# BIO ADVANCE

SECURING AMERICA'S BIOTECH CENTURY

# EXECUTIVE SUMMARY

## AMERICA'S LEAD IN BIOTECHNOLOGY IS AT RISK, AND THE WINDOW TO PROTECT IT IS CLOSING.

Since the Second World War, American researchers and entrepreneurs have pushed the boundaries of science to save countless lives, grow our economy, and safeguard our national security. They've founded startups that revolutionized and pioneered entire industries, including the biotech sector.

Today, the U.S. bioscience industry comprises more than 156,000 businesses. It attracts a massive share of global venture capital investment: approximately $19 billion in 2024, or nearly twice as much as the rest of the world combined. And that investment fuels growth and economic opportunity in communities across the country. In 2025, bioscience supported roughly 9.7 million American jobs and drove approximately $3.2 trillion in economic output across all 50 states, the District of Columbia, and Puerto Rico.

## BUT PAST SUCCESS IS NO GUARANTEE OF FUTURE LEADERSHIP.

For decades, China has steadily elevated biotechnology as a strategic priority, directing massive state resources toward the sector in every new five-year plan. Those investments are paying off. China now launches more than a quarter of the world's clinical trials, and runs early-stage trials much faster and at lower cost than in the United States. Between 2016 and 2021, the value of China's biotechnology industry grew more than 100-fold. On September 18, China released its five-year biopharma plan for 2026-2030, which referred to biotechnology as a "pillar industry" and declared China's ambition to develop at least 25% of the world's first-in-class drugs by 2030.

From clinical research and contract services to manufacturing, supply chains, and data analysis, there is increased competition for U.S. companies, our economy, our health, and our security. That creates a growing risk that the United States could lose global prominence and fall behind in developing and manufacturing next-generation medicines.

The biotechnology race is this generation's space race. The country that wins will not only shape the future of medicine. It will gain an enduring economic and national security advantage. Success will take an all-of-government effort that unites policymakers, industry, and the research community.

BIO calls on Congress and the administration to act on **seven priorities** – tailored to America's strengths – to ensure our nation remains the **global biotech leader** for decades to come:

01 Establish a White House Office of Biotechnology.

02 Accelerate the path to first-in-human clinical studies.

03 Modernize and streamline development at all stages in the United States.

04 Improve patient access to clinical trials.

05 Ensure sustained support for academic and government biomedical research.

06 Enable and incentivize U.S. contract manufacturing capacity and expertise.

07 Strengthen intellectual property protections and economic incentives that drive access to capital.

***"Scientific progress and technological innovation underpin U.S. economic growth, trade, and our high standard of living. Our Nation's global competitiveness in the 21st century will depend on maintaining our comparative advantage in science and technology."***

- President Ronald Reagan
June 17, 1987

# AN ACTION PLAN FOR THE AMERICAN BIOTECH CENTURY



***"To 21st-century America, let us pledge that ... America will lead the world toward shared peace and prosperity, and the far frontiers of science and technology."***

– President William J. Clinton
January 27, 2000

COORDINATE

# 01 ESTABLISH A WHITE HOUSE OFFICE OF BIOTECHNOLOGY.

America's continued biotechnology leadership will depend on a vast array of policy reforms spanning scientific research, capital markets, regulation, data, workforce development, manufacturing, trade, and national security. Yet responsibility for these issues is currently divided among numerous federal agencies that do not always coordinate closely. America can't win the biotech race with a fragmented policy system. Keeping pace with global competitors takes speed, focus, and alignment across the entire federal government.

In other strategically important sectors, federal policymakers have established dedicated bodies — such as the National Artificial Intelligence Initiative Office and the National Quantum Coordination Office — to coordinate policy across the federal government. Biotechnology warrants the same specialized focus. Policymakers should establish and sustain a White House Office of Biotechnology to develop a unified national strategy, align biotech policy efforts across relevant agencies, and coordinate initiatives with trusted allies.

## KEY POLICIES

a. **Create a permanent White House Office of Biotechnology.** Congress and the administration should ensure the office has dedicated staff and stable multi-year funding so that it can effectively set and accomplish long-term goals.

b. **Develop and implement a national biotechnology strategy.** The office should be responsible for identifying key policy priorities to promote U.S. biotech competitiveness, assigning responsibilities to federal agencies, and coordinating engagement with private industry and trusted allies.

c. **Benchmark U.S. capabilities and report progress.** The office should continually measure American performance against global competitors and publish implementation reports to keep policymakers apprised of America's standing in biotechnology.

BUILD CAPACITY

# 02 ACCELERATE THE PATH TO FIRST-IN-HUMAN CLINICAL STUDIES.

Biotechnology companies must be able to efficiently test the safety and dosage of their innovations — and iterate quickly based on those results — to attract investment for early-stage research. Particularly for companies with limited venture capital, efficiently demonstrating a product's early promise can determine whether its development continues. This reality is increasingly driving companies to conduct early-stage drug development outside the United States, where the process is often faster, more predictable, and less expensive.

To remain globally competitive, the FDA must accelerate the path to first-in-human studies in the United States. It should ensure that regulatory requirements are tailored to each development stage and to a product's risks. By setting clearer expectations and establishing more efficient processes, the FDA can help reduce uncertainty, delays, and setbacks for companies and give American patients earlier opportunities to participate in innovative research.

The United States must also address the regulatory and operational barriers that slow clinical development — by centralizing approval processes across local trial sites and reducing administrative burdens. It must also make better use of its world-class scientific and medical expertise by expanding research capacity across institutions and communities. Much clinical research remains siloed and unevenly distributed, creating acute capacity constraints for specialized Phase 1 studies and studies in rural and medically underserved settings.



# KEY POLICIES

a. **Implement risk-based requirements for first-in-human trials, and improve regulatory engagement and review processes.** Before human trials for an investigational product can begin, sponsors must submit an Investigational New Drug (IND) application to the FDA. This allows the FDA to determine whether sufficient evidence supports initiating safe clinical testing. However, current IND requirements are not always calibrated to each product's risk profile, which can create unnecessary burdens and delays without meaningfully improving participant safety. The FDA should tailor its requirements to ensure that products based on well-understood technologies and those supported by preexisting data are not subject to the same requirements as those with new or uncertain risks. Where streamlined requirements already exist, the agency should also ensure they are applied consistently across review divisions. The FDA could further increase efficiency in early drug development by including earlier, more iterative engagement, clearer phase-specific expectations during pre-IND meetings, rolling submissions, and other streamlined review mechanisms aligned with risk-based IND requirements. As noted in BIO's recommendations to the FDA and public comments, these approaches could reduce avoidable delays and significantly accelerate trial initiation.

b. **Advance alternatives to animal testing.** The United States must continue building on recent momentum to advance new research methods that replace or reduce animal studies. By collaborating with industry to address remaining scientific gaps and clarify regulatory requirements, the FDA can support broader adoption of these new tools.

c. **Reduce unnecessary delays in Institutional Review Board (IRB) review, contracting, and site activation.** Before a clinical trial can begin enrolling patients, sponsors must obtain ethics approval from Institutional Review Boards, negotiate contracts with participating institutions, and complete numerous site start-up activities. These processes can take months, delaying patient access to clinical research and increasing development costs. Policymakers could help reduce duplicative reviews and accelerate trial start-up by finalizing and implementing requirements that allow a single IRB to review multi-site studies. The FDA and IRBs could also reduce avoidable delays across sites by allowing reviews to proceed in parallel when appropriate and expanding the use of standardized forms and contracts.

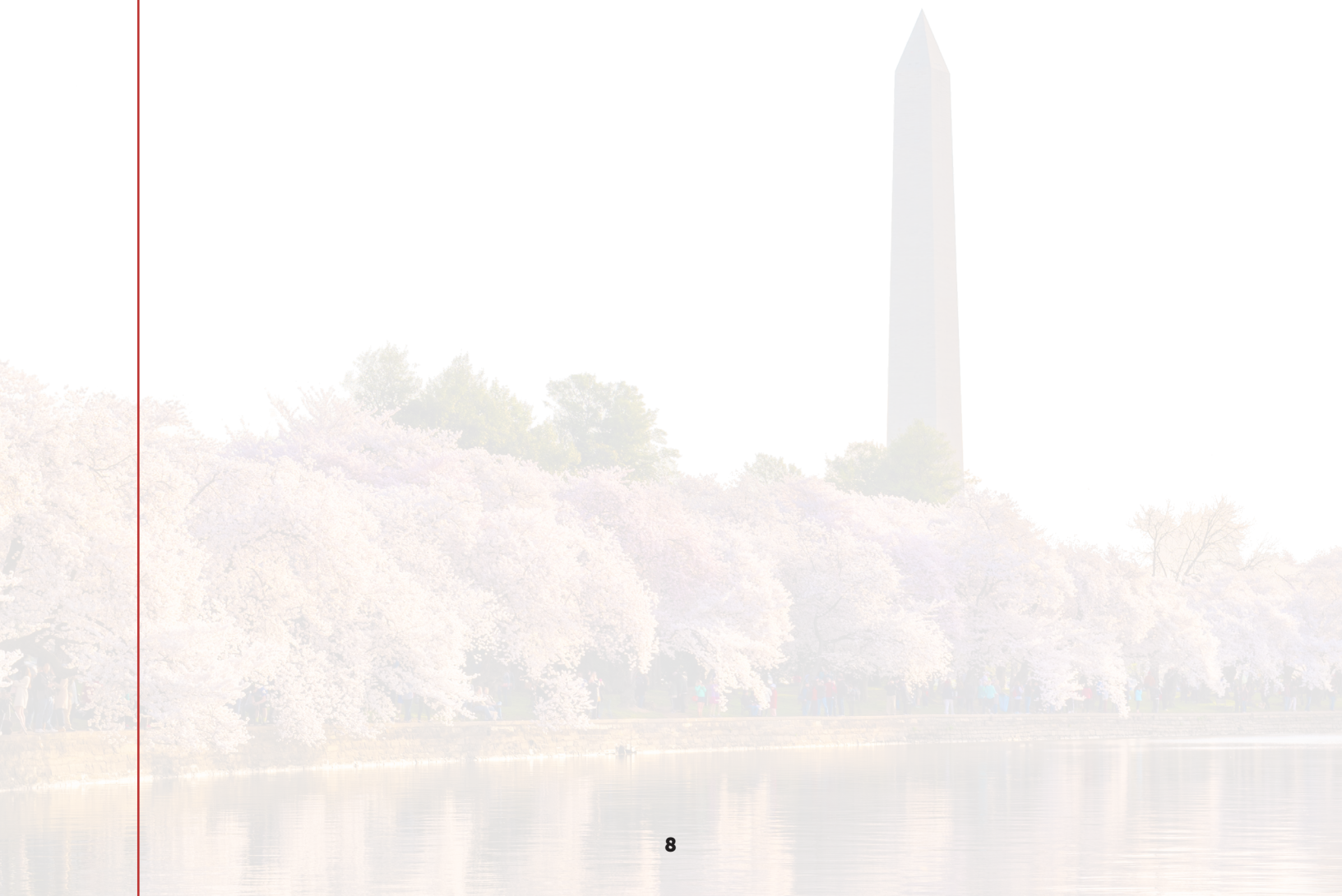
d. **Build a national Phase 1 clinical trial network.** Early-stage studies require specialized expertise, facilities, and operational capabilities that are not consistently available across the country. To ensure broader access to these resources, Congress and the Department of Health and Human Services should support a dedicated network of trial-ready Phase 1 sites, including in underserved regions. Sustained federal investment would help these sites develop and maintain the workforce, infrastructure, and systems needed to initiate studies quickly and expand access to early-stage research.

BUILD CAPACITY

# 03 MODERNIZE AND STREAMLINE DEVELOPMENT AT ALL STAGES IN THE UNITED STATES.

Roughly 12,000 active commercial INDs are overseen by the FDA each fiscal year, but only a fraction ultimately result in approved therapies. This high failure rate makes sponsors highly sensitive to regulatory costs, timelines, and operational complexity as they work to demonstrate their treatments' safety and effectiveness. China's investments in research infrastructure and streamlined development pathways are allowing it to capture a growing share of the world's clinical trial activity — and threatening the competitiveness of America's domestic clinical research ecosystem.

To meet this challenge, the United States must address the scientific, regulatory, and operational barriers that slow drug development. America's research infrastructure, regulatory procedures, and evidentiary frameworks must adapt to emerging science and cutting-edge technology.



# KEY POLICIES

a. **Ensure that regulatory frameworks are able to accommodate emerging science.** The standards for determining the safety, efficacy, and quality of drugs and biologics, especially those that leverage emerging modalities such as cell and gene therapy and those that target rare diseases, need to be right-sized for the benefits offered, risks posed, and populations impacted.

b. **Leverage innovative technologies and approaches to improve trial efficiency.** The FDA and trial sponsors should promote more informed decisions across clinical development by advancing innovative, fit-for-purpose trial designs, as well as technologies such as artificial intelligence and biomarkers to enable the development of safe and effective medicines for patients. The FDA should support adoption of these approaches by establishing clear regulatory expectations and consistent opportunities for regulatory engagement. This requires both investment and ecosystem-wide support.

c. **Strengthen and expand existing clinical trial networks to support the broader clinical research ecosystem.** Federal agencies and industry cannot stop at improving specialized Phase 1 capacity. They should also identify opportunities to build on successful clinical trial networks by extending their capabilities across therapeutic areas, development stages, and regions, rather than creating duplicative structures. Sustainable funding and incentives would enable participating sites to share best practices and maintain trial-ready capacity between individual studies.

BUILD CAPACITY

# 04 IMPROVE PATIENT ACCESS TO CLINICAL TRIALS.

Sponsors' challenges identifying trial-ready sites and enrolling studies on competitive timelines are not the only barriers to clinical research in the United States. The country also risks losing clinical research opportunities when patients and clinicians cannot find relevant studies or navigate the path from a potential match to enrollment, and when health systems lack the staff and resources to incorporate research into routine care.

Making trials easier to find and enabling more clinicians and care settings to participate would help sponsors conduct studies more efficiently in the United States, while also giving more Americans the opportunity to access cutting-edge treatments through clinical research.

## KEY POLICIES

a. **Make trials easier for patients and clinicians to find and navigate.** Policymakers should ensure trial information is accessible through user-friendly tools that help patients and clinicians identify relevant studies and move efficiently from a potential match to referral and enrollment. Targeted education could also help patients and clinicians understand trial options and the value of early-stage research.

b. **Provide reimbursement for clinicians engaging in clinical trial-related activities.** The Centers for Medicare & Medicaid Services and other payers should develop payment policies that compensate clinicians and health systems for time and resources devoted to identifying potential participants, discussing trial options, making referrals, and coordinating care. Appropriate reimbursement would reduce practical barriers to integrating research into routine care and enable more clinicians and care settings to participate in clinical trials.

BUILD CAPACITY

# 05 ENSURE SUSTAINED SUPPORT FOR ACADEMIC AND GOVERNMENT BIOMEDICAL RESEARCH.

Sustained public support for basic research through institutions and programs such as the National Institutes of Health, Food and Drug Administration, National Science Foundation, Biomedical Advanced Research and Development Authority, and Advanced Research Projects Agency for Health has long been a cornerstone of U.S. biotech growth and given us a fundamental advantage over other nations. NIH-funded research alone underlies virtually every newly approved drug and generates roughly $2.50 in short-term economic returns for each dollar invested.

America's commitment to publicly funded research dates back to the aftermath of World War II, when scientist Vannevar Bush laid the foundation for sustained federal investment in basic research in his landmark 1945 report, "Science, the Endless Frontier." As Bush wrote, "...without scientific progress no amount of achievement in other directions can insure our health, prosperity, and security as a nation in the modern world."

Eight decades later, at a moment of extraordinary scientific possibility, America must renew that commitment through sustained NIH investment and meaningful reforms. The government has a vital role in advancing high-risk, long-term research that could unlock the next generation of breakthroughs.

To strengthen America's national preparedness and sustain its biotech discovery pipeline, policymakers must ensure that America's research enterprise, especially academia and small biotech innovators, continues to have access to consistent, unbiased, and merit-based research funding. They should also provide clear and reliable pathways to help U.S. universities and research institutions attract and retain the world's leading scientists, researchers, and engineers.



# KEY POLICIES

a. **Provide ample and predictable federal research funding.** Congress and the administration should sustain support for NIH, FDA, NSF, BARDA, ARPA-H, and other programs that finance basic and translational biomedical research. Once research grants are approved, agencies should honor those commitments through completion, provided researchers continue to meet established performance expectations.

b. **Ensure stable, merit-based grant administration.** Agencies should ensure that grants continue to be awarded through merit-based processes, including peer review, and that grant rules do not restrict scientific communication and collaboration.

c. **Advance policies that attract the world's best and brightest scientists, researchers, and engineers.** America's research enterprise depends not only on funding, but also on the scientists, researchers, and engineers who generate new knowledge and turn it into breakthrough technologies. The U.S. should provide reliable pathways for talented minds from around the world to study and work here so that American universities and federal laboratories remain at the forefront of biotechnology.

BUILD CAPACITY

# 06 ENABLE AND INCENTIVIZE U.S. CONTRACT MANUFACTURING CAPACITY AND EXPERTISE.

To maintain its global leadership and protect American interests, the United States must be able to compete at every stage of the innovation process — from early clinical development through commercial-scale manufacturing. That will require a more robust and resilient network of U.S. and allied clinical sites, contract development and manufacturing organizations (CDMOs), equipment suppliers, and trained workers.

Smaller and earlier-stage biotechnology companies, in particular, depend on CDMOs for facilities, specialized equipment, technical expertise, and regulatory support. Yet Chinese CDMOs often offer lower prices and greater capacity than their U.S. counterparts, attracting companies that want to focus resources on core competencies such as drug development. Policymakers should use targeted tax incentives and funding to expand domestic CDMO capacity and help American biotech entrepreneurs scale their companies here at home.

Policymakers must also ensure that U.S. laboratories and manufacturing facilities have the talent and expertise they need to operate. Turning scientific discoveries into patient-ready products requires skilled manufacturing workers, bioengineers, scientists, regulatory specialists, and data experts who can solve the complex problems that arise as technologies move from initial discovery toward commercial scale. Investments in workforce development, education, and data infrastructure must therefore be an essential part of strengthening U.S. manufacturing.

## KEY POLICIES

**a.** **Support the development and use of advanced manufacturing technologies that make domestic production economically viable.** Many pharmaceutical ingredients and materials are manufactured overseas because traditional production can be expensive, low-margin, or difficult to sustain in the United States. Policymakers should support technologies that change those economics, including continuous manufacturing, greener chemistry, automation, process improvements, AI-enabled quality systems, and other approaches that reduce cost, improve reliability, and maintain high environmental standards. The government should also incentivize the construction of integrated manufacturing campuses that can handle multiple stages of production in one location. By providing grants, tax incentives, credit tools, and direct funding for pilot-scale facilities to encourage broader adoption of these emerging technologies, policymakers can help spur domestic manufacturing growth and reshore the production of strategically important medicines and ingredients.

**b.** **Ensure biotech manufacturers have reliable access to necessary equipment and input materials.** America's manufacturing facilities cannot compete if they must wait months or years for specialized machinery, components, or raw materials. Yet currently, certain types of critical equipment can have lead times of 18 to 24 months. The federal government should work to shorten these timelines by establishing a National Strategic Biomanufacturing Priority List that identifies long-lead equipment and materials important to U.S. competitiveness. Then, it should implement clearer funding mechanisms, tax credits, and priority procurement for domestic suppliers of these resources. This would help ensure that America's biotech manufacturers can consistently and quickly access the materials and equipment they need for production and reduce U.S. reliance on potentially vulnerable international supply chains.

**c.** **Incentivize biotech firms to move their contract development and manufacturing operations to the United States.** Firms that are already reliant on overseas contract partners will face significant logistical difficulties relocating their contract development and manufacturing operations domestically. The process will not only be expensive and time-consuming, but could also cost companies by reducing their production and sales during the interim period. To ease and encourage this transition, policymakers should provide targeted incentives — such as tax credits for technology transfer, additional forms of capital, extended patent terms and regulatory exclusivity, and federal procurement commitments — to offset the costs companies may face as they transfer their development and manufacturing pipelines.

d. **Streamline permitting for biotechnology manufacturing facilities.** Lengthy and unpredictable environmental review processes can delay construction projects, deter investment, and make it difficult to build domestic manufacturing capacity quickly. Federal policymakers should work with state and local governments to streamline and accelerate environmental reviews for biotechnology facilities while preserving high safety standards.

e. **Bolster biomanufacturing education and workforce training.** Federal and state governments should work with universities, community and technical colleges, workforce organizations, and industry to establish clear pathways into biomanufacturing careers. These should include two-year degree programs and flexible, stackable credentials aligned with Current Good Manufacturing Practice standards. Standardized, government-endorsed credentials would help companies confidently identify workers with relevant skills while enabling employees to move more easily among biotechnology employers and regional hubs.

Policymakers should also complement these educational pathways with practical training opportunities. Greater federal funding for tuition assistance, earn-and-learn apprenticeships, and hands-on instruction at pilot-scale facilities would help new workers enter the field, while accelerated certificate and retraining programs would allow scientists, engineers, and technicians to add manufacturing and regulatory skills to their existing expertise. Together, these efforts would help companies meet pressing workforce needs while expanding career opportunities for Americans with a wide range of educational backgrounds.

f. **Expand access to shared scientific infrastructure, data, and expertise.** Biotech companies frequently focus on only one or a handful of products and lack the capital to independently build advanced laboratories, manufacturing facilities, biobanks, or clinical-trial networks. To ensure these innovative companies can still access this expert support when they need it, federal policymakers should establish clear, standardized partnership agreements that let companies access federal laboratories, regulatory-science expertise, public clinical infrastructure, pilot-scale manufacturing facilities, and specialized equipment.

Similarly, the government should work with industry and research institutions to develop secure, interoperable, and AI-ready biological and manufacturing data infrastructure. Researchers throughout the biotech industry increasingly rely on large datasets to identify promising drug targets, predict how potential medicines will behave, design more efficient clinical trials, and anticipate potential manufacturing and quality-control problems. By making broader pools of high-quality data accessible to America's small biotechs — while still safeguarding proprietary information, intellectual property, and sensitive biological data — policymakers could help these companies make faster, better-informed decisions throughout the drug development process.

FUEL CAPITAL

# 07 STRENGTHEN INTELLECTUAL PROPERTY PROTECTIONS AND ECONOMIC INCENTIVES THAT DRIVE ACCESS TO CAPITAL.

Small and mid-sized companies are the foundation of America's biotech industry, accounting for more than half of new FDA filings. Yet these companies, which usually rely on outside investors and venture capital to fund risky research and development, face steep barriers to entry. Bringing a new medicine to market typically costs nearly $2.7 billion, and 90% of new drug candidates fail.

Strong patents and other intellectual property protections are essential to securing that capital. Without reliable protections against unauthorized copying, companies and investors would not be able to justify the costs and risks of drug development. Unfortunately, in recent years, Washington has inadvertently eroded IP protections. Meanwhile, China is actively strengthening its own IP system, even as it remains notorious for stealing intellectual property owned by U.S. innovators.

To make the United States a more attractive place to invest, launch companies, and commercialize new technologies, policymakers must ensure that Americans can reliably protect and enforce their intellectual property rights. They should also reduce unnecessary regulatory burdens and adopt tax and economic incentives that encourage investment in innovative startups. These reforms would help emerging U.S. biotechs preserve capital for research, attract more private investment, and grow here in the United States rather than seeking capital or partnerships abroad.



## KEY POLICIES

**a.** **Restore clarity around patent eligibility criteria.** In recent years, a series of Supreme Court decisions has made it harder to determine which biotech inventions are eligible for patenting. Congress should pass the Patent Eligibility Restoration Act to clarify protection for important biotechnology inventions and spur greater investment in areas such as diagnostics, personalized medicine, and gene therapies.

**b.** **Prevent serial and abusive patent challenges.** Loopholes at the Patent Trial and Appeal Board currently allow repeated and duplicative challenges to the same patent, putting small innovators at a disadvantage. Congress should pass the PREVAIL Act to prevent gamesmanship and ensure biotech companies can resolve patent disputes without wasting money that could otherwise fund research and development.

**c.** **Restore meaningful remedies for infringement.** Since the Supreme Court's 2006 decision in *eBay v. MercExchange*, patent injunctions have become much harder to obtain, leaving biotech companies with no reliable way to permanently halt infringement. Congress should pass the RESTORE Patent Rights Act to reestablish injunctions as the default infringement remedy and make small companies' patent rights more secure.

**d.** **Strengthen enforcement against foreign IP theft.** Policymakers should better utilize existing enforcement tools, such as the U.S. International Trade Commission's power to block infringing imports, to ensure foreign countries and companies face meaningful consequences when they steal American biotechnology.

**e.** **Implement tax reforms to support high-risk research and long-term investment.** Congress should preserve and expand tax deductions for research expenses to help make high-risk research more attractive to investors. Maintaining U.S. leadership requires a tax code that encourages innovation, investment, and growth. Policymakers should ensure that the United States is a competitive location to build and finance cutting-edge biotech companies that are globally competitive.

**f.** **Enable more investors to support emerging biotechnology companies.** Congress should pass the Equal Opportunity for All Investors Act, included in the INVEST Act, to simplify the process for investors to become accredited and allow financially knowledgeable individuals to invest in early-stage, private biotech firms.

**g.** **Make public markets more accessible to growing companies.** Congress should advance the Expanding Access to Capital Act and related provisions in the INVEST Act to expand eligibility for the 2012 JOBS Act's "emerging growth company" designation, reduce compliance burdens on young public companies, and make it easier for them to scale.

# THE TIME TO ACT IS NOW

In 1776, America's founders established a nation built on discovery, enterprise, and the freedom to pursue new ideas. In 1976, as our nation marked its bicentennial, American scientists and entrepreneurs helped launch the modern biotechnology industry.

In 2026, the United States faces another pivotal strategic moment: the opportunity to act decisively to secure another century of American biotech leadership.

The reforms outlined in this brief are designed to address the central risks to America's biotech sector. Strengthening capital formation would keep investment, talent, and entrepreneurial companies here at home. Modernizing FDA processes and expanding domestic capacity for clinical development and manufacturing would reduce our reliance on foreign competitors for the medicines Americans depend on. Bolstering intellectual property protections would reinforce the foundation of our innovation ecosystem – and help ensure the next great discoveries are developed, owned, and brought to market in the United States.

By acting now to advance these policies, U.S. leaders can support the development of new treatments, create high-paying jobs, strengthen the government's ability to respond to threats to our health and national security, and secure another century of American biotech leadership.




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