotechnology ecosystem with intentionality. The People's Republic of China (PRC) has engaged in a decades-long effort to pivot from a generics-focused pharmaceutical market to an innovation-driven biotechnology market. China set national goals and is building an environment to enable the achievement of those goals. From 2005 to 2022, PRC national regulatory authorities issued a total of 38 major policy documents to promote the biopharmaceutical industry and R&D.[1] The Made in China 2025 industrial strategy, released in 2015, China's 13th Five-Year Plan (2016-2020), and successive Five-Year Plans clearly signal China's intention to

[1] Junnan Shi et al., "The evolving regulatory system of advanced therapy medicinal products in China: a documentary analysis using the World Health Organization Global Benchmarking Tool standards," Cytotherapy 26, no. 8. (2024), https://www.isct-cytotherapy.org/article/S1465-3249(24)00682-0/abstract.

be a biopharma world leader. The PRC's March 2026 outline for the 15th Five-Year Plan further lays out its ambitions to be a global leader in biotechnology.[2]

There are several indicators of China's progress in innovative biotechnology medicines – for example, China is now the world's second-largest source of new drug candidates – and the Chinese ecosystem's progress has been buoyed in large part by PRC policy interventions.[3] Additional indicators of China's competitiveness in innovative medicines biotechnology include:

Drug approvals

- Drugs originating in China are projected to account for 35% of U.S. Food and Drug Administration (FDA) approvals by 2040.[4]
- From 2019 to 2023, the number of approved innovative drugs by China's National Medical Products Administration (NMPA) increased from 20 to 66.[5]
- In 2023, the PRC approved 33 more novel drugs than the United States.[6]
- In 2024, the NMPA's average review time was 105 days and it approved 83 new drugs while the FDA's was 356 days and it approved 50 new drugs.[7]

Clinical trials

- The PRC became the top location for clinical research in 2021 with about 29 percent of new global clinical trials involving China.[8] [9]

[2] Ruirong Tan et al., "Current landscape of innovative drug development and regulatory support in China," Signal Transduction and Targeted Therapy 10, no. 220 (2025), https://www.nature.com/articles/s41392-025-02267-y.
[3] Meghan Ostertag, "Fact of the Week: China Is the Source of 30 Percent of New Innovative Drugs Produced Globally," Information Technology and Innovation Foundation, May 4, 2026, https://itif.org/publications/2026/05/04/china-source-30-percent-new-innovative-drugs-produced-globally/.
[4] National Security Commission on Emerging Biotechnology, "The Future of U.S.–China Biotechnology Competition" (Washington, DC: The Future of U.S.–China Biotechnology Competition, 2025), 4, https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf.
[5] Ibid, 9.
[6] Juan Valencia S. and Angel Shao, "China's New Drug Approvals Again Hit Record High in 2024," DIA Global Forum 18, no. 6 (2026), https://globalforum.diaglobal.org/issue/march-2025/chinas-new-drug-approvals-again-hit-record-high-in-2024/.
[7] Yanzhong Huang, "A Biopharmaceutical Superpower: China's Rise, Its Limits, and What Comes Next," Center for International Relations and Sustainable Development, accessed July 15, 2026, https://cirsd.org/horizon-article/a-biopharmaceutical-superpower-chinas-rise-its-limits-and-what-comes-next/.
[8] Spe Chen, "China Drugmakers Catching Up to US Big Pharma With New Medicine Innovation," Bloomberg News, July 13, 2025, https://www.bloomberg.com/authors/AV33fniD9Gc/spe-chen.
[9] Alexander Brown and Jeoren Groenewegen-Lau, "Lab leader, market ascender: China's rise in biotechnology," (Berlin: Mercator Institute for China Studies, April 24, 2025), https://merics.org/en/report/lab-leader-market-ascender-chinas-rise-biotechnology.

- In 2024, China listed more than 7,100 clinical trials in the World Health Organization's (WHO) International Clinical Trials Registry Platform. The United States listed about 6,000 trials.[10]

Drug candidates

- About 25 percent of innovative drug candidates under active development originate from China, and about 46 percent of new drug molecules which began human trials in the first half of 2025 are from PRC companies.[11]
- In 2023, China made up 23 percent of the global pipeline of innovative drug candidates compared to 36 percent for the U.S. In 2025, China accounted for 30.5 percent compared to 33 percent for the U.S.[12]
- PRC drugs now account for 48 percent of bispecific monoclonal antibodies (mAbs) in development, and 48 percent of Chimeric Antigen Receptor T-cell (CAR-T) therapies in development.[13]
- PRC companies have a substantial lead in antibody-drug conjugate (ADC) development, accounting for 51 percent of ADCs in development. PRC firms make up half of the ten largest ADC developers worldwide (by active pipeline ADC count).[14] [15]

Licensing

- In 2025, Chinese biotechs generated $135.7 billion in license-out transaction value, compared to $51.9 billion in 2024.[16]
- 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.[17]

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[10] National Security Commission on Emerging Biotechnology, The Future of U.S.-China Biotechnology Competition, 8.
[11] Goldman Sachs, "China Is Increasing Its Share of Global Drug Development," December 17, 2025, https://www.goldmansachs.com/insights/articles/china-is-increasing-its-share-of-global-drug-development.
[12] Lee Hyo Jung, "China's Biotech Pipeline Nears U.S. Share, Driving Big Pharma and Korean Partnerships," Aju Press, April 14, 2026, https://www.ajupress.com/view/20260414083070128.
[13] Kelly Bilodeau, "Can China sustain a surge in oncology drug innovation?," PharmaVoice, July 2, 2025, https://www.pharmavoice.com/news/china-cancer-oncology-akeso-merck-keytruda/752097/.
[14] Ibid.
[15] Pharmaceutical Technology, "Chinese companies lead ADC pipeline," May 1, 2024, https://www.pharmaceutical-technology.com/analyst-comment/adc-chinese-companies-pipeline/?cf-view.
[16] Julie Zhang, "Chinese drug makers strike a record US$136 billion in out-licensing deals in 2025," South China Morning Post, January 8, 2026, https://www.scmp.com/business/china-business/article/3339011/chinese-drug-makers-strike-record-us136-billion-out-licensing-deals-2025.
[17] National Security Commission on Emerging Biotechnology, The Future of U.S.-China Biotechnology Competition, 4.

Moreover, one team comprehensively studied new experimental medicines tested in clinical settings between 2000 and 2025, analyzing more than 17,000 different drugs, biologics, and biologicals to identify the organizations responsible for the development of each.[18] When national contributions were compared on an annual basis, China had not only surpassed the collective output of Europe and the rest of Asia, but gained parity with the United States. The growth occurred almost entirely over the past decade. As an example, China's output in terms of new drug discovery had increased from about 30 new medicines in 2013 to more than 400 a decade later. Output by American sources has remained comparatively flat since 2018, while China's contributions nearly tripled in that same period.

China is also taking action to advance its basic and translational research infrastructure, including providing ample research grants that fuel innovation at universities and other research institutions. Without a similarly robust innovation pipeline in part supported by strong and predictable U.S. government funding, ex-U.S. scientific discoveries will be used to support drug development more regularly.

All of this should contribute to motivating the U.S. to take coordinated action to advance the country's competitiveness in biotechnology.

4. The U.S. must take concerted actions to advance its biotechnology ecosystem and outcompete China

a. Modernizing the clinical trial ecosystem will strengthen U.S. biotechnology leadership

Compared to the United States, conducting clinical trials costs significantly less and launching Phase 1 clinical trials is far simpler and faster in China.[19] Over the past few years China has made reforms to their clinical trial system to make it significantly more efficient while maintaining quality. For innovative biotech companies where time is money, they are turning to the Chinese clinical trial system for early "first in human" trials, because proving the concept quickly and then repeating trials elsewhere is more cost effective overall. Numerous factors contribute to this increased efficiency including streamlined workflows, a dense contract research organization (CRO) ecosystem, talent pool, and government support, including expanding the number of NMPA reviewers from 200 in 2017 to 1,300 in 2024, and recent changes within China's regulatory review process such as the introduction of an "implied approval" system for investigational new drug (IND)

[18] Michael Kinch and Kevin Gardner, "We crunched the numbers on drug discovery in the U.S. vs. China. The results were alarming," Stat News, December 16, 2025, https://www.statnews.com/2025/12/16/china-drug-discovery-us-leadership-falling/.

[19] Seamus Grims and Marcela Miozzo, "Big Pharma's Internationalization of R&D to China," European Planning Studies 23, no. 9 (2015), https://www.tandfonline.com/doi/full/10.1080/09654313.2015.1029442.

applications in 2018.[20] Under this system, clinical trials can begin if China's NMPA does not raise objections within a certain period, replacing the old, open-ended approval timelines that often stretched beyond a year. The U.S. FDA already had and continues to implement a 30-day IND review process which has a similar premise.

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.[21] Due to these deliberate actions, the number of clinical trials launched in China has increased year after year.

The integration of Chinese sites into multi-regional clinical trials (MRCTs) at earlier stages was further enabled when China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017, of which the U.S. FDA is a founding member.[22] These efforts contributed to 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.

To maintain global competitiveness, the efficiency of the U.S. clinical trial ecosystem needs to be improved upon. The Department of Health and Human Services' (HHS) recent announcement of Operation Trialblazer is a step in the right direction.[23] This effort includes a range of actions intended to accelerate and modernize drug development in the U.S. Early-stage drug development is the mechanism through which laboratory discoveries become next-generation medicines for patients in need, and Operation Trialblazer takes important steps toward protecting America's global leadership in scientific advancement. Additional steps to reduce the cost and complexity of early drug development in America should also be taken, as outlined in the Reagan-Udall Foundation report "Enhancing Early-Stage Drug Development in the United States."[24] In brief, the measures are:

Modernizing IND Requirements and Processes

- Adopt risk-proportionate IND submission requirements and triage review processes.
- Advance rolling IND submissions.

[20] Reagan-Udall Foundation for the FDA, "Enhancing Early – Stage Drug Development in the United States," (Washington, DC: Reagan-Udall Foundation for the FDA, June 2026), 7, https://www.reaganudall.org/sites/default/files/2026-06/Enhancing%20Early-Stage%20Drug%20Development%20in%20the%20US_1.pdf.

[21] National Security Commission on Emerging Biotechnology, The Future of U.S.-China Biotechnology Competition.

[22] Ibid.

[23] U.S. Department of Health and Human Services, "HHS Launches Unprecedented Department-Wide Effort to Restore American Leadership in Clinical Trials," June 22, 2026, https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.

[24] Reagan-Udall Foundation for the FDA, "Enhancing Early – Stage Drug Development in the United States."

- Modernize nonclinical requirements and practices.
- Update and streamline chemistry, manufacturing, and controls (CMC) requirements.
- Clarify required and presumed-required IND data.
- Improve safe-to-proceed and clinical hold communications.
- Enable a Phase 1 Clinical Trial Notification pathway.

Modernizing Phase 1 Clinical Trials and Tools

- Support greater use of innovative clinical trial designs.
- Increase inclusion of patient perspectives in early-stage drug development.
- Develop artificial intelligence (AI)-enabled sponsor-facing decision support tools.

Optimizing FDA–Sponsor Early-Stage Engagements and Processes

- Enhance pre-IND meeting and IND review best practices.
- Capture IND regulatory decision-making trends.
- Incentivize fit-for-purpose IND submissions and engagements.

Building a Streamlined and Dedicated U.S. Phase 1 Infrastructure as part of a National Clinical Trial Infrastructure and Coordinating Strategy

- Build and fund a dedicated network of Phase 1-capable clinical trial sites.
- Create a national Phase 1 coordinating strategy.
- Streamline Institutional Review Board (IRB) and site activation processes.

Mitigating Litigation Risk for Phase 1 Clinical Trial Sites

- Explore safe harbors and insurance reforms for First-in-Human (FIH) and Phase 1 trials.

Having a well-staffed FDA is also an important aspect of an efficient clinical trial ecosystem, with the capacity and technical expertise to work in partnership with the biotechnology industry to ensure that world-class treatments to patients.

b. Expanding the capacity, talent, and infrastructure needed for U.S. biotechnology leadership

America's biotechnology leadership depends on more than scientific innovation alone. Sustaining competitiveness requires a strong domestic foundation that enables companies to discover, develop, and manufacture breakthrough therapies in the U.S.

Investments in biomanufacturing capacity, workforce development, infrastructure, and targeted incentives can help ensure that the U.S. remains the preferred location for biotechnology innovation and commercialization. As the industry continues to grow, policymakers should focus on strengthening the physical, human, and financial resources that support long-term biotechnology leadership.

Growth of the biotech manufacturing ecosystem is critical in the United States, and contract manufacturing organizations are a key part of this. The journey from discovery to FDA approval is long and costly—typically spanning 10 to 15 years and requiring nearly $1 billion in investment. Out of every 10,000 compounds that enter the discovery phase, only one will make it through to approval, highlighting the immense scientific and financial hurdles involved. To navigate this demanding landscape, biotech companies increasingly rely on contract manufacturers. These strategic partners provide the physical infrastructure, expertise, and regulatory know-how needed to develop and manufacture complex therapies. Contract manufacturers support every stage of product lifecycle—from early research and clinical trials to commercial-scale production—allowing biotech firms to focus on innovation without having to build costly facilities or hire specialized staff. Their role is especially critical for small to mid-size companies that lack the resources to build and manage in-house manufacturing capabilities.

While U.S. companies want to be able to use contract manufacturing services in the United States, they regularly find it difficult to identify adequate capacity and capabilities, particularly for smaller volume and more advanced product types. This forces U.S. companies to turn to ex-U.S. service providers, often in China or in Europe. A 2024 BIO survey found that 79% of biopharma companies had at least one contract or product with a China-based or China-owned contract development and manufacturing organization (CDMO)/CMO, and they'll need up to eight years to switch manufacturing partners—or millions of patients could be affected.[25] The survey covers a broad cross-section of the industry: 124 unique biopharma and biotech companies—large, medium, and small, as well as pre-clinical companies and companies with products in clinical development. More than two-thirds (68%) of these companies are small, emerging companies with fewer than 250 employees.

American biotechnology companies of all sizes want to take part in the Trump Administration's drive to bring research, development, and manufacturing back to America. Since January 2025, close to half a trillion dollars has been committed to U.S. manufacturing from the biotech industry—driven mainly by larger, multi-national companies. But for smaller biotechnology companies to also take part, there must be sufficient contract manufacturing capacity within the United States. As service providers, contract manufacturers are not well positioned to quickly scale up without support. Infrastructure and supply chain investment, financial incentives, and workforce

[25] Biotechnology Innovation Organization, "BIO survey reveals dependence on Chinese biomanufacturing," May 9, 2024, https://www.bio.org/bio-news/bio-survey-reveals-dependence-chinese-biomanufacturing.

development programs are critical areas where government can assist. Success means American biotechnology companies choosing American-based contract manufacturers for developing new products and shifting existing product manufacturing back onshore. Interim success, that is until the United States builds sufficient domestic capacity, means reducing reliance on Chinese contract manufacturing by working with trusted partners where capacity already exists and to support specialized training of the U.S. workforce.

Supporting U.S. contract manufacturers for biotechnology products is not just a strategic choice—it's a national imperative. A strong contract manufacturing ecosystem directly correlates to a strong biotechnology ecosystem—creating high-quality American jobs, driving exports that fuel economic growth, and securing our health supply chains to ensure that Americans have access to critical medicines when they need them.

Targeted incentives—tax, capital, and IP benefits—will help small and mid-sized firms, and their contract manufacturers, build the infrastructure needed to bring production back to the U.S. BIO respectfully offers the following recommendations for supporting a robust U.S. contract manufacturing ecosystem, thereby strengthening and reinforcing US leadership in biotech innovation.

First, to enable mechanisms like effective technology transfer policies, translational programs, and commercial incentives to accelerate the path from laboratory to market in biotechnology with maximal impact, federal oversight and coordination must be established.

- Create a formal mechanism in the Federal government for oversight and to coordinate these efforts across HHS, Department of Defense (DoD), Department of Commerce (DoC), and others (e.g., an interagency task force or a National Biomanufacturing Strategy Office). Without central leadership, implementation of these recommendations risks duplication or gaps. A national strategy could provide policy directives and position biotechnology manufacturing as critical infrastructure. A dedicated coordinating body ensures accountability and maximizes the return on federal investment. This coordinating body could also provide benchmarking against global competitors.

Transferring technology to the U.S. should be incentivized, specifically for biotechnology.

- Provide incentives for biotech companies to choose U.S. contract manufacturers or move existing contract pipelines to the U.S. Incentives could include targeted tax credits for the incremental costs of transferring technology from one facility to another, access to other forms of capital, patent term extensions, additional exclusivity, federal procurement commitments, etc. Technology transfers between facilities, including from international facilities to the U.S., require significant spend, such as on production batches, equipment upgrades, labor, validation, and

regulatory documentation. Incentives reduce barriers to commercialization, encourage U.S. domestic scaling, and derisk capital commitment from investors.

Translational programs for biotechnology that leverage government guarantees to attract private investment and reward technology adoption and innovative facilities should be launched.

- Expand government-backed grant and credit tool programs tailored to biotechnology manufacturing projects. These could include structures like credit guarantees, flexible/convertible loan instruments, specialized mechanisms (e.g. U.S. International Development Finance Corporation (DFC)/Defense Production Act (DPA), etc. Biomanufacturing requires significant upfront investment. Federal guarantees reduce capital costs, attract private investment, and accelerate growth in this strategic sector.
- Provide funding and tax incentives for adoption of advanced technologies (e.g. continuous processing, AI-driven quality systems) and support direct funding for pilot-scale (i.e. low production volume) facilities in emerging modalities such as cell and gene therapy or mRNA. Cutting-edge technologies and early-scale capacity are essential for efficient production and rapid translation of scientific breakthroughs. Public support builds resilience and positions the U.S. as a global leader.

A series of commercial incentives would supercharge the biotechnology ecosystem.

- Incentivize Servicing Low-Volume Contracts. Apply preferential tax rates for contract manufacturers serving low-volume contracts or orphan sponsors. Implement accelerated depreciation for qualifying capital expenditures and expand interest deductibility for biotech infrastructure investments. These policies reduce cost barriers, improve cash flow, and make it financially attractive to prioritize smaller U.S. innovators while expanding domestic capacity.
- Lower Barriers to Making Capital-Intensive Investments. Offer financial incentives, such as tax credits, targeted grants, or partial loan forgiveness for capital-intensive investment. These could include greenfield facility builds, buildouts of existing sites, purchasing of specialized equipment and upstream materials, etc. Greenfield builds, site expansions, and capital investments carry high upfront risk but deliver resilient, future-ready facilities. Incentives de-risk private investment and anchor long-term capacity in the U.S.
- Encourage Integrated End-to-End Facilities. Explicitly reward fully integrated contract manufacturing campuses that bring end-to-end capabilities (from the creation of drug substance through to final drug product) under one roof. Incentives may include preferential tax treatment and grants. End-to-end integration reduces

friction, eliminates the need for tech transfer across multiple contract manufacturers, lowers regulatory burden, and strengthens supply chain security. End-to-end models speed time-to-market and increase U.S. competitiveness.

- Ensure Manufacturing Equipment and Raw Materials are Available. Establish funding mechanisms and tax credits for upstream suppliers of critical biotechnology equipment and materials, including raw inputs, prioritizing domestic production. Reliable access to specialized equipment and inputs is essential. Domestic support reduces reliance on international vendors, secures U.S. supply chains, and ensures timely access to essential equipment.
- Prioritize Long-Lead Equipment and Materials. Create a National Strategic Biomanufacturing Priority List for long-lead equipment and critical materials, with incentives for domestic sourcing and priority procurement under federal oversight. Key equipment often has 18–24 month lead times. Federal prioritization shortens timelines and strengthens long-term security.
- Encourage Public-Private Manufacturing Clusters. Promote development of regional contract manufacturer-anchored biotechnology manufacturing clusters through incentives for shared infrastructure, workforce, and collaborative innovation. Clusters lower capital burdens, foster collaboration, and strengthen regional economies through localized supplier networks and talent pools. They accelerate product development by providing shared access to advanced facilities, expertise, and supply chains.
- Facilitate Access to Land and Infrastructure. Work with state and local governments to offer land grants, infrastructure support, and site development incentives in underutilized industrial or economic development zones. Subsidizing land and infrastructure attracts biotech investment, creates jobs, and revitalizes regions while aligning with national innovation goals.

Workforce development is necessary so that professionals can take advantage of well-paying jobs and businesses can hire well-trained staff.

- Establish Standardized Educational Pathways for Biomanufacturing Careers. Create a nationally coordinated framework for biomanufacturing education, including two-year degree programs, modular training, and micro-credentialing aligned with current Good Manufacturing Practice (cGMP) standards. A standardized credential system ensures consistent training quality, accelerates workforce readiness, and enables mobility across biotech hubs. Flexible, stackable pathways will meet industry demand while expanding access to high-value careers for diverse learners.

- Fund Workforce Development for Institutions and Learners. Provide federal and state funding for accredited biomanufacturing training programs, including tuition grants, earn-and-learn apprenticeships, and institutional support for curriculum development and infrastructure. Millions of Americans without college degrees represent an untapped workforce. Funding incentives reduce barriers to entry, promote inclusive economic growth, and empower educational institutions to build capacity and meet urgent labor needs.
- Expand Cross-Training for Science and Technology Professionals. Support accelerated certificate and retraining programs that equip current science and technology professionals with hands-on biomanufacturing and regulatory skills. Retraining leverages existing technical talent and shortens time to workforce deployment. Applied coursework and apprenticeships provide industry-ready skills, strengthening the talent pipeline and maximizing return on prior education investments.

Lastly, to fully unleash the U.S. as an engine for biotechnology, major utilities and logistics barriers must be addressed, and environmental review must be streamlined.

- Advance policies to improve utilities and transportation networks critical to biotech manufacturing operations. Stable utilities and efficient logistics are essential. Coordinated State, Local, and Federal investment reduces risk and increases competitiveness of U.S. biotech hubs. Examples of utilities include power grid reliability, water and sewage systems, etc.
- Work with state and local governments to simplify and expedite environmental review processes for biotechnology facility construction, while maintaining safety standards. Long review timelines delay build-out and deter investment. Streamlining accelerates expansion and enhances public health readiness.

Beyond manufacturing issues, it's vital that the U.S. government consider additional ways to support small- and medium-sized biotechnology companies. These companies play a critical role in the U.S. innovation ecosystem, serving both as primary drivers of early scientific breakthroughs and as early adopters of emerging technologies across drug discovery, development, and manufacturing. Federal policies can strengthen this role by reducing barriers to participation, improving access to capital and infrastructure, and aligning incentives with the unique risk profile of biotech innovation.

First, federal funding and contracting mechanisms should be tailored to the scale and constraints of small- and medium-sized biotech firms. Expanding and modernizing programs such as Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)—through larger award sizes, faster decision timelines, and greater flexibility in eligible costs—would enable smaller companies to advance high-risk,

high-impact research. Streamlined application, reporting, and compliance requirements would further reduce administrative burdens that disproportionately affect smaller organizations.

Second, federal policies should improve access to shared infrastructure, data, and expertise. Small and mid-sized biotech companies often lack the capital to independently build advanced laboratories, manufacturing capabilities, or clinical trial networks. Policies that facilitate access to federal laboratories, biobanks, regulatory science resources, and public-sector clinical trial infrastructure—under clear, standardized partnership agreements—would accelerate innovation and adoption of emerging technologies.

Third, procurement and partnership policies should explicitly enable participation by smaller biotech firms. Increased use of milestone-based contracts, Other Transaction Authorities (OTAs), and phased procurement models would allow early-stage companies to demonstrate capability without requiring scale prematurely. Advance market commitments and predictable demand signals, particularly in areas such as pandemic preparedness and medical countermeasures, would further incentivize early adoption of novel platforms.

Fourth, federal policies should strengthen capital formation and de-risk early adoption of new technologies. Predictable and enhanced R&D tax incentives, refundable credits for pre-revenue companies, and co-investment models that leverage federal funding to crowd in private capital would improve the ability of smaller biotech firms to invest in emerging tools such as AI-enabled discovery, novel modalities, and advanced manufacturing.

Finally, a stable and predictable policy and regulatory environment is essential. Clear guidance on IP protections, data rights, and regulatory expectations enables small- and medium-sized biotech companies to plan, partner, and scale effectively. Policies that promote regulatory science collaboration and early engagement with FDA can further support rapid and responsible technology adoption.

These approaches would strengthen the capacity of small- and medium-sized biotech companies to drive innovation, adopt emerging technologies, and contribute to a resilient, competitive U.S. biotechnology ecosystem that delivers new therapies for patients and strengthens public health preparedness.

c. A strong intellectual property framework is essential to U.S. biotechnology competitiveness

Countries with strong IP systems are attractive to the biotechnology industry, and trade secrets are a particularly important form of IP for the industry. Strong IP and trade secret protections are foundational to U.S. biotechnology competitiveness and should be made

even more robust. Undermining IP rights will only serve to cede ground to China. Because biopharmaceutical innovation requires years of investment and extensive confidential technical know-how, the U.S. should modernize domestic IP policy and pursue stronger international commitments to protect trade secrets and proprietary information across global markets. China is taking steps to improve its IP system, and the U.S. should as well.[26] In the U.S., modernization of IP and licensing management would stimulate more investment, safeguard innovation, and help America maintain a competitive edge.

Furthermore, trade secrets are an important form of IP vital to the U.S. biopharmaceutical industry. These valuable assets result from billions of dollars and many years of investment and complement patent protection of a drug development pipeline. Many biopharmaceutical companies rely on trade secrets to protect drug manufacturing technologies, for example. Frequently overlooked and underappreciated, trade secrets backstop a competitive advantage of U.S. companies reflected in the availability of high-quality biologic medicines, cell and gene therapies, and many other life-saving health interventions provided to patients here and abroad. Moreover, the loss of trade secrets anywhere in the world has potential global implications and can cause irreparable harm to biopharmaceutical companies everywhere to an extent that goes beyond other IP protections.

World Trade Organization (WTO) member countries are required to comply with the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) by ensuring the protection of trade secrets through legal frameworks that prevent unauthorized use or disclosure of confidential business information. This includes adopting measures to safeguard trade secrets against unfair competition practices, in line with Article 39 of the agreement. Members must provide remedies for rights holders to enforce these protections effectively. Accordingly, U.S. biopharmaceutical firms expect reasonable protections of trade secrets when, for example, certain trade secrets may be disclosed in documents submitted to regulatory bodies as part of a clinical trial or marketing authorization application.

But many trading partner countries pose significant risks to these trade secrets, through a combination of known corruption, connections to nation state threat actors, and lack of mechanisms for enforcement. Without TRIPS-compliant measures in place to adequately protect trade secrets and provide remedies for misappropriation, U.S. biopharmaceutical companies often face a Hobson's choice of putting valuable trade secrets at risk in these jurisdictions or foregoing the ability to conduct a clinical trial or market a drug in these countries.

[26] Aaron Wininger, "China's National Intellectual Property Administration publishes 2026 Plan for Building a Strong Intellectual Property Nation", China IP Law Update, 23 May 2026, https://www.chinaiplawupdate.com/2026/05/chinas-national-intellectual-property-administration-publishes-2026-plan-for-building-a-strong-intellectual-property-nation/

Countries with weak governance structures provide limited oversight, making regulatory employees susceptible to various forms of inducement to improperly share trade secrets. This risk is particularly acute in countries where government officials may have dual roles in both regulatory oversight and commercial enterprises, creating inherent conflicts of interest. Moreover, the lack of transparency and clear conflict of interest rules in such countries compound this concern.

China, in particular, has established a concerning pattern of promulgating laws and policies designed to facilitate access to foreign companies' proprietary information. For example, China's Biosecurity Law and Human Genetics Regulation require foreign firms to partner with Chinese entities and share records, data, and other information as part of doing business in China. Furthermore, China considers its domestic biopharmaceutical industry an integral part of national security.

Compounding all such threats to trade secrets, from wherever the threat materializes, is the distinct lack of enforcement mechanisms and remedies available for loss or misappropriation. Although loss or misappropriation of trade secrets has severe (and generally permanent) consequences — economic harm, loss of competitive advantage, devaluation of substantial investment, loss of high value American jobs, among others — U.S. biopharmaceutical companies frequently cannot pursue legal recourse or obtain meaningful remedies when their trade secrets are compromised in foreign jurisdictions.

The reality is that in many foreign countries, the judicial system lacks transparency, independence, or technical expertise to adjudicate complex IP disputes. In many cases, trade secret laws may not exist or, if they do, may not provide adequate protections. Additionally, enforcement agencies may be unwilling or unable to act against their own governments, state-owned enterprises, or affiliated entities.

Even where nominal legal frameworks exist, procedural barriers, lengthy litigation timelines, and the risk of retaliatory regulatory action often deter U.S. companies from even bringing claims. Effectively, this leaves U.S. biopharmaceutical innovators without practical means to recover losses or prevent further dissemination of misappropriated trade secrets. Moreover, the systemic lack of enforcement mechanisms and remedies further emboldens nation state actors and corrupt insiders to target U.S. biopharmaceutical trade secrets.

To address these threats to the valuable trade secrets of U.S. biopharmaceutical companies, BIO recommends that the Federal government:

- Pursue strong trade secret commitments in bilateral and multilateral trade agreements, consistent with the Defend Trade Secrets Act and provisions in the United States–Mexico–Canada Agreement (USMCA);

- Develop coordinated responses with allies to address nation state-sponsored trade secret theft, including potential sanctions or other measures against entities that benefit from misappropriated trade secrets; and
- Enhance information sharing between government and industry regarding specific threats to biopharmaceutical IP, allowing companies to better protect their trade secrets in high-risk jurisdictions.

BIO urges the Administration to prioritize these issues in its engagement with trading partners, recognizing that the protection of trade secrets is fundamental to maintaining U.S. leadership in biopharmaceutical innovation and ensuring continued investment in developing life-saving medicines for patients worldwide.

5. A proactive U.S. competitiveness agenda for biotechnology

The United States has led the world in biotechnology for decades — not by chance, but by design. China is now investing at unprecedented speed and scale, with a coordinated national strategy to dominate biotechnology and biomanufacturing. At the same time, here in America, our system for R&D of newer and better medicines has grown overly complex, too costly, and too time-consuming. Well-intentioned policies, particularly absent a coordinated national biotech strategy, can even burden the U.S. biotech ecosystem and slow down American innovation.

A science-driven, well-resourced, and globally respected biotechnology ecosystem is essential to not only provide Americans health and hope but also to provide national security. As described above, improving the efficiency of the U.S. clinical trial ecosystem is central to our success; we must ensure that the FDA is equipped — in authority, staffing, and resources — to fulfill its mission effectively. Taking action to reduce the cost and complexity of early drug development in America will help ensure that patients benefit from the full promise of American innovation. In addition, as the industry invests in domestic manufacturing, policymakers must consider the full biomanufacturing ecosystem. Targeted incentives—tax, capital, and IP benefits—will help small and mid-sized firms, and their contract manufacturers, build the infrastructure needed to bring production back to the U.S. Finally, IP is a foundational issue that must be considered, and the U.S. IP system should be modernized.

The U.S.-China biotechnology competition is real, including in innovative biotechnology medicines. Advancing the U.S. ecosystem through effective policy measures that supercharge the American ecosystem is what it will take to maintain U.S. competitiveness and our global biotech leadership.