The Future of Biotech: Maintaining U.S. Competitiveness and Delivering Lifesaving Cures to Patients
October 29, 2025

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Chairman Cassidy, Ranking Member Sanders, and distinguished Members of the Committee:

Thank you for the opportunity to appear before you today on behalf of the Biotechnology Innovation Organization (BIO), which represents more than 1,000 biotechnology companies, academic institutions, and research centers across the United States.

I am John Crowley, President and CEO of BIO. For me, the future of biotech and delivering lifesaving cures to patients isn't just professional — it's deeply personal.

Twenty-five years ago, my two youngest children, Megan and Patrick, were diagnosed with Pompe disease, a rare and fatal neuromuscular disorder. At the time, there was no treatment — no hope beyond comfort care. I left my job, went back to graduate school, and eventually helped start a small biotech company dedicated to developing an enzyme replacement therapy.

That therapy — born from the ingenuity and perseverance of American scientists, and approved by the FDA — gave my children a chance at life. Today, Megan and Patrick are living full, meaningful lives.

That experience taught me two things I will never forget: first, that science can save lives, and second, the biotech ecosystem is complex, interdependent, and each piece is critical for success.

So when I speak today about America's biotechnology ecosystem and our global competitiveness, I speak not only as a CEO, but as a father who owes everything to innovation and the people who make it possible.

BIO's members are developing new medicines, vaccines and technologies that improve and save American lives. Biotechnology not only strengthens our nation's health, and is a key driver for the U.S. economy, but is also critical for our national security. We are deeply committed to ensuring that the Food and Drug Administration (FDA) remains the global gold standard for medical product regulation — protecting public health while ensuring that patients have timely access to safe and effective treatments, but also that the United States maintains its global dominance in biotechnology.

The Current Biotech Landscape

Nearly 50 years ago, the biotechnology industry was born in the United States with groundbreaking discoveries by American companies, including the development of synthetic insulin. Today, this sector generates over $3 trillion in annual economic output, employs nearly 2.3 million Americans, and supports 8 million additional jobs across the country.[1]

At the heart of this economic strength is a uniquely innovation-driven ecosystem: approximately 76% of all new medicines originate in small, start-up biotech companies.[2] These early-stage innovators take on extraordinary scientific and financial risk- often long before larger partners or investors come on board. Their ability to translate scientific discovery into medical breakthroughs drives progress in global health- and in turn, fuels the economic growth, job creation, and regional development that define the U.S. biotech sector.

And this leadership is national in scope. While hubs like Cambridge, MA, and California are widely recognized, the biotech sector is thriving in every region- from the fast-growing biosciences industries in Texas and Ohio to research hubs in Missouri, Connecticut, and Arkansas. Building on this broad geographic footprint is essential to maintaining our momentum.

Yet the pathway from scientific discovery to approved therapy is long and uncertain. Biotech R&D faces a failure rate exceeding 90%, takes 10–15 years, and can cost more than $2.6 billion.[3] Investors will not fund this work unless developers can rely on a predictable environment that includes strong intellectual property (IP) protections, clear regulatory pathways and access to capital.

This challenge is compounded by growing global competition. Maintaining America's dominance in biotechnology is now a national security imperative, particularly in the face of aggressive efforts by China to dominate global health technologies. The bipartisan National Security Commission on Emerging Biotechnology (NSCEB) has warned that China is rapidly closing the innovation gap and may soon overtake the United States as the global leader.[4] The numbers are telling: as of March 2025, China accounts for 30% of global clinical trial starts, nearly matching the U.S. share of 35%.[5] In 2024, China's innovative drug assets represented 32% of the global

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[1] BIO and TECONOMY. The U.S. Bioscience Economy: Driving Economic Growth and Opportunity in States and Regions. December 2024.
[2] Data analyzed from Biomedtracker.
[3] Pharmaceutical Research and Manufacturers of America. Innovation in Biopharmaceuticals. Washington, DC: PhRMA; 2021. https://cdn.aglty.io/phrma/global/resources/import/pdfs/Innovation_in_Biopharmaceuticals.pdf.
[4] National Security Commission on Emerging Biotechnology. April 2025. "Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity." https://www.biotech.senate.gov/final-report/chapters/
[5] IQVIA Institute for Human Data Science. Global Trends in R&D 2025: Progress in recapturing momentum in biopharma innovation. March 2025. Available from www.iqviainstitute.org

biopharma pipeline, up from just 4% a decade earlier, according to data from Citeline's Pharmaprojects database.[6]

Beijing's expanding biotech footprint is not merely economic, it is strategic. China is leveraging its position to manipulate pharmaceutical supply chains, control data flows, and appropriate intellectual property. These actions threaten not only U.S. competitiveness, but also the health security of our allies and trading partners.

To confront these threats and secure America's biotech future, we must take proactive, strategic action. Below I will focus on our urgent opportunities for strengthening the regulatory process through the FDA, spurring innovation through Congressional action and revitalizing the biotechnology manufacturing ecosystem here in the United States. However, securing America's biotech future also includes protecting IP, strengthening trade partnerships, and avoiding policies that undermine access and innovation. These solutions will be essential to unleashing the full power of U.S. biotechnology and ensuring it continues to serve as the global gold standard.

Strengthening America's Biotech Future: Strategies for Enhancing FDA as Global Gold Standard

The US biotechnology ecosystem depends on the FDA as the global gold standard. Its rigor and integrity underpin public trust in every new medicine. Today, the FDA stands at an inflection point. Under new leadership, and amid rapid scientific and technological change, the Agency has an extraordinary opportunity to harness expertise and modernize its policies and operations to meet the needs of 21st-century innovation.

The FDA's mission has always been dual: to safeguard the public and to enable access to innovation. These are not competing objectives — they are mutually reinforcing. When FDA's processes are predictable, science-driven, and transparent, patients benefit first. If we are to keep pace with global innovation, the FDA must continue to evolve — embracing its role as both gatekeeper and catalyst for biomedical progress. We can and must continually modernize the FDA to keep it strong, nimble, and the global gold standard.

To ensure that FDA can continue to lead the world, BIO respectfully offers three overarching strategies. We must pursue reforms that make clinical development more efficient, regulatory review more predictable, and stakeholder engagement more effective and transparent.

1. Reduce the Time, Cost and Complexity of Early Drug Development

Processes for opening clinical sites and preparing IND submissions are costly, duplicative, and inconsistent. Standardizing expectations and applying risk-based flexibility will lower barriers in the US without compromising patient safety. BIO recommends the following:

[6] Citeline, Pharmaprojects, accessed July 2025. https://www.citeline.com/en/products-services/clinical/pharmaprojects

- Reduce administrative burdens in clinical trials (e.g. uniform contracts, streamline Form 1572 and standardize informed consent) to accelerate opening clinical sites;
- Explore expansion of single Institutional Review Boards (sIRBs) policies within FDA and across HHS and leverage new technologies for centralizing document collection and coordination;
- Outline expectations and support collaborative efforts to reduce animal testing with the goal of further enabling New Approach Methods (NAMs);
- Clarify toxicology data requirements minimally necessary to initiate clinical testing and expand the use of risk-based approaches that can be scaled based on modality, mechanism of action and clinical risk profile;
- Further Quality Risk Management (QRM) in manufacturing to accelerate the start of INDs and ultimately product approval; and
- Ensure rapid/frequent communications with sponsors throughout drug development but especially during the pre-IND and early IND period.

2. Strengthen FDA's Regulatory Review: Predictability and Efficiency

Predictability and early communication are essential to innovation. By improving first-cycle success rates, advancing modern trial methodologies, and reducing inspectional bottlenecks, the FDA can help maintain the United States' status as the preferred market for global clinical development.

In Fiscal Year 2024, FDA met its overall review time goals — "the trains ran on time" — but only 56% of standard and 77% of priority applications were approved in the first cycle, down significantly from recent highs of 67% and 92%, respectively. Moreover, the Agency is meeting only 23 of 32 procedural and processing goals related to meeting management and timely communications per FDA FY 2024 PDUFA Performance Report.

To strengthen FDA's global leadership, BIO recommends the following:

- Improving first-cycle review performance through consistent application of the PDUFA "Enhanced Review Program."
- Streamlining inspections by expanding Remote Interactive Evaluations and leveraging Drug Master Files and mutual reliance on trusted foreign regulators.
- Advancing innovative trial designs (Complex Innovative Designs, Real-World Evidence, Model-Informed Drug Development) and integrating successful pilot programs into routine practice.
- Accelerating biomarker qualification and closing the translational gap through clear evidentiary standards and adequate resourcing.
- Expanding the Platform Technology Designation (PTD) to facilitate review of well-characterized technologies across multiple products.
- Applying expedited development tools and flexible frameworks for chronic diseases, where innovation has lagged despite enormous public health burden.

- Supporting efforts to fulfill PDUFA meeting management goals and continue to evolve meeting best practices. Explore the potential for existing meeting types to be used more effectively to resolve urgent drug development questions.

3. Support New Models for External Engagement and Transparency to Accelerate Innovation

Innovation moves quickly, and no single entity — not even the FDA — can maintain expertise across every emerging field. Sustained engagement with the broader ecosystem will help the Agency keep pace with scientific advances and apply policy consistently.

The US biotechnology ecosystem depends not only on the FDA but also on the patients it serves, the medical community that deploys the products it regulates, and the companies that develop and manufacture them. In order to maintain pace with innovation, the entire ecosystem must be further leveraged. BIO recommends the following:

- Further FDA's ability to augment its expertise on emerging science and innovation by evolving the use of Advisory Committees to focus on questions of science rather than questions about the regulations, ensuring appropriate training and balanced participation while updating conflict-of-interest rules.
- Establish common platforms for shared learning across the innovation ecosystem to address cross-cutting scientific and regulatory challenges.
- Fill FDA positions focused on consistently advancing the FDA vision for regulatory science and ensuring consistent implementation across review divisions.

Strengthening America's Biotech Future: Growing U.S. Manufacturing Capacity to Support Industry, Especially Small to Midsize Biotechs

BIO is dedicated to supporting growth of the biotech manufacturing ecosystem in the United States. As outlined in the introduction, 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.

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 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.

Supporting 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.

Contract manufacturing facilities

- Incentivize servicing low-volume contracts (e.g., preferential tax rates, depreciation benefits, etc.).
- Lower barriers to capital-intensive investments with incentives for facility and equipment buildouts.
- Leverage government guarantees by expanding grant and credit tool programs for biotech manufacturing projects.
- Reward technology adoption and innovation with incentives for advanced systems and pilot-scale facilities.
- Encourage integrated end-to-end facilities through grants and tax benefits.

Biotechnology companies using contract services

- Incentivize transferring technology to the United States.

Equipment and critical raw materials suppliers

- Ensure availability of biotech equipment and critical raw materials by funding and incentivizing domestic production.
- Prioritize long-lead biotech equipment through a national list and incentives for domestic sourcing.

The combined ecosystem

- Encourage regional biotech clusters by incentivizing shared infrastructure, workforce development, and expertise.
- Facilitate access to land and utilities through grants and infrastructure support in development zones.
- Address utilities and logistics barriers by improving infrastructure essential to biotech manufacturing operations.
- Streamline environmental reviews to accelerate biotech facility construction while upholding safety standards.

Workforce development

- Establish standardized biomanufacturing education through national frameworks, degrees, and cGMP-aligned programs.
- Fund biomanufacturing workforce development through grants, apprenticeships, and institutional training support.
- Expand cross-training by funding accelerated programs to upskill science professionals in biomanufacturing.

Federal oversight and coordination

- Establish federal oversight and coordination mechanisms to unify biomanufacturing efforts across HHS, Commerce, and other agencies.

Strengthening America's Biotech Future: Spur Innovation and Address Unmet Needs for the Most Vulnerable Through Congressional Action

Rare disease drug development faces many barriers. Just 5% of the 10,000 known rare diseases have an approved treatment on the market. The Rare Pediatric Disease Priority Review Voucher (RPD PRV) program was created by Congress in 2012 to spur treatments that offer hope to children with few or no treatment options and to provide uniquely American incentives for biotech investment. The RPD PRV serves as a powerful incentive to stimulate the development of therapies for diseases that are not economically viable to pursue - and does so at no direct cost to taxpayers. To date, 53 PRVs have been awarded across 39 rare pediatric diseases. Prior to the creation of the RPD PRV, only 3 of those 39 diseases had any FDA approved treatment.

74% of qualifying drugs who were awarded a RPD PRV are first in disease, indicating that trailblazing innovation is underway and has already improved treatment options for children.

Administered by the FDA, the program has been reauthorized every four years (in 2016 and 2020). Despite bipartisan backing, the program's authorization lapsed in December 2024, halting a vital incentive for drug developers who have historically relied on it to advance novel treatments for rare pediatric diseases. Holding or selling a RPD PRV can be transformative for small and mid-size biotechs, attracting investment or providing critical capital to fund additional

research and development. At the same time, the program helps expedite broader patient access to urgently needed treatments. BIO recommends:

- Congress urgently reauthorize the PRV to provide the most vulnerable patients the treatment and hope they so desperately need as well as protect and advance American biotech innovation.

Conclusion

The United States has led the world in biotechnology for decades — not by chance, but by design. 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. FDA is central to our success; we must ensure that the FDA is equipped — in authority, staffing, and resources — to fulfill its dual mission effectively. By modernizing its processes, strengthening collaboration, and embracing its role as both gatekeeper and catalyst, the FDA can continue to ensure that patients benefit from the full promise of American innovation.

Congress must also do its part and act now to spur innovation and address unmet needs for the most vulnerable by reauthorizing the Rare Pediatric Priority Review Voucher (PRV). Finally, 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.

BIO and our member companies stand ready to partner with Congress, FDA, and all stakeholders to advance these goals.

Thank you for your leadership and commitment to this critical mission. I look forward to your questions.