February 2026

Shaping the Future of Biotechnology

NSCEB 2025 | Year in Review & Year Ahead

Message from the Chair and Vice Chair

Time is running out on the global biotechnology race, and the United States is losing. In April 2025, we warned policymakers that they had three years to act to secure America's longstanding lead in biotech or risk ceding it to China. We warned, "there is time to act, but no time to waste," and we were right. The Chinese Communist Party continues to pull every lever to eclipse America in emerging biotech.

China is moving faster than we expected, and the window to act is closing.

As China surges on, the NSCEB has not taken a moment for granted:

- We hit the road—18 states, coast to coast—to meet with investors, researchers, farmers, and manufacturers. Our findings were clear: local ecosystems will power America's biotech future if supported, not hindered, by government policy.
- A shifting innovation ecosystem and geopolitical landscape demanded more analysis. NSCEB staff published discussion papers on three critical topics: the future of science, the future of U.S.-China biotech competition, and the future of biotech regulation.
- We worked with Congress to turn words into action. As of January 1, 2026, biotech champions in both chambers have taken legislative action on 32 provisions that reflect NSCEB recommendations. 21 of those provisions have been signed into law, and the White House has taken executive action on 9

> NSCEB recommendations.

This is real progress, but we cannot take our foot off the gas. U.S. biotech innovators still face complex regulatory, scale-up, and workforce challenges. Meanwhile, China blazes ahead with focus and coordination.

Biotechnology will shape the next chapter of American innovation. As we prepare to celebrate America's 250th birthday, we reflect on who we are and where we're going. Our nation's history is one of ingenuity, grit, and leadership, and our future is what we make it.

The following document details the NSCEB's work in 2025 and sets a bold legislative agenda for 2026, our final year. Together, we will cement U.S. biotech leadership for generations to come.

Senator Todd Young
Chair

Dr. Michelle Rozo
Vice Chair

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Section 01

NSCEB by the Numbers

2025 was a year of major wins for U.S. biotechnology. The following statistics represent a snapshot of the biotech momentum that is building in government and across the country. The NSCEB is grateful to all who helped drive this work forward in 2025 and stands ready to turn today's biotech momentum into enduring U.S. leadership in 2026.

NSCEB By the Numbers

21 Provisions signed into law

11 Provisions pending in Congress

312 Meetings on Capitol Hill

40+ Members of the Bipartisan House BIOtech Caucus

3 New discussion papers

18 States visited #biotechacrossamerica roadshow

250+ Roadshow participants

31 Bioliteracy initiatives highlighted across 22 states

700+ Report launch attendees

27 Press releases

150+ NSCEB media mentions since April

159,678 Social media engagements

~6,500 NSCEB staff cups of coffee

Section 02

Biotech Across America Roadshow

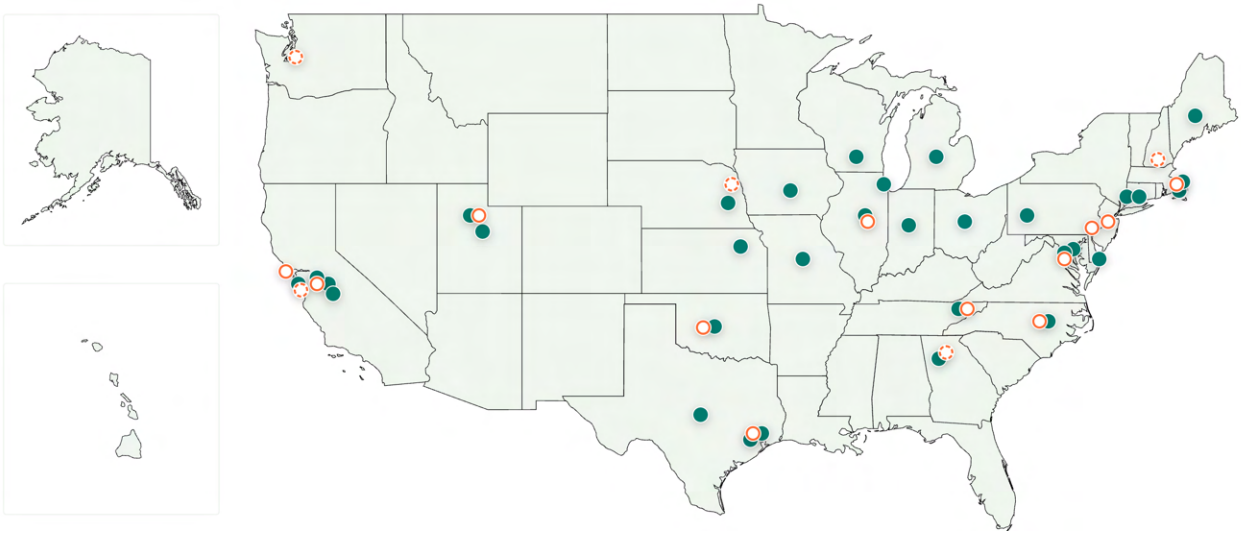
BIOTECH ACROSS AMERICA ROADSHOW

In 2025, the NSCEB's Biotech Across America Roadshow visited 18 states to learn more about the companies, academic institutions, industry alliances, workforce development programs, and policy initiatives that will drive the future U.S. biotechnology industry.

Filter Map

All | Roadshow | Bioliteracy

Commissioner events
Staff events



California

- Commissioners met with Central Valley Agriculture stakeholders at UC Merced before traveling to Modesto to learn more about the agricultural biotechnology economy from experts at BEAM Circular, VOLT Institute, and Caribou Biofuels.
- In Berkeley, the NSCEB visited Lawrence Berkeley National Laboratory and toured the Advanced Biofuels and Bioproducts Process Development Unit (ABPDU), the Agile BioFoundry (ABF), and the Joint BioEnergy Institute (JBEI).
- Biotechnology industry leaders, students, and investors across the Bay Area were eager to discuss California's unique challenges and opportunities.

Delaware

In Newark, the NSCEB joined Senator Chris Coons (D-DE) and Representative Sarah McBride (D-DE) in visiting the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) to see firsthand how government and industry partnerships drive innovation.

Illinois

In Urbana-Champaign, the NSCEB and Senator Tammy Duckworth (D-IL) visited the University of Illinois Urbana-Champaign and the iFAB Tech Hub before traveling to Decatur to see the region's

biomanufacturing capacity with tours of the ADM Decatur plant and Primient.

New Jersey

In Princeton, the NSCEB and Congressman Herb Conaway (NJ-03) spoke with leaders from Princeton University, BioNJ, and Amicus Therapeutics, as well as regional officials and students, about the impact of AIxBio convergence.

North Carolina

In Raleigh, the NSCEB joined experts from Novonesis North America, NCBiotech, and NCLifeSci to meet with state lawmakers and explore the local biotech industry landscape.

Oklahoma

In Oklahoma City, the NSCEB joined Commissioner Congresswoman Stephanie Bice (OK-05) for meetings with biotech industry leaders, state officials, and members of academia at Innovation Hall.

Pennsylvania

In Phoenixville, the NSCEB joined Congresswoman Chrissy Houlahan (PA-06) at Technical College High School, Pickering Campus, to discuss the biotech workforce needs of tomorrow. The group then visited Ocugen, a life sciences company, in Malvern.

Tennessee

In Johnson City and Kingsport, the NSCEB met with experts from East Tennessee State University, the ETSU Research Corporation, and local industry leader Limulus to learn more about how biotech is transforming the regional economy. Commissioners also toured the Niswonger Foundation-powered BioBuilder Learning Lab.

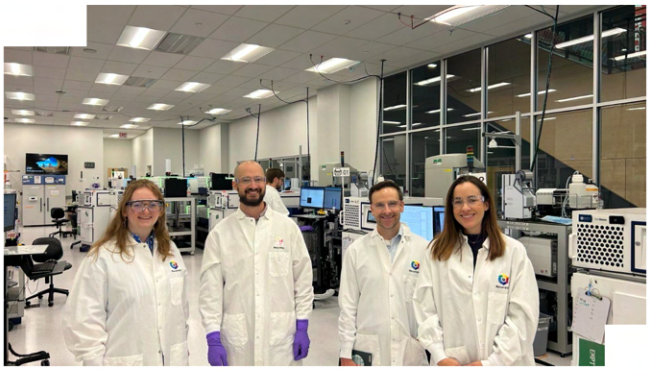
Texas

In Houston, the NSCEB met with biotech stakeholders from the Greater Houston Partnership, the University of Houston, the Texas Medical Center, and Cemvita to learn about the city's broad biotech

ecosystem.

Utah

In Salt Lake City, the NSCEB met with stakeholders from industry organizations BioUtah and BioHive, as well as innovators from biotech companies Recursion, Blackrock Neurotech, and Cleanjoule, before taking part in the Utah Life Sciences Summit.



Virginia

In Manassas, the NSCEB joined the American Type Culture Collection (ATCC), a nonprofit that equips scientists to conduct critical life science research, for a conference on biotechnology and American competitiveness.

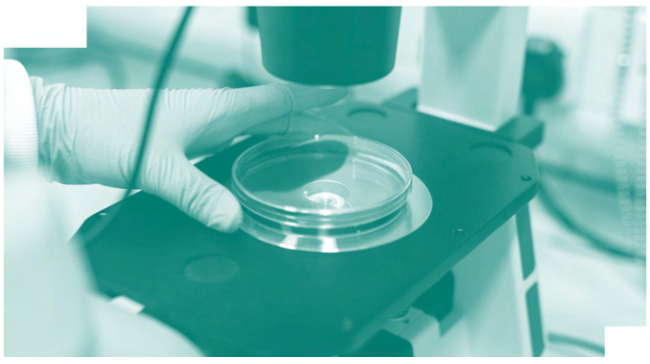
Section 03

New Analysis Since April 2025

After delivering its comprehensive report and action plan to Congress in April 2025, the Commission continued to assess the biotechnology landscape and provide updated analysis in three areas to foster ongoing discussion in Congress and among U.S. biotechnology stakeholders.

This new analyses on *The Future of Science, The Future of U.S.-China Biotechnology Competition,* and *The Future of Biotechnology Regulation* represent observations from the NSCEB, drawn from extensive stakeholder consultations, that may support future policy recommendations.

Staff at the NSCEB authored the following discussion papers with input from NSCEB Commissioners. The content and recommendations of these papers do not necessarily represent positions officially adopted by the NSCEB.



The Future of Science

The NSCEB found clear warning signs that the United States is losing its innovation edge, not only in biotechnology but in science broadly. This discussion paper identifies ways to make the federal government a better partner to industry, philanthropy, and academic institutions to maximize impact and deliver breakthroughs for all Americans.

This discussion paper explores three main topics:

- Making the federal government a better partner in science and technology;
- Enabling autonomous scientific discovery; and
- Unlocking science across America.

Read *The Future of Science* online or in Appendix A.

The Future of U.S.-China Biotechnology Competition

In this discussion paper, the NSCEB assessed that unless the United States takes swift policy action, the CCP's whole-of-government approach to biotechnology will further undercut the U.S. industry, sending jobs, research and discovery, and opportunities for industry growth to China.

Read *The Future of U.S.-China Biotechnology Competition* online or in Appendix A.

The Future of Biotechnology Regulation

The NSCEB launched new regulatory analysis, including 83 policy options to modernize and accelerate U.S. regulatory review of biotechnology products across the federal government.

These papers build on the Commission's April 2025 report to Congress and include 30 government-wide policy options and 53 in-depth policy options across four major product areas—medical products, plants, microorganisms, and animals—to unleash American innovation and support economic and national security.

Read *The Future of Biotechnology Regulation* online or in Appendix A.

Section 04

NSCEB Recommendation Tracker

The NSCEB is driving bipartisan biotechnology policy across the federal government. As of January 1, 2026, biotechnology champions across both chambers of Congress have taken legislative action on 32 provisions that reflect NSCEB recommendations. 21 of those provisions have been signed into law, and the White House has taken executive action on 9 NSCEB recommendations.

Additionally, Commissioner Congresswoman Stephanie Bice (R-OK-05) and Congresswoman Chrissy Houlahan (D-PA-06) launched the Congressional House BIOtech Caucus in June 2025 to drive bipartisan biotechnology policy on Capitol Hill—including NSCEB recommendations—and strengthen bioliteracy among Members of Congress. By the end of 2025, more than 40 members had already joined the Caucus.

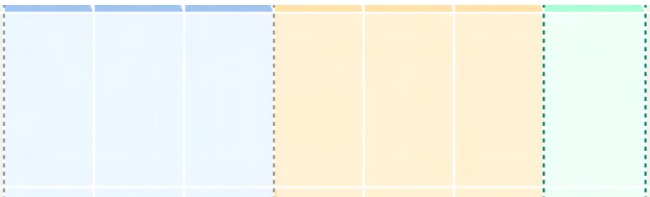
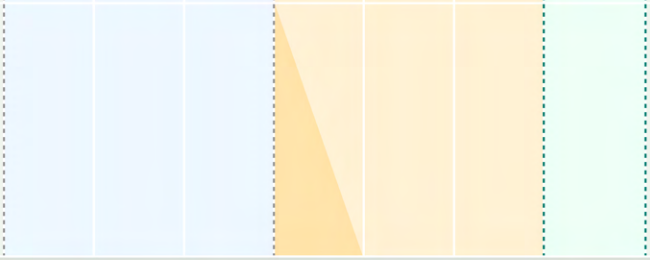
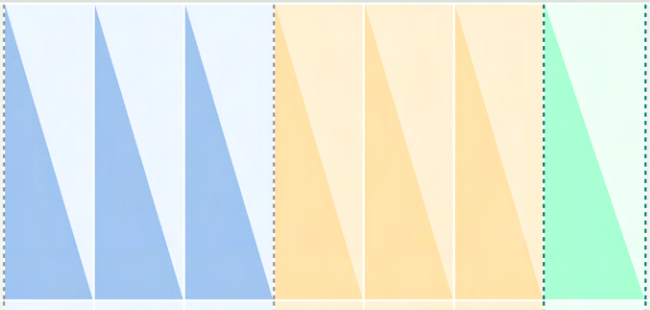
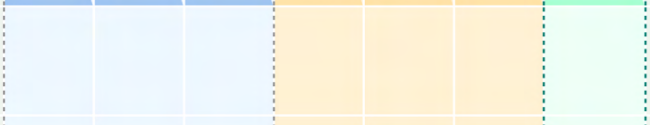
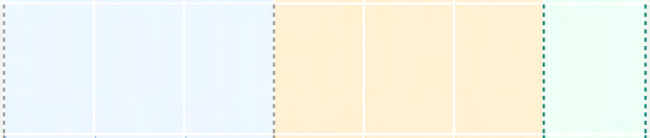
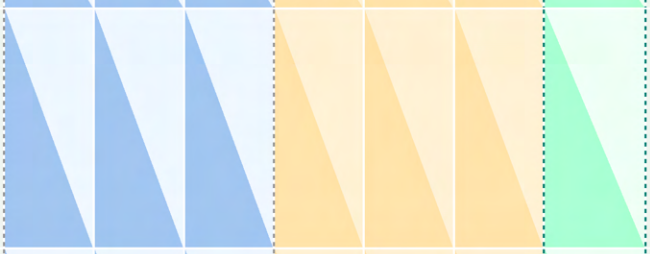
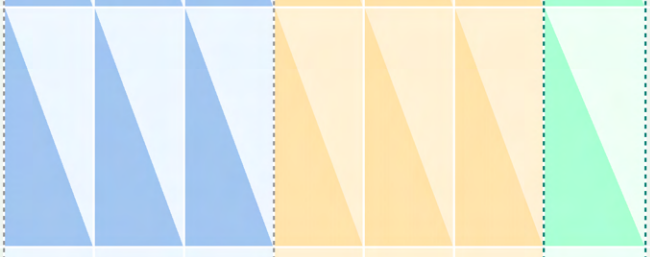
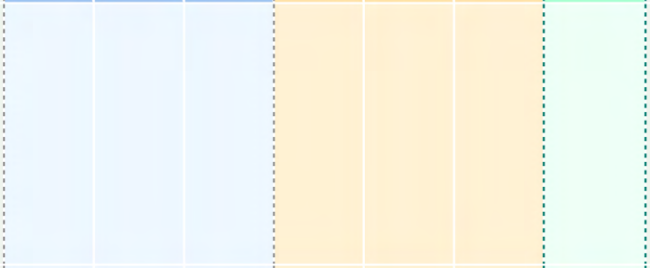
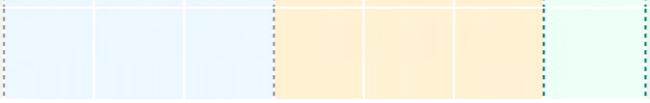
Below is a snapshot of the NSCEB's recommendation tracker as of January 1, 2026. Each row of the tracker shows an NSCEB recommendation, whether there is legislation associated with it, and where those bills are in the legislative pipeline, among other details. The tracker also shows executive branch progress on NSCEB recommendations.

As the NSCEB advances its legislative agenda in 2026, the most current version of this tracker is available online.

NSCEB Recommendation		House			Senate			Signed Into Law	Notes
		Introduced	Committee	Floor	Introduced	Committee	Floor		
Chapter 1									
1.1a	Establish a National Biotechnology Coordination Office (NBCO)	✓			✓				Introduced as the National Biotechnology Initiative Act (S. 1387 and H.R.2756) More
1.2a	Designate senior agency officials to lead biotechnology policy	✓			✓				• Introduced as the National Biotechnology Initiative Act (S.1387 and H.R.2756) • DOD-specific provision included in FY26 NDAA (S.1071) More
1.3a	Establish the Office of Global Competition Analysis								Related provisions included in the National Biotechnology Initiative Act (S.1387 and H.R.2756) More
Chapter 2									
2.1a	Create simple pathways to market and exempt familiar products from unnecessary regulation	✓			✓				Introduced as the National Biotechnology Initiative Act (S.1387 and H.R.2756) More
2.1b	Prepare for novel products to come to market by establishing a Federal biotechnology regulatory research program				✓				Introduced as the National Biotechnology Safety Act (S.2697) More
	Prepare for novel products to come to market by bolstering regulatory agency capacity								Related provision included in the Continuing Appropriations and Extensions Act (H.R.5371) More
	Prepare for novel products to come to market by establishing a foundation to enable biotechnology innovation				✓				Introduced as the Foundation for Enabling Biotechnology Innovation Act (S.2696) More
2.2a	Establish an Independence Investment Fund	✓							Introduced as the Independence Investment Fund Act (H.R.6412) More
2.2b	Use advance market commitments and offtake agreements (DOE)	✓	✓	✓	✓	✓	✓	✓	Included in the Senate Appropriations Energy and Water Development Act (S.3293) report language More
	Use advance market commitments and offtake agreements (HHS)								
2.2c	Restore full expensing of research and development (R&D) expenditures	✓	✓	✓	✓	✓	✓	✓	• Introduced as American Innovation and Jobs Act (S.1639) • Included in the One Big Beautiful Bill (H.R.1, sec. 70302)
2.2d	Improve the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs								
	Develop a network of								

2.3a	manufacturing facilities for precommercial bioindustrial product scale-up (DOE)								
	Develop a network of manufacturing facilities for precommercial bioindustrial product scale-up (DOC)								
2.3b	Create a biopharmaceutical manufacturing center of excellence	✓			✓				Introduced as the Biomanufacturing Excellence Act (S.3188 and H.R.6089) More
2.4a	Ensure that the biotechnology sector is protected as "critical Infrastructure"								
	Ensure that sensitive biological data is protected as "critical Infrastructure"								
2.5a	Require public companies to disclose single points of supply chain vulnerability located in foreign countries of concern								
2.5b	Prohibit companies that work with U.S. national security agencies and HHS from using certain Chinese biotechnology suppliers	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
2.5c	Reform the Committee on Foreign Investment in the United States (CFIUS)								• Related provision included in FY26 National Defense Authorization Act (S.1071) • Reflected in Presidential Memorandum "America First Investment Policy" More
2.5d	Direct the International Trade Commission (ITC) to investigate Chinese dumping of biotechnology products and services	✓	✓	✓	✓	✓	✓	✓	Included in the Senate Appropriations Committee Commerce, Justice, Science, and Related Agencies Appropriations Act 2026 report language (S.2354) More
Chapter 3									
3.1a	Define principles for ethical use of biotechnology for the U.S. military	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
3.2a	Build commercial facilities across the country to biomanufacture defense products	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
3.2b	Support BioMADE's efforts	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
3.2c	Change military specifications (MIL-SPECs) to more easily sell biotechnology products to the DOD	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
	Enter into advance								Included in FY26 National Defense Authorization Act (S.1071)

3.2d	market commitments (AMCs) and offtake agreements for defense biotechnology products	✓	✓	✓	✓	✓	✓	✓	More
3.2e	Train the national security workforce for biotechnology	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
3.3a	Require outbound investment rules to ensure that U.S. capital does not support Chinese development of certain biotechnologies								
3.3b	Consider country-wide export controls blocking the sale of specific U.S. biotechnology items to China								
3.3c	Incorporate emerging biotechnology into DOD wargaming exercises	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
3.3d	Prioritize understanding adversaries' development of biotechnology	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
Chapter 4									
4.1a	Create a Web of Biological Data (WOBD)								Reflected in Executive Order 14363 "Launching the Genesis Mission"
4.1b	Create standards so U.S. biological data is ready for use in AI models								• DOD-specific provision included in FY26 National Defense Authorization Act (S.1071) • Reflected in White House AI Action Plan More
4.1c	Create a Sequencing Public Lands Initiative								Reflected in White House AI Action Plan
4.1d	Establish a network of "cloud labs"				✓				• Introduced as the Cloud LAB Act (S. 2676) • Reflected in National Programmable Cloud Laboratories Network Act (S.3468) • Reflected in White House AI Action Plan • Recommendation referenced in NSF solicitation (NSF 25-541: Test Bed: Toward a Network of Programmable Cloud Laboratories) More
4.2a	Ensure that China cannot obtain bulk and sensitive biological data from the United States								
4.3a	Establish Centers for Biotechnology within the existing National Laboratory network								Reflected in Executive Order 14363 "Launching the Genesis Mission"
4.3b	Initiate a grand research challenge focused on making biotechnology predictably engineerable								• DOD-specific provision included in FY26 National Defense Authorization Act (S.1071) • Reflected in Executive Order 14363 "Launching the Genesis Mission" More

4.3c	Initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive		Reflected in Executive Order 14363 "Launching the Genesis Mission"
4.4a	Advance safe, secure, and responsible biotechnology research and innovation		• Reflected in Biosecurity Modernization and Innovation Act (S.3741) • Reflected in White House AI Action Plan • Reflected in Executive Order 14292 "Improving the Safety and Security of Biological Research" More
Chapter 5			
5.1a	Provide workforce training in biotechnology across the interagency		• DOD-specific provision included in the FY26 National Defense Authorization Act (S.1071) • USDA-specific provision included in the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction, and Veterans Affairs Extensions Act (H.R.5371) More
	Develop a national biotechnology workforce framework		
	Conduct an interagency assessment of biotechnology workforce needs		
	Establish guidance for hiring and public-private talent exchange		DOD-specific provision included in the FY26 National Defense Authorization Act (H.R.4776) report language More
5.1b	Ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues by initiating security clearances for additional biotech personnel		Intel-specific provision included in FY26 National Defense Authorization Act (S.1071) More
	Ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues by maintaining bench of experts with security clearances		Intel-specific provision included in FY26 National Defense Authorization Act (S.1071) More
	Ensure that federal agencies have the necessary expertise across national security and emerging biotechnology issues by expanding the number of biotech professionals in the Department of State		
	Ensure that federal agencies have the necessary expertise		

	across national security and emerging biotechnology issues by training U.S. diplomats on biotechnology								
5.1c	Ensure Congress receives accurate, timely, and nonpartisan scientific and technical counsel by codifying GAO's Science, Technology Assessment, and Analytics (STAA) office								
	Ensure Congress receives accurate, timely, and nonpartisan scientific and technical counsel by establishing the Office of the Congressional Science and Technology Advisor (OCSTA)								
	Ensure Congress receives accurate, timely, and nonpartisan scientific and technical counsel by establishing a standing Congressional Commission on Responsibility and Ethics in Innovation (CREI)								
5.2a	Maximize the impact of domestic biomanufacturing workforce training programs by expanding existing training programs	✓	✓	✓	✓	✓	✓	✓	DOD-specific provision included in the House Defense Appropriations Act of 2026 (H.R. 4016) report language More
	Maximize the impact of domestic biomanufacturing workforce training programs by standardizing biomanufacturing skills and accreditation								
5.2b	Expand educational efforts in biotechnology for American students by supporting student-to-career pathways								
	Expand educational efforts in biotechnology for American students by creating a Biotechnology Scholarship for Service program								DOD-specific provision included in the FY26 National Defense Authorization Act (H.R.4776) report language More
	Expand educational efforts in biotechnology for American students by strengthening high school biotechnology education								DOD-specific provision included in the FY26 National Defense Authorization Act (H.R.4776) report language More
5.3a	Authorize new green cards for biotechnology talent, especially from allied and partner countries								
5.3b	Optimize the vetting process for foreign								

	nationals to prevent illicit technology transfer								
Chapter 6									
6.1a	Include biotechnology in the scope of the International Technology Security and Innovation (ITSI) Fund								
6.1b	Promote the U.S. biotechnology industry in foreign markets								
6.1c	Expand regulatory diplomacy for biotechnology								
6.1d	Form reciprocal biological data-sharing agreements with other countries								
6.1e	Encourage North Atlantic Treaty Organization (NATO) countries to aggregate demand and pool purchasing power for biotechnology products	✓	✓	✓	✓	✓	✓	✓	Included in FY26 National Defense Authorization Act (S.1071) More
6.2a	Support the development of international norms and standards, including defining shared values and interests in biotechnology	✓			✓				Included in the National Biotechnology Initiative Act (S.1387 and H.R.2756) More
6.2b	Create a strategy for harmonizing multilateral export controls								

Section 05

Looking Ahead to 2026 and Beyond

Message from the Executive Director

As the Commission prepared to launch our final report and action plan last year, we knew 2025 would be pivotal. Some shifts were predictable—a change in the U.S. Administration, a new Five-Year Plan from the CCP, and the relentless pace of biotech discovery. Other successes were hoped for but never guaranteed: namely, the warm reception of the NSCEB's work and the pace and significance of legislative progress we've made in less than a year.

Since the materials scientists among us haven't yet fashioned a functioning crystal ball, we will leave the long-range forecasting to others. However, one thing is certain: 2026 will be a defining year for biotechnology policy in the United States.

The decisions made in the coming months will likely dictate the next several decades of American bio-innovation. The question remains: will policymakers take the decisive action necessary to retain—or in some cases, regain—U.S. leadership in this critical field?

The answer depends on you.

The Commission's work stands on decades of effort from the organizations and individuals who preceded us. Our goal has been to catalyze that foundation of expertise into a unified purpose and

to bridge the “bioliteracy” gap among policymakers.

By design, the Commission’s statutory authority sunsets at the end of 2026. We are immensely proud of the momentum we have built since April, and we intend to run through the tape. But we cannot achieve our ambitions without deepening and broadening this coalition.

If you have been waiting for the right moment to get involved, this is your sign. And if you have been with us since the beginning, thank you for your steadfast partnership.

We have 10 months to turn recommendations into reality and ensure that the future of biotechnology is defined by American values and ingenuity. Let’s get to work.

Caitlin Frazer
Executive Director

Section 06

About the Commissioners

Established as part of the 2022 annual defense authorization bill (FY22 NDAA) the National Security Commission on Emerging Biotechnology (NSCEB) was given a clear and urgent mandate: to conduct a comprehensive review of emerging biotechnology's impact on national security and provide practical recommendations to preserve American dominance in this field.

The NSCEB is an independent commission currently comprised of 11 commissioners appointed by a bipartisan group of Members of the House and Senate. We include four Members of Congress—two from each chamber, and two from each party—and seven prominent industry leaders, academic experts, and former government officials from the defense and intelligence communities.

Our work is short-term in nature. Our directive is to provide recommendations and support their implementation, after which point this Commission will dissolve (December 2026).

NSCEB Commissioners

Senator Todd Young
(R-IN) Chair

Dr. Michelle Rozo
Vice Chair

Senator Alex Padilla
(D-CA)

Representative Stephanie Bice
(R-OK)

Representative Ro Khanna
(D-CA)

Paul Arcangeli

Dr. Angela Belcher

Dawn Meyerriecks

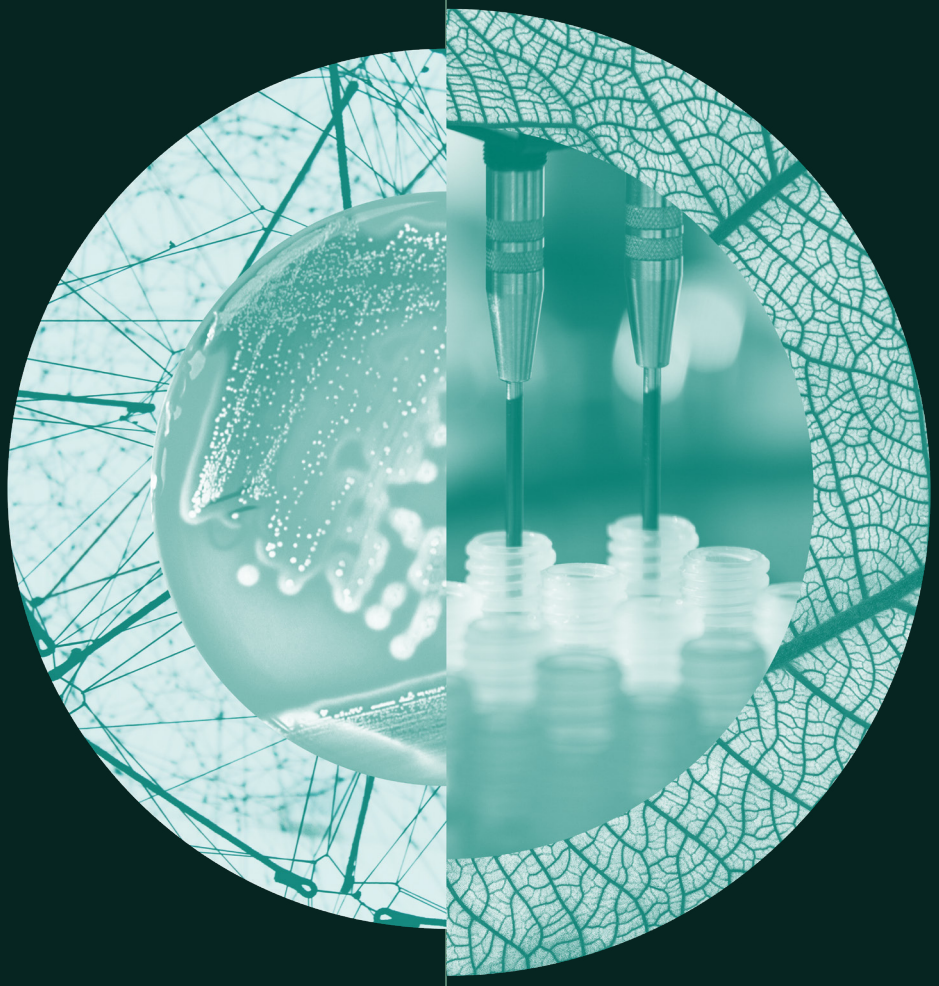
Dr. Eric Schmidt

Dr. Alexander Titus

Dr. Dov Zakheim

NSCEB
National Security Commission on Emerging Biotechnology

NOVEMBER 2025



The Future of Science

A Playbook for Accelerating American Innovation

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The Future of Science: Modernizing the U.S. Scientific Enterprise

American leadership in scientific innovation is no longer guaranteed. While U.S. funding stagnates and researchers are bogged down in complex funding application processes, China is doubling down on science, racing to position itself as the innovation engine of the world. This is an ideal moment to reimagine the federal science enterprise. Leveraging major advances in artificial intelligence (AI) and automation while pushing against the status quo could move science forward. If we change the way that we think about and fund innovation, we could generate more impact and deliver breakthroughs for all Americans.

After engaging with thousands of scientists, business executives, academic leaders, philanthropists, and government officials across the country, the National Security Commission on Emerging Biotechnology (NSCEB) found clear warning signs that the United States is losing its innovative edge, not only in biotechnology but in science more broadly. We heard calls for change; we also heard suggestions that have been circulated in the scientific community for some time. Now is the time to listen and take action.

This paper series builds on the Commission's April 2025 report with additional analyses and specific policy options to secure the United States' long-standing global leadership in scientific innovation.[1] These papers focus on how to position the United States to lead at the convergence of increasingly automated, AI-powered scientific discovery, allowing us to be more efficient with taxpayer dollars, reducing overhead costs and administrative burdens, and distributing the benefits of science across all corners of the United States.

An outdated innovation ecosystem

For the past 80 years, the United States has led the world in science and technology innovation. Though home to only 5 percent of the world's population, the United States accounts for roughly 30 percent of global spending on research and development (R&D), the most of any one country.[2] For decades, this has translated into the United States being the headquarters of the world's most valuable tech companies and nearly half of the world's biopharmaceutical companies.[3] In short, this research delivers for Americans.

But after more than 20 years of steady growth, Chinese scholars now publish a larger fraction of the top 1 percent most-cited papers globally than scientists from any other country.[4] Through targeted investments, China now leads or is on par globally in commercial nuclear power and electric vehicles and batteries.[5] Additionally, China is making a substantial investment in AI and autonomous science to accelerate innovation.[6]

The United States must now adapt the way it funds and performs science research to maintain and extend its lead. To start, the federal government is one of the most challenging partners to work with because:

- Grant processes are overloaded with administrative and regulatory burdens;
- Federal research databases are poorly maintained; and
- Government agencies struggle to communicate clearly, move quickly, or take necessary risks.

At the same time, automation and AI are rapidly changing the way researchers experiment and innovate. Automation helps improve standardization, reproducibility, speed, and cost, and AI helps researchers leverage data in previously unimaginable ways. This modern approach to discovery will deliver rapid technological advances. Here in the United States, companies are cropping up weekly at the intersection of AI, automation, and scientific discovery, but the federal government is not yet acting like the catalyst it should be.

Further, for too long, U.S. scientific discovery has been an endeavor that is often only open to those considered well-credentialed at certain institutions. Individuals in every part of the country are closest to the problems in their communities, and they should have the tools and federal support to use science to solve them. A stronger scientific ecosystem means making it easier for more Americans, no matter where they live or who they are, to participate in science and reap the benefits of the investments their tax dollars make possible.

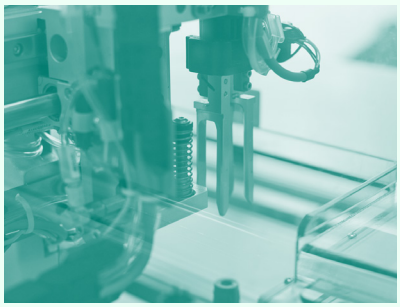
> The United States is losing its innovative edge, not only in biotechnology but in science more broadly.

Defining a New Approach to American Innovation

In this new paper series, the Commission offers actionable policies for the federal government to keep—and extend—America's lead in innovation.

These policies span three categories:

Making the Federal Government a Better Partner in Science and Technology



Enabling Autonomous Scientific Discovery

Unlocking Science Across America

The underlying theme of these policies is simple: the federal government must reform its approach to science funding to maximize and encourage industry and philanthropies to co-invest in U.S. science.

To this end, this series identifies ways that the federal government can make the down payment for the infrastructure of the scientific ecosystem—from cutting-edge research facilities to modern data infrastructure—that individual colleges or small companies cannot finance on their own. These targeted federal reforms would open the door for broader collaboration, accelerate scientific progress, and increase investments by the private sector. This would allow the government to maximize the impact of taxpayer dollars.

The policy options outlined here recognize the federal government's unique role in funding basic research. This type of research, driven by curiosity and not tied to immediate commercial outcomes, is the foundation of nearly all modern technologies. Federally funded investments to understand DNA, atomic structure, and abstract math have led to cancer treatments, nuclear energy, and modern computing.[7] These advances were made possible because the U.S. government was willing to invest in research with long timelines and uncertain outcomes, which private industry often cannot. Continued support for basic research is essential to ensuring future breakthroughs that improve the health, safety, and economic well-being of all Americans.

A modern scientific ecosystem also requires thoughtfully retooling existing federal programs into more innovative and efficient ways of funding science. Updating the funding process would make research more efficient and impactful.

The funders and performers of research in the United States today mainly operate independently, with little visibility on each other's goals and outcomes. The federal government can reposition itself as the coordinator and catalyst for burden-sharing and collaboration among funders.

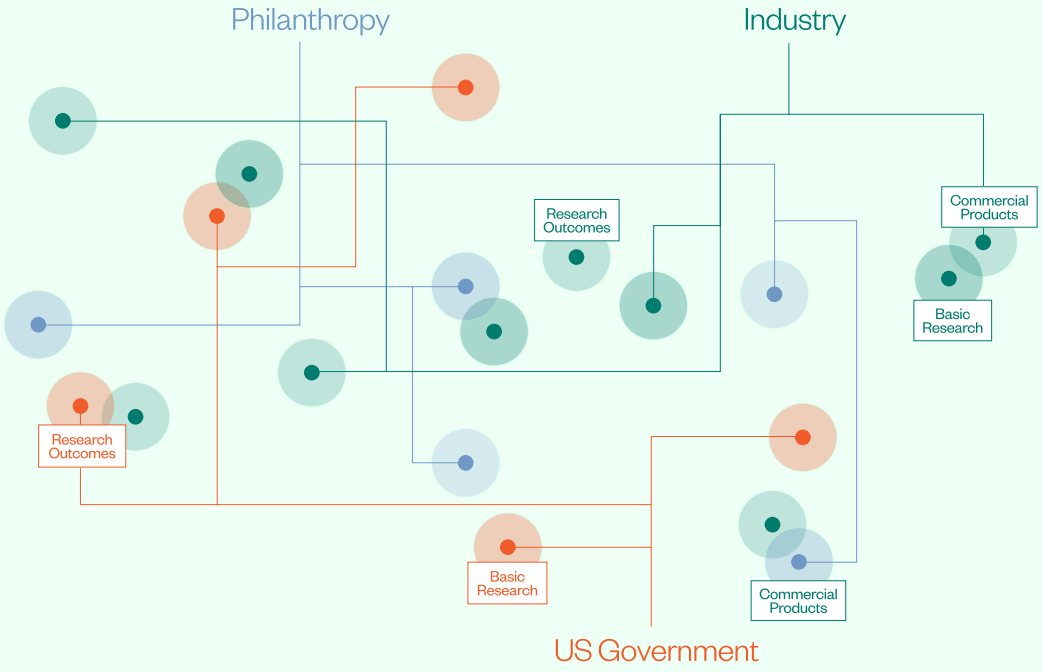
Strengthening the United States' commitment to scientific discovery requires a modernized scientific ecosystem, one that fosters collaboration across sectors and directs funding toward high-impact research. Now is the time to secure the future of science and ensure that the American people enjoy greater prosperity, better health, and increased safety for generations to come.

A Collaborative Approach to Funding Science

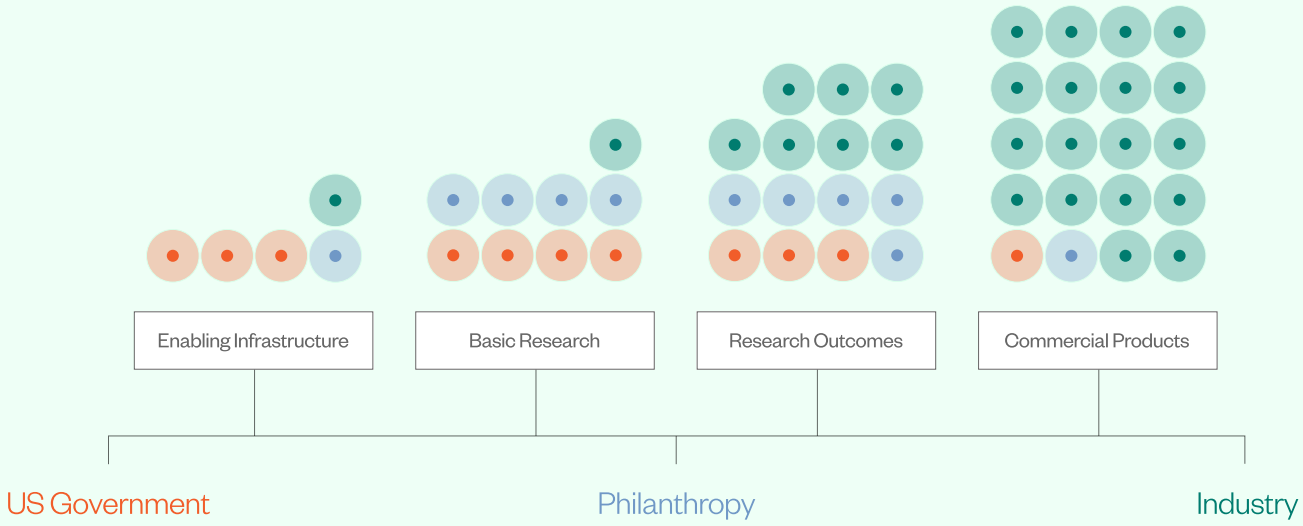
If the U.S. government acts as a better partner by convening funders and providing initial resources for enabling infrastructure for the innovation ecosystem, then the benefits of research and innovation will be more widely felt across the population and taxpayers will experience greater return on their investment.

US Government Philanthropy Industry

Current: Dispersed Efforts



Goal: Coordinated Strategy

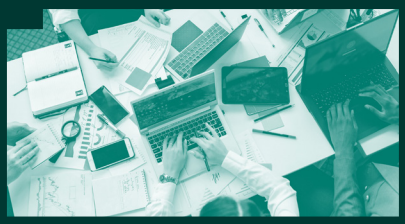


Making the Government a Better Partner in Science and Technology

Scientific and technological innovation is more complicated, interdisciplinary, and diffuse than any time in the past. How the federal government funds and supports research shapes scientific discovery in academia, philanthropy, and industry. But funding opportunities are complex for researchers to navigate; many of the government's funding systems rely on outdated measures of success and are weighed down by layers of administrative and regulatory requirements.

The federal government must make strategic changes by updating both how scientists apply for federal research funding and how federal science agencies evaluate research ideas. It must also rebalance existing funds between effective, traditional funding mechanisms and novel ones. These new mechanisms would encourage innovation and establish important infrastructure that would unlock collaboration and investments from the private sector.

This paper offers policy options around three main goals for the U.S. government to be a better partner in science and technology:



Streamline the funding application process

Offer new ways of evaluating proposed research

Use novel funding mechanisms to open up collaborations with the private sector

1.1

Streamline the Funding Application Process

Scientific researchers at universities report that they spend over 40 percent of their time on administrative tasks, time that could otherwise be spent on research.[8] Several entities, including the White House, have called for streamlining these application and reporting requirements.[9] Removing bureaucratic hurdles in the research funding process will free scientists to spend more time on research, rather than paperwork.

Streamlined grant proposals

Federal science agencies should comprehensively review their grant solicitations to streamline the application process, identifying and eliminating unnecessary regulations and reporting requirements. While funding applications should still explain key aspects of the research project such as feasibility, potential impact, and the plans to spend the money, agencies should consider removing components of applications such as duplicative budget justifications, excessive progress reporting, and documentation requirements that are not essential to assessing the quality or outcomes of the research.

An interoperable funding application process

The federal government should have a single platform for submitting scientific funding applications. Such a platform would increase efficiency by allowing researchers to more easily apply for different funding opportunities with fewer applications. This could also enable funding agencies to share and view unfunded proposals from other agencies without requiring scientists to rewrite their proposed project ideas.

Greater transparency around federal funding priorities

Federal science agencies should provide detailed information about their planned research priorities to funding applicants. Government funding agencies must eliminate uncertainty by communicating their scientific interest areas, how much they plan to fund in specific research areas, and the funding mechanisms they plan to use. This information would help federal funding agencies, industry, and philanthropy deduplicate funding priorities and find areas for collaboration.

A modern scientific ecosystem also requires thoughtfully retooling existing federal programs into more innovative and efficient ways of funding science. Updating the funding process would make research more efficient and impactful.

1.2

Offer New Ways of Evaluating Proposed Research

The typical federal grant review process has historically relied heavily on outdated metrics of success, such as how many publications a scientist has; it does not adequately measure potential impact, and it favors well-established researchers working in well-resourced institutions.[10] The United States must reimagine how scientists and their ideas are evaluated to enable a future of science that emphasizes the importance of data, interdisciplinary research, and bold ideas.

New incentive structures and metrics of success

Metrics of successful research should deemphasize how many publications a researcher accrues, the prestige of the institution at which they work, and the journals in which they publish. Instead, federal science agencies should make other metrics more prominent, such as high-quality data generation and reproducibility, evidence of cross-disciplinary collaboration, novelty of tools or techniques discovered, products or technologies patented or commercialized, and the quality of mentorship the researcher provides.

Additionally, funding agencies should incorporate different mechanisms to emphasize these new metrics and pave the way for funding potential breakthrough science. These include: "golden ticket" opportunities where each reviewer can select one or more proposals for funding that they believe will be high-impact, regardless of how other reviewers scored the proposals; the inclusion of scientific generalists on review panels; or rewarding the potential impact of the science, rather than focusing on its feasibility.[11]

Eliminating preliminary data in grant proposals

Federal science agencies should remove or minimize considerations of preliminary data from funding review criteria and look for other ways to establish feasibility. Institutions such as the National Institutes of Health (NIH) effectively require that researchers prove that their research already works by asking for preliminary data in grant applications. This requirement skews funding toward well-established labs or labs proposing research that represents incremental progress, while disadvantaging scientists who propose novel, paradigm-shifting research.[12] Some agencies, such as the Defense Advanced Research Projects Agency (DARPA), do not require preliminary data to establish the feasibility of a project and more should move in this direction.

Deploying artificial intelligence (AI) to assist with science funding

Federal science agencies should collaboratively build models that monitor the world of scientific discovery and propose novel or emerging areas of science. Additionally, all agencies should consider how to use AI to complement the human review process. For example, federal science agencies could employ AI models to scan submitted proposals and provide suggestions of potential breakthrough ideas, identify funding overlaps, and increase review efficiency.

1.3

Use Novel Funding Mechanisms to Open Up Collaborations with the Private Sector

The classic scientific funding model of one academic lab receiving one grant to work on one project no longer reflects how innovation happens today. Many breakthroughs have occurred through bigger-picture, cross-sector efforts, involving government researchers, businesses, and universities. While agencies such as the Advanced Research Projects Agencies (ARPAs) have shown how federal investment can accelerate high-risk, high-reward research, more must be done to increase public-private sector collaboration. This includes incentivizing research efforts that are designed to translate into real-world products, services, or technologies.

Research-to-commercialization projects

Federal science agencies should develop programs that connect existing funding mechanisms together so that interdisciplinary teams of scientists, technologists, and entrepreneurs can apply to a single program to move their ideas from basic science concept to product commercialization. Current funding models might fund one or two stages of this process, leaving researchers struggling to find new funding for the following stages while good ideas stall. These programs would leverage more flexible federal funding mechanisms, such as Other Transactional Authorities (OTAs), to help fill gaps. These programs could have gating mechanisms at different technology readiness levels (TRLs) to unlock new allocations of money, culminating in business loans to assist with commercialization.

Quick-decision funding mechanisms

Federal science agencies should establish more quick-decision funding mechanisms—such as rapid funding for time-sensitive opportunities—that have short applications, rapid review windows, and quick final decisions.[13] Federal agencies need to be able to quickly fund and begin research on important, time-sensitive ideas.[14] All departments and agencies should employ these mechanisms regularly to ensure opportunities for fast turnaround research funding.

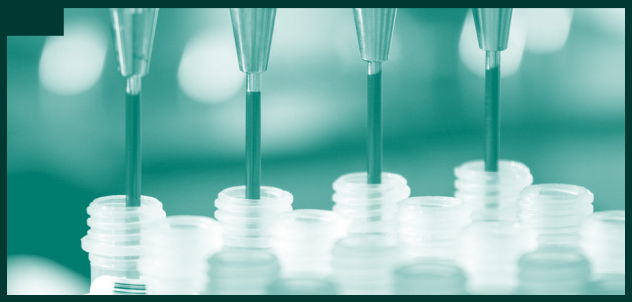
Burden sharing for scientific research

Federal science agencies should design funding opportunities to encourage private fund matching. The topics and goals of these opportunities would be designed in agreements between the government and the private sector, with input from relevant researchers. This matching process would encourage government, industry, and philanthropic donors to better align funding priorities and efforts, allowing the private sector to burden share with the government and maximize returns on large-scale research projects.

Enabling Autonomous Scientific Discovery

Scientific discovery is transforming as artificial intelligence (AI), robotics, high-performance computing, and automation converge to accelerate the scale and pace of research. These frontier technologies will transition scientific experimentation from a largely hands-on manual process into an automated one, where AI-driven robots can run thousands of experiments in a fraction of the time with high reproducibility. Realizing this potential requires targeted federal actions to develop these technologies, empower scientists to adopt them, and crowd-in private and philanthropic investment in their development and adoption.

Today, scientists spend most of their time manually conducting experiments, repeating and refining them step by step. Two emerging technologies are fundamentally changing that dynamic:



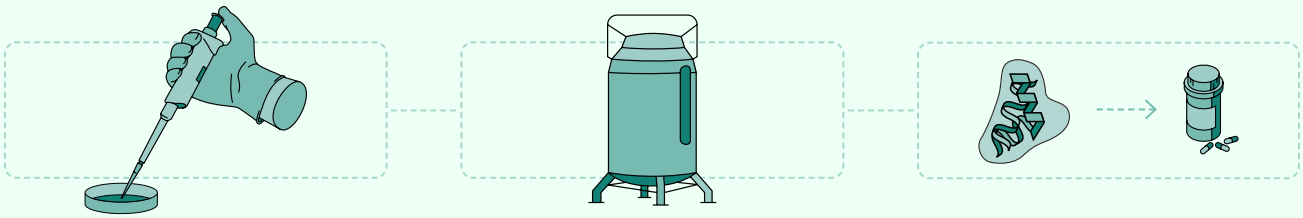
Automated laboratories
Automated labs use robotics, computers, liquid handling systems, and other advanced technologies to run scientific experiments based on scientists' direction. Many industries, such as the biopharmaceutical sector, already rely on automation to run large-scale experiments.

Autonomous laboratories
Instead of requiring scientists to specify each step, autonomous labs take a more open-ended prompt or a specific end-goal and use AI and robotics to design and run experiments. The lab then analyzes the results and iterates on the process until achieving that specific end goal, all with minimal human intervention.

Biotechnology Innovation of Today

Years to decades

$$$
Billions of dollars



Manual Experimentation → Scale-up → Commercialization

Biotechnology Innovation of Tomorrow

Days to months

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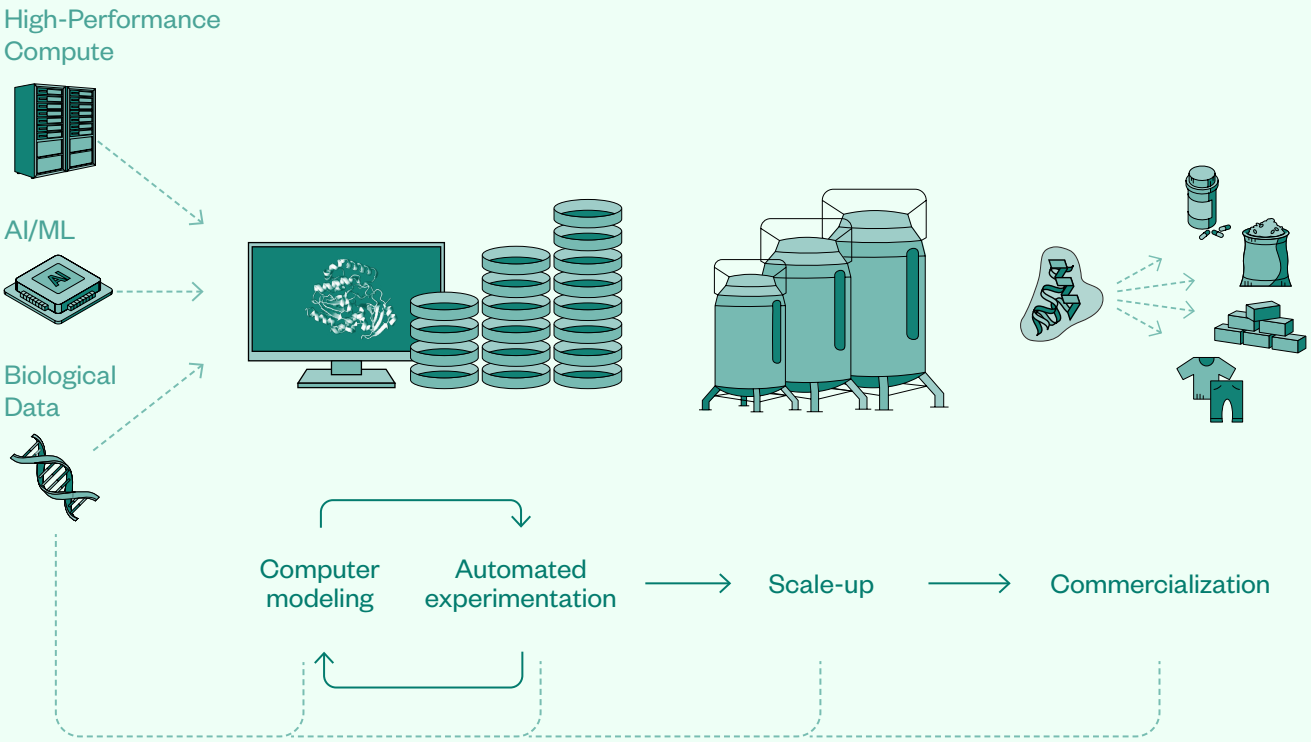
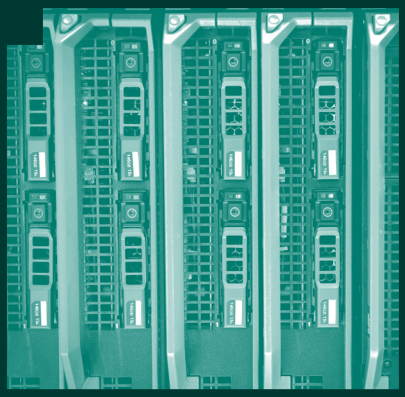
Thousands of dollars



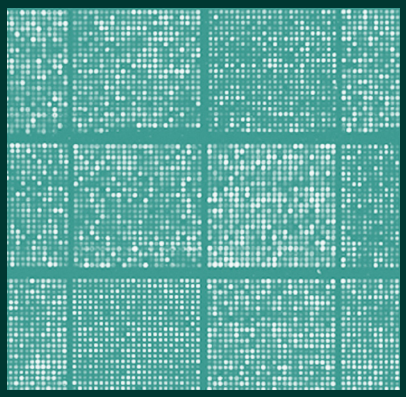
Despite the immense potential of these new automated research technologies, current federal policies do not sufficiently enable their adoption. There are insufficient data and data systems, an outdated research infrastructure, and a lack of incentives for scientists to embrace these technologies.

To realize a future where U.S. science accelerates through automated and autonomous research capacity, the federal government must make targeted investments in the country's underlying data infrastructure. With this infrastructure in place, alongside policy recommendations that drive data collection and remove barriers to infrastructure access, the United States can position academia, industry, and philanthropy to more efficiently and effectively advance a new age of scientific discovery.

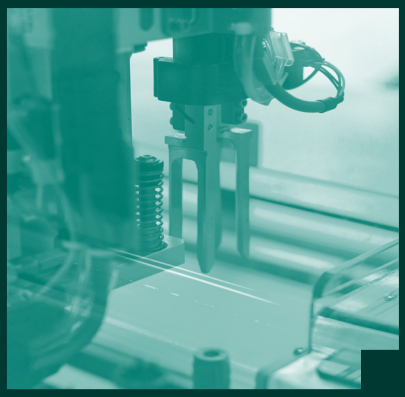
This paper offers policy options to achieve the following three goals:



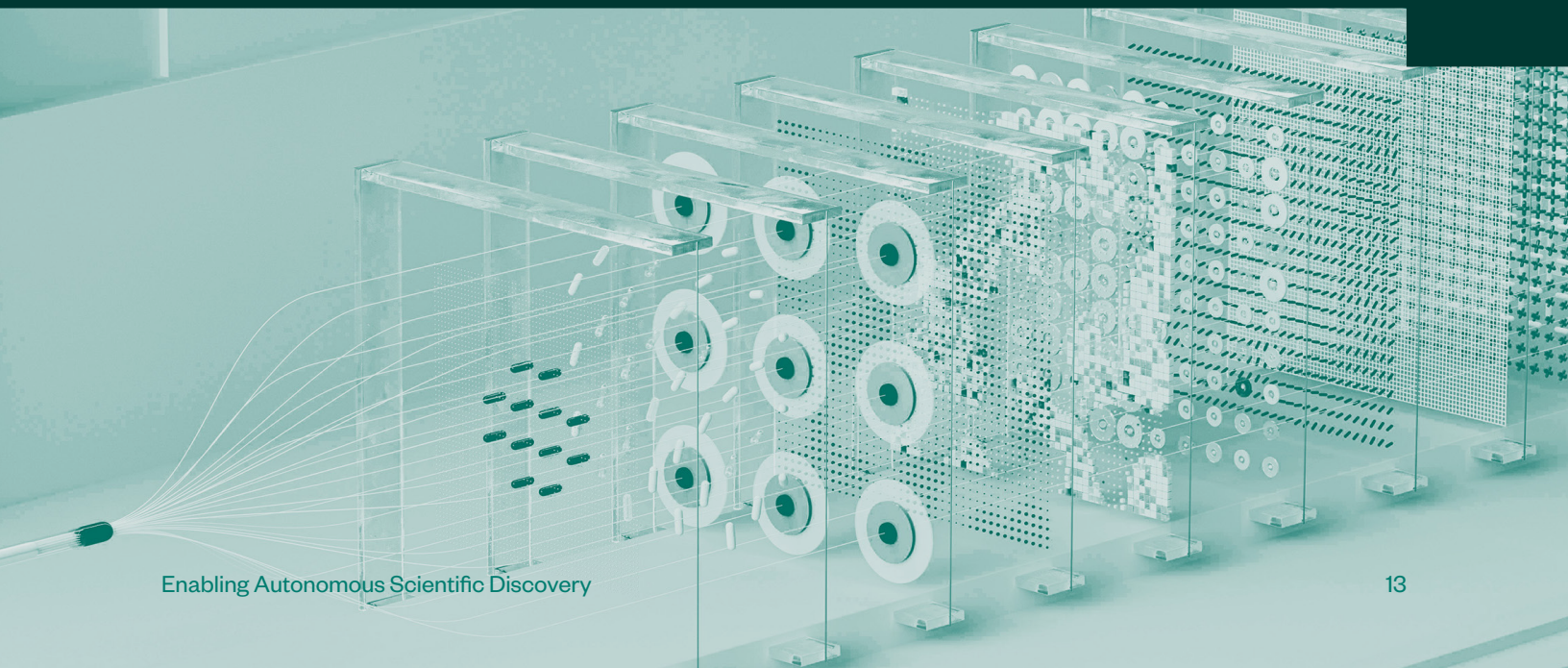
Modernize U.S. research infrastructure



Generate more high-quality training data



Create collaborative, technology-enabled research ecosystems



2.1

Modernize U.S. Research Infrastructure

Despite the increasing importance of high-quality data for discovery, the underlying digital infrastructure that would allow scientists to handle large datasets does not exist, meaning the scientific community cannot effectively share, store, and use research data. The United States must make strategic investments to modernize its underlying data infrastructure. Building on an April 2025 Commission recommendation to create a "Web of Biological Data", a single-point-of-entry to all federally funded biological data resources, the U.S. government must make a robust initial investment in American research infrastructure. With this infrastructure, researchers across sectors would be able to:

- More effectively share data;
- Enable more data collection to power autonomous labs; and
- Incentivize research investments from academia, industry, and philanthropy to develop more powerful AI tools.

Modernizing data and computing architecture

The federal government should continue ongoing, and initiate new, partnerships with the private sector to fund and develop computational and data infrastructure that supports the full data lifecycle—from generation and analysis to long-term storage and reuse. While the government produces vast amounts of scientific data, much of it remains underused due to fragmented storage and inconsistent management practices. The newly planned Department of Energy (DOE) supercomputers with NVIDIA, Oracle, and AMD represent critical investments in computational power to drive AI and scientific discovery. To realize their full value, Congress should invest in scalable, hybrid data infrastructure—combining secure government data facilities with cost-efficient commercial cloud resources. Establishing a federal data lifecycle fund to preserve the lifespan of data beyond individual grants, as well as aligning agency standards, and cloud partnerships along an interoperable ecosystem, would maximum the usability of taxpayer-funded scientific data and the return on public investment.

Requirement for depositing data

Federal science agencies should require that researchers deposit their research data and related information into the systems as described in the previous recommendation as a condition of federal funding. This is a requirement of most federal funding already, but agencies rarely enforce it and the government lacks a repository for the data. Additionally, these requirements should be updated to better capture a holistic picture of the data that researchers generate—including the context, thought processes, and experiential knowledge not captured in traditional published papers. Agencies should also direct researchers to share more comprehensive research outcomes as a condition of federal funding, including negative results.

Dedicated funding for compute

Federal science agencies should fund compute access and data storage as a standardized and separate allocation of money in science funding proposals. Currently, if researchers need to purchase expensive compute and data storage for their research, those dollars must come out of their total funding allocation. With a shift toward more data- and computation-intensive research, standardizing and separating compute funding would allow researchers to advance their AI and advanced computational capabilities without reducing funding for other needs.

2.2

Generate More High-Quality Training Data

AI-powered autonomous labs require vast amounts of high-quality training data including data that scientists typically do not publish, such as negative results. Directed federal policies would require scientists to release a broader range of high-quality data that could be used in autonomous labs.

Comprehensive research data, including negative results

When researchers publish results, they often present polished stories that omit unsuccessful experiments—data that are invaluable for other scientists and for training AI models for autonomous labs. To increase publication of these negative data, federal agencies should consider researchers' history of releasing high-quality positive and negative data as a success metric in grant review processes and prioritize funding for applicants with demonstrated data-sharing track records. This should be adapted into requirements, as described above.

NIST-led standards for machine-readable research data

Building on an existing April 2025 Commission recommendation to promote AI-ready biological data (Recommendation 4.1b), the National Institute of Standards and Technology (NIST) should collaborate with the private sector to develop standards for AI-ready research data to promote data interoperability and sharing. These standards should be used when depositing data into the comprehensive data repositories described in the recommendation above. These standards would make research-related data machine-readable and include important contextual information, such as experimental workflows.

Digitizing existing biological datasets

Congress should establish cost-sharing partnerships between the government and the private sector to digitize biological samples, which would bolster the amount of scientific data available for research and ensure broader scientific access to such data. Following the model of industry partners such as Regeneron and GSK's partnership with the UK Biobank, U.S. industry partners would contribute funding and technical expertise to help with data digitization in exchange for limited periods of exclusive access to the collected data.[16]

The United States could implement such a program to unlock the data from biological samples held by federally funded programs, such as the Joint Genome Institute, the National Institute of Health's (NIH) All of Us program, and the Department of Veteran Affairs' (VA) Million Veteran Program (MVP), which currently lack adequate resources to make data widely and securely available to researchers.

Comprehensive clinical datasets for AI training

Federal agencies, such as the NIH and the Food and Drug Administration (FDA), should collaborate with academia and industry to curate and centralize clinical datasets. These datasets could include de-identified electronic health records, health outcomes, lab values, images, and negative results from failed trials. These comprehensive datasets would better train AI models that could inform future clinical trials. These data would also give researchers a better understanding of why certain clinical trials succeeded or failed and how to improve clinical trials in the future.

2.3

Create Collaborative, Technology-Enabled Research Ecosystems

Researchers face consistent barriers, such as cost or exclusivity, when seeking access to the newest autonomous technologies or AI capabilities. Removing these barriers would enable novel research, especially where computational modeling and robotic experimentation could drive faster discovery with less hands-on experimentation.

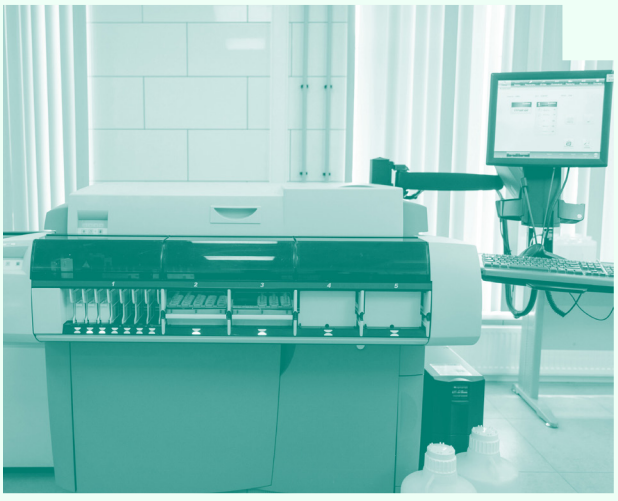
Federal partnerships to expand open-access AI tools

Federal departments and agencies should negotiate broader open-access provisions in federally funded AI systems. This could include requirements that AI tools developed under federal grants and contracts include open-access components, research-use exemptions, and ensure that academic institutions and nonprofit organizations have access.

"Lab of the Future" grand challenge

Federal science agencies should establish a grand challenge, in collaboration with the private sector, to advance the convergence of AI, robotics, and automation for physical lab infrastructure. Part of the funding should provide targeted investments in autonomous lab infrastructure and emerging AI-robotics systems. The resulting, underlying instrumentation and methodologies built through such a grand challenge would open opportunities to a wide range of researchers to use these technologies and advance science more efficiently.

With this infrastructure in place, alongside policy recommendations that drive data collection and remove barriers to infrastructure access, the United States can position academia, industry, and philanthropy to more efficiently and effectively advance a new age of scientific discovery.



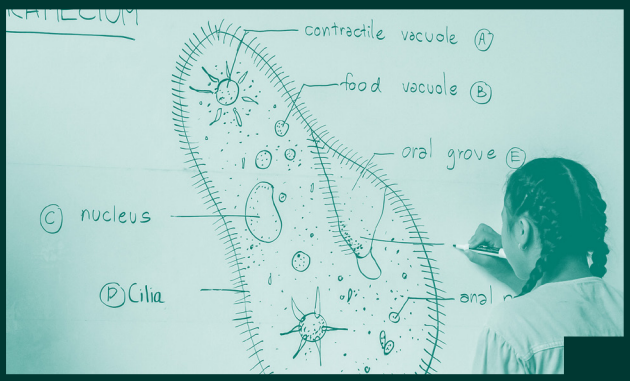
Unlocking Science Across America

A strong U.S. innovation ecosystem requires new policies that unleash talent and problem-solving from every part of the country.

The federal government's current research apparatus favors a relatively small group of elite institutions and highly trained scientists in established hubs. Instead, the federal government should adopt a more comprehensive vision for science that enables participation from universities, researchers, and students across the country.

This paper provides targeted actions that the federal government could take to unlock scientific potential across the country. The proposed policy options would:

Advance science to solve local problems



Open opportunities for more Americans to participate in science

3.1

Advance Science to Solve Local Problems

The federal government can enable scientific discovery in all parts of the country. Federal cost-sharing and collaboration should be provided to local communities to advance science that serves them.

Science Extension programs at universities across America

Modeled after the Agricultural Cooperative Extension System, the federal government should partner with local universities and industry to establish Science Extensions.[17] Whether created in new offices or by expanding existing ones, such as technology transfer offices or Tech Hubs, these Science Extensions would enable scientists to collaborate with their communities to identify local problems and co-fund research projects to find solutions.

"Laboratories of Innovation Initiative" for states

The federal government should launch the "Laboratories of Innovation Initiative," which would provide matching funds for state and local governments that want to award and test alternative research funding mechanisms, such as those presented earlier in this series. For example, the National Institutes of Health (NIH) could give money directly to state governments — to be pooled with state and local funds — for disbursement to test these new funding mechanisms. This initiative would also allow states and local governments to leverage local expertise and pursue scientific topics most relevant to their communities.

"Emerging Innovation Collaborative" for scientific entrepreneurship

The federal government should convene early-career scientists and emerging business leaders, such as Master of Business Administration (MBA) students or process engineers, through an "Emerging Innovation Collaborative" to help create go-to-market plans for early-stage basic research projects. While many basic research projects yield promising results in a lab, discoveries are often not economically feasible when transitioned to the commercial market because they use expensive inputs or face scale-up challenges. Including these interdisciplinary collaborations early in the process would increase the likelihood of successful commercialization.

Tax credits for industry-academia partnerships

The federal government should offer a tax credit to spur local industry-academic partnerships. This credit would go toward companies that fund cooperative research and development (R&D) agreements with local universities and provide guaranteed pathways to employment at their own company or other related companies in the sciences. For example, this type of tax credit could support partnerships similar to the May 2025 agreement between Purdue University and Eli Lilly and Company meant to accelerate pharmaceutical innovation.[18]

Local user-facilities

Building on an April 2025 Commission recommendation to establish community labs, federal science agencies should establish localized user facilities. Establishing community-level user facilities with shared resources and cloud lab access could lower research costs, open up jobs for skilled technicians on-site to assist researchers, and increase broader access to instrumentation.[19] Additionally, federal funding agencies should make travel and user fees allowable costs under existing research grants to further enable access to such user-facilities.

3.2

Open Opportunities to More Americans to Participate in Science

A strong U.S. innovation base requires leveraging the strengths of all Americans to advance scientific discovery, not just those who hold PhDs. The federal government, in close coordination with the private sector, must expand pathways for every American to engage in, and benefit from, the scientific endeavor.

Small dollar grants to jumpstart research

Federal science agencies should break up larger existing grants to establish mini grants for discovery research. These mini grants could jumpstart new researchers' careers or fund completely novel research areas. In the current system, recent graduates compete with incumbent researchers and cannot pave their own research paths. The proposed mini grants would be small dollar amounts (<$100k) with minimal reporting requirements. Early-career scientists would be eligible to use these funds in any research capacity, whether at a university or as independent scientists.

G.I. Bill extension for emerging technologies

Congress should establish a new Veterans for Emerging Technologies Program within the G.I. Bill that funds graduate, trade, or vocational training related to emerging technologies such as biotechnology, artificial intelligence (AI), and quantum. Additionally, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) could:

- Increase the monthly housing allowance when veterans are enrolled in a STEM program;
- Expand DOD outreach to companies working on emerging technologies to participate in the SkillBridge Program; and
- Revise the Transition Assistance Program curriculum to educate separating service members about career pathways in emerging technologies.

Emerging TECHnical Workforce Program

The federal government should provide pooled funds with state and local governments to establish technical and vocational training pathways for emerging technologies. These certification programs, hosted by local businesses and universities, would provide individuals the opportunity to upskill in the technical roles needed for emerging technologies. The state-level programs would include in-classroom training as well as full-time employment at local industries in technical roles, such as biomanufacturing technicians or data center engineers.

Separating training grants from research grants

The White House should lead an effort to assess and execute an initiative to separate training grants from research grants. When federal agencies issue research grants, researchers use them not only to run their labs, but also to support their graduate student trainees. However, there is often a mismatch in timing between three-year grants and five+ year graduate programs. This form of funding also ties graduate students to traditional forms of research. Offering separate research and training grants would provide the next generation of scientists with stable funding while allowing them to pursue new research paths, including those outside of traditional academic settings.

Opportunities for federal employees to gain experience in the private sector

Federal science agencies should establish a "Federal Innovation Exchange Program" for federal employees to work and gain experience in the private sector. Federal employees and scientists are best suited to serve the American people when they understand how the private sector operates within the broader innovation ecosystem. As a requirement for leadership positions, science agencies should mandate that federal employees participate in a one-year externship, co-funded by the private sector, to better understand how industry, academia, or philanthropy operate and bring those lessons learned back into the government.

Strengthening the United States' commitment to scientific discovery requires a modernized scientific ecosystem, one that fosters collaboration across sectors and directs funding toward high-impact research.

Now is the time to secure the future of science and ensure that the American people enjoy greater prosperity, better health, and increased safety for generations to come.

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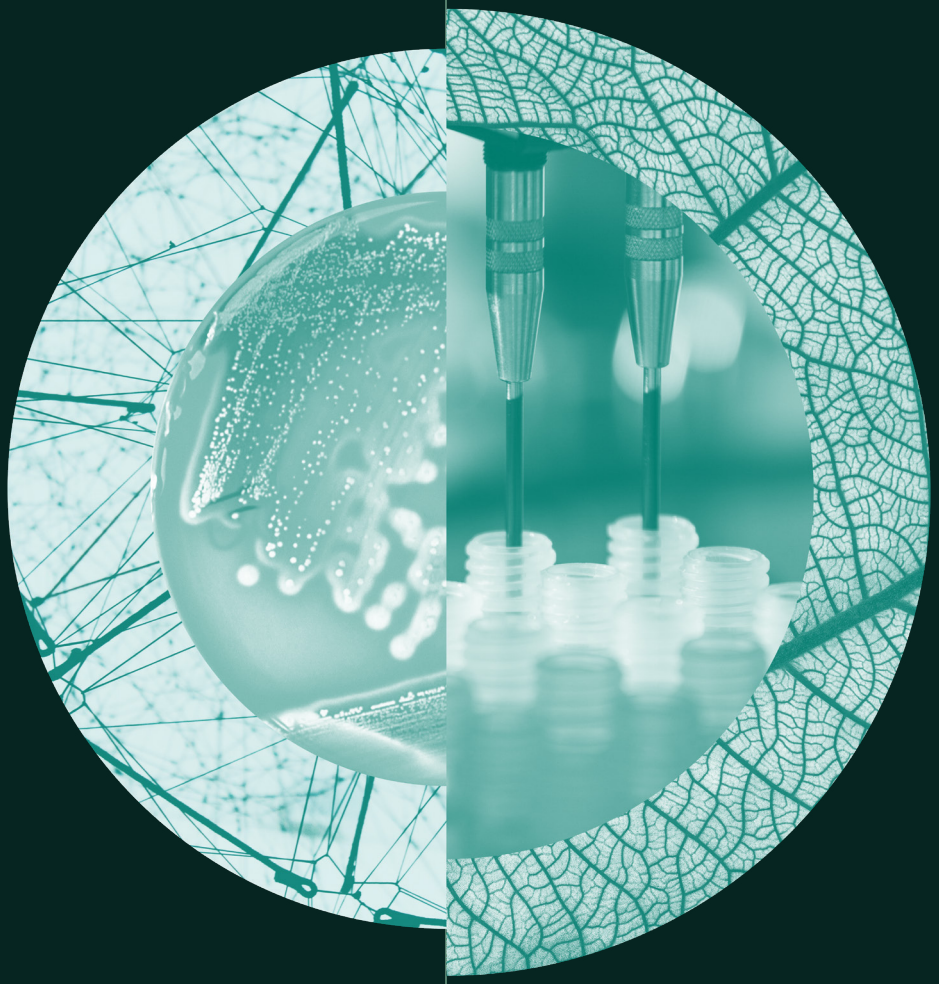

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The Future of U.S.–China Biotechnology Competition

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

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

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

Since the publication of that assessment, the trajectory the Commission identified has continued—and in several respects intensified. Emerging evidence indicates that China is now surpassing the United States in certain domains of biopharmaceutical innovation, marking a new inflection point in this great-power competition. Specifically, China is moving beyond copycat generic medicine manufacturing and is now driving a significant share of global biopharmaceutical innovation.[1] If the United States loses its primacy in biopharmaceutical innovation, it risks weakening the financial and intellectual engine that drives broader biotechnology leadership—undermining not only healthcare competitiveness but also strategic capabilities in agriculture, energy, and defense.

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

[1] Here, "brute force economics" refers to a set of policies designed to increase China's dominance in strategically important sectors, including biotechnology.

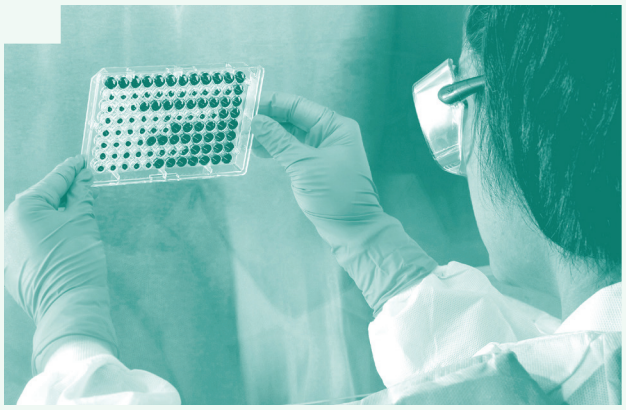
China is Demonstrating That it Can Out-Innovate the U.S. in Biopharma

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

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

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

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

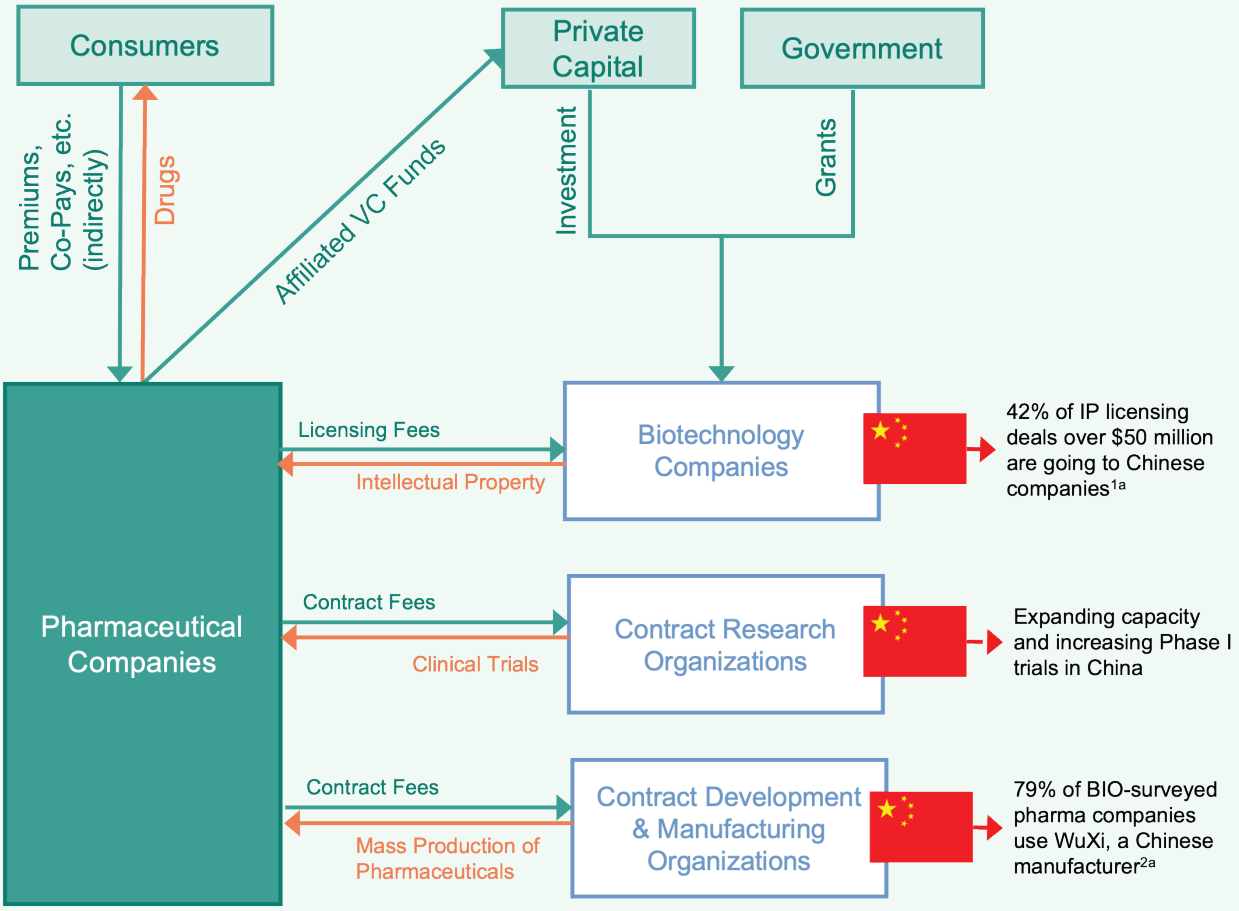


U.S. policymakers have a three-year window to retain, or in some cases regain, biotechnology leadership or risk ceding profound military, geopolitical, and economic advantages to China.

Figure 1.

China is Capturing the Biopharmaceutical Value Chain

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



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

China's ascension in biopharmaceutical innovation is due, in part, to deliberate government policies. Reforms to the nation's clinical trial system, the establishment of government guidance investment funds, and stronger coordination between early-stage research and commercial-scale manufacturing have accelerated China's emergence in biotechnology. Moreover, these efforts build on the unfair advantages China has obtained from years of well-documented nonmarket practices and brute force economics.[*,6] In this paper, the Commission examines the specific policies that have positioned Chinese biotechnology firms to be globally competitive.

A Warning for the Future

If the United States cedes biopharmaceutical innovation to China, the U.S. biotechnology industry will never look the same. Biopharmaceuticals represent the most profitable segment of the biotechnology industry, with high-profit-margin therapies that are overwhelmingly financed through the U.S. healthcare market.[7] Those profits, generated predominantly by American consumers, create the reinvestment capacity that fuels basic science, venture capital (VC) activity, and the next generation of biotechnology startups.

This cycle creates a flywheel effect: revenues from breakthrough drugs sustain research infrastructure, attract top global talent, and underwrite future innovation in adjacent domains such as agricultural biotechnology, gene editing, and biomanufacturing.[8] Surrendering this cycle to China would facilitate the decline of U.S. biotechnology leadership and provide unrivaled advantages to a foreign adversary.

Competing Against China's Regulatory Playbook

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

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

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

How China's Clinical Trial Reforms Have Fostered Innovation

Over the past decade, China has transformed its clinical trial regulations, shifting from one of the slowest approval systems in the world to one of the fastest, with reforms also improving quality and alignment with international standards. Historically, long approval backlogs and rigid requirements discouraged investment in innovative drug development in China.[10] Beginning in 2015, the State Council launched comprehensive reforms to clear these bottlenecks and accelerate the development pipeline.[11]

One of the most important changes was the introduction of an "implied approval" system for investigational new drug (IND) applications in 2018. Under this system, clinical trials can begin if China's National Medical Products Administration does not raise objections within a certain period, replacing the old, open-ended approval timelines that often stretched beyond a year.[12] 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.[13] Due to these regulatory shifts, the number of clinical trials launched in China has increased year after year.[14]

To further harmonize with international standards, China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017, of which the U.S. FDA was a founding member.[15] These efforts have enabled the integration of Chinese sites into multi-regional clinical trials (MRCTs) at earlier stages, cutting redundancy and allowing Chinese patients earlier access to experimental therapies.[16] In adherence to international standards set by ICH, China also began accepting foreign clinical trial data for new drug registrations when scientifically justified.[17]

China's efforts to streamline and harmonize its clinical trial system have bolstered the nation's drug innovation ecosystem to be globally competitive with the United States. Compared to the United States, conducting clinical trials costs significantly less and launching Phase 1 clinical trials is far simpler and faster in China.[18] Moreover, the expanded use of IITs, with numerous research institutions and large hospitals in China actively engaged, is providing early safety and efficacy data while avoiding the additional regulatory constraints of industry-sponsored trials (ISTs) in the country.[19]

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

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

How China Compounds Regulatory Reforms to Accelerate Domestic Innovation

In addition to reforms to clinical trial processes, in 2015, China's State Council amended definitions of innovative drugs and introduced reforms to accelerate the review and approval of innovative drugs to market, thus incentivizing domestic biopharmaceutical innovation. The definition of innovative drugs was amended from "drugs not previously introduced to the Chinese market" to "drugs not yet introduced to the global market."[24] In doing so, China incentivized domestic entities to develop biopharmaceutical products that can compete globally.[25] Moreover, a special review system was implemented to expedite the approval of innovative drugs.[26] As a result, from 2019 to 2023, the number of approved innovative drugs by China's National Medical Products Administration (NMPA) increased from 20 to 66.[27]

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

China's efforts to streamline and harmonize its clinical trial system have bolstered the nation's drug innovation ecosystem to be globally competitive with the United States.

China's Rise Threatens U.S. Competitiveness

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

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

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

How China Successfully Finances and Commercializes Biotechnology

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

The Chinese government, by contrast, has adopted innovation policies that channel capital into biotechnology as a strategic industry and address key barriers that impede the transition of early-stage technologies into commercial products. While these policies are generally viewed as fair and legitimate, they operate alongside—and are reinforced by—China's long-standing predatory nonmarket practices and brute force economic tactics. Since April 2025, the Commission has continued to hear from U.S. stakeholders, especially biotechnology founders and investors, about unabated IP theft, copycat activity, and artificially low prices that allow Chinese companies to undercut their U.S. competitors. Together, these approaches allow China to exploit U.S. market failures and accelerate its progress in this critical technology sector.

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

Investment as Strategy:

China's Use of Government-directed Venture Capital to Shape Strategic Industries

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

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

Overly complicated regulatory processes, limited pre-commercial scale infrastructure, and an uncertain market increase risk for private sector investments in biotechnology.

The Innovation Chain:

China's Strategy to Commercialize Emerging Biotechnologies

Since at least 2016, the CCP has pursued a policy of technology-driven development, viewing technological progress as fundamental to economic prosperity.[38] Key to this effort, the CCP has pursued policies that connect a technology from invention to commercialization, also known as the "innovation chain."[39] China has been building an innovation-driven system by focusing resources not just on research and development (R&D), but on fortifying supply chains and fostering the broader ecosystems needed to carry new technologies from the lab to market.[40]

China has established innovation clusters that physically co-locate research institutes, regulatory authorities, and industrial-scale manufacturing within the same geographic area. This co-location catalyzes collaboration across laboratory research, pilot testing, and mass production. According to the U.S.-China Economic and Security Review Commission's (USCC) 2025 report, "Chinese scientists and lab technicians appear increasingly convinced that innovation accelerates when R&D and production are co-located [in biotechnology]."[41]

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

Case Study

How 3SBio Became a Globally Competitive Biopharmaceutical Company

In July 2025, 3SBio marked a major milestone for China's biopharmaceutical industry by clinching one of the largest biopharmaceutical licensing deals ever for a single drug.[42] NSCEB staff examined the innovation policies behind 3SBio's success and found that 3SBio benefited from public-private capital flows that supported the company's scaling and expansion. Moreover, the company's location in Shenyang offered strategic advantages by co-locating early-stage research with supply chain inputs and manufacturing.

Case Study Continued

How Coordinated State and Market Capital Propelled 3SBio

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

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

How Shenyang's Innovation Ecosystem Fostered 3SBio

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

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

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

These ideas are not new. In fact, the Commision proposed a suite of policy recommendations to address these very issues in the United States in its April 2025 report. The alarming success of 3SBio and other Chinese biopharmaceutical firms are heightening the urgency for U.S. policy action now. Success at the biopharmaceutical frontier fuels the talent, financing, and technical know-how that spill over into other biotechnology verticals.

In what the USCC describes as "interlocking innovation flywheels," China's innovation gains in the biopharmaceutical sector will soon reverberate across its pre-existing investments in biomanufacturing.[52] With recent announcements by China's Ministry of Industry and Information Technology (MIIT) and National Development and Reform Commission (NDRC) to significantly expand the nation's pilot-scale biomanufacturing capacity, China's innovation trajectory in biotechnology could soon outpace the United States.[53] Unless the U.S. government adopts the necessary policies to catalyze its own domestic biotechnology industry, China's competitive edge in biopharmaceuticals may soon expand into an unsurmountable lead.

Unless the U.S. government adopts the necessary policies to catalyze its own domestic biotechnology industry, China's competitive edge in biopharmaceuticals may soon expand into an unsurmountable lead.

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JANUARY 2026

The Future of Biotechnology Regulation

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Creating Clear Regulatory Pathways for Biotechnology

Novel biotechnology products, which span defense, industrial, biomedical, agricultural, and other sectors, are emerging faster than regulations can keep pace. Innovators need efficient, risk-proportionate regulatory pathways to quickly bring safe products to market. This is the first in a series of discussion papers on the future of regulation. Subsequent papers include detailed policy options for medical products, plants, microbes, and animals.

In its April 2025 report, the National Security Commission on Emerging Biotechnology (NSCEB) recommended creating simple pathways to market (Rec. 2.1a) and preparing regulatory agencies for novel products (Rec. 2.1b). After the release of the report, the NSCEB conducted extensive outreach across industry, academia, and government, including a survey and a series of listening sessions. Stakeholders provided a wide range of thoughtful ideas and perspectives, which the NSCEB carefully weighed for their potential impact and feasibility. Through this additional engagement, the NSCEB identified specific Congressional actions needed to improve biotechnology product regulation and achieve the outcomes that were laid out in the report. The NSCEB looks forward to working with Congress, federal agencies, and other stakeholders to implement these policy options, including through legislation, oversight activities, and other efforts.

The NSCEB recommends passing the National Biotechnology Initiative Act of 2025 (S.1387 and H.R.2756), which would create a National Biotechnology Coordination Office (NBCO) to streamline and coordinate biotechnology product regulation. This office would map clear regulatory pathways, build shared digital tools for collaboration, and improve communication with developers. Alongside the NBCO, targeted efforts are needed to clarify agency roles, reduce duplication, and enable efficient, risk-based oversight. Appropriate resources would ensure agencies have the expertise they need to keep up with scientific advancements. Such reforms would make regulation more straightforward, focused on risks, and responsive to emerging biotechnology products, while maintaining safety.

Modernizing Regulation so the United States Can Compete and Win

Biotechnology developers in the United States face slow and complex regulatory processes that push research and development (R&D) overseas as China and other competitors charge ahead with faster, more predictable systems.[1] Regulatory delays raise costs, create uncertainty, and deter investment, especially for first-of-a-kind products such as microbes engineered for biomining critical minerals. The root cause of these challenges is a regulatory system built on laws that predate biotechnology, and that were not written with the rapid advancement of emerging biotechnology products in mind.

Three primary agencies are responsible for biotechnology product regulation: the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA) within

the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA). A federal policy called the Coordinated Framework for Regulation of Biotechnology directs these and other agencies to regulate products based on their intended use, not the method used to create them.[2] As a result, biotechnology products often fall under the jurisdiction of multiple agencies and statutes. Biotechnology developers and other stakeholders overwhelmingly support the Coordinated Framework and its product-based approach, but they report that the current system creates uncertainty, raises costs, and delays commercialization.

Forty years after its creation, the Coordinated Framework has not kept pace with scientific advances, leaving a system marked by regulatory gaps. Oversight is fragmented, duplicative, and spread across multiple agencies. Deviating from the Coordinated Framework's original premise of regulating based on intended use, reviews are often triggered by how a product is made, rather than actual risk, causing lengthy review for familiar products and uncertainty for new ones. Inefficient regulation hinders the deployment of biotechnology products that can help the United States defend, build, nourish, and heal. Without reform, the United States risks falling behind as other countries adopt more streamlined oversight that can adapt more quickly to scientific advances.

The United States now has advanced scientific and regulatory tools that did not exist when the Coordinated Framework was created, but Congress needs to unlock them. Regulatory agencies have made significant progress in streamlining regulation with the tools available to them. However, additional progress requires clear Congressional direction. Congress must act to reduce unnecessary regulatory burden, empower and resource regulators to work efficiently, and uphold safety and transparency for consumers. If implemented, the policy options below would reduce review times, increase U.S. competitiveness, and ensure that Americans can benefit from new technologies and products.

Case Study

How Regulation Can Save an Industry... or Slow It to a Crawl

Efficient, risk-proportionate regulation is possible. The USDA, EPA, and FDA conducted a thorough but expedited review of engineered, virus-resistant Rainbow papaya in just two years. Available for commercial planting in 1998, Rainbow papaya saved Hawaiian farms from the devastating ringspot virus, and it is still grown in Hawaii today.[3]

By contrast, U.S. approval of engineered mosquitoes that produce only non-biting male offspring has been delayed for over ten years because jurisdiction shifted from the USDA to FDA, then to the EPA.[4] In Brazil, regulators initiated a rigorous review in 2011 and approved commercial sale in 2020, leading to a 90% reduction of dengue-spreading mosquitoes.[5]

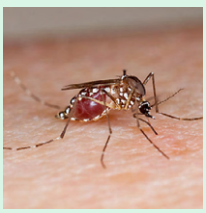
Virus-resistant papaya: 6 years from field trials to full U.S. approval and commercialization.

1991
Application for USDA field trials

1992–1995
USDA-regulated field trials

1996–1997
USDA, EPA, & FDA review & approve product

Sterile mosquito: 15 years without U.S. approval (compared to 9 years to approval in Brazil.)



2010
Application for USDA field trials

2011
Hand-off from USDA to FDA

2011–2016
FDA conducts Environmental Assessment

2018–2020
Application for EPA field trials

2021–2024
EPA-regulated field trials

Winning the Race with Smarter Regulation

Regulatory challenges impact U.S. national security by delaying biotechnology products used to defend, build, nourish, and heal. With extensive stakeholder input, the NSCEB developed targeted statutory amendments and regulatory reforms that are consistent with the themes below.

Regulatory Roadblocks	Clear Pathways
Ambiguous jurisdiction Developers can spend months or years just to learn what regulatory process to follow. Smaller companies are hit hardest because they lack resources to navigate complex regulations.	**Clear roles** Agencies clearly define responsibilities in interagency agreements so both developers and regulators know which agencies are involved and what processes to follow.
Process-based triggers Regulation is often based on how a product is made rather than its intended use. Familiar products face the same scrutiny as novel ones, wasting time and resources without improving safety.	**Risk-tiered processes** Agencies sort products into tiers: exempt or fast-track review for familiar products, streamline review for moderate-risk products, and reserve the highest scrutiny for novel products.
Redundant reviews A single product may face multiple, overlapping reviews. Agencies often ask for the same data but rarely share it with each other.	**Single point of entry** A short intake form confirms the lead agency and next steps. One application with product-specific annexes enables data sharing and reduces duplication.
Unpredictable and lengthy timelines Uncertainty deters investment and discourages companies from entering the market. Agencies are persistently understaffed even as backlogs grow.	**Streamlined review** Agencies coordinate effectively. Along with clear pathways, adequate staffing and focused expertise reduce backlogs and make timelines predictable.
No pathways for emerging products Truly innovative products fall into regulatory gaps with no clear process for review. Delays slow the commercialization of beneficial products.	**Continuous improvement** Horizon scanning identifies new products before they enter the regulatory system. Regulatory pilots are used to test new and improved regulatory pathways.
International competition Other countries are modernizing their regulations and putting U.S. global leadership at risk. Developers are seeking approval and building facilities in other countries rather than investing in the United States.	**Regulatory diplomacy** Working with allies and partners on shared solutions, such as international standards, data sharing, and complementary regulatory frameworks, helps to open markets for American-made products.

Policy Options for Modernizing Biotechnology Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes 30 policy options in six key areas for modernizing oversight of biotechnology products: clear regulatory pathways, preparing for future products, digital infrastructure and data, guidance and bioliteracy, regulatory agency resources, and international coordination. The ideas presented here apply across all product types. The NSCEB also developed detailed policy options for medical products, microbes, plants, and animals, which are presented in separate discussion papers.

Clear Regulatory Pathways

1. Establish federal coordination for biotechnology.
2. Require interagency agreements for clear regulatory pathways.
3. Expand exemptions for familiar products and increase use of tiered, risk-based review.
4. Leverage information from prior reviews to speed review of similar products.
5. Adopt platform-based regulatory frameworks.
6. Incorporate risk-benefit analysis into regulatory decisions.
7. Work with states to harmonize requirements.

Prepare for Future Products

8. Pilot new regulatory approaches for emerging products.
9. Use conditional approvals to manage uncertainty.
10. Establish horizon scanning for emerging technologies and products.
11. Remove barriers for regulated biotechnology research.
12. Reduce duplicative requirements for biotechnology research
13. Recognize voluntary consensus standards.
14. Conduct continuous regulatory improvement.

Digital Infrastructure and Data

15. Establish a single point of entry for biotechnology regulation for non-medical products.
16. Create a centralized public repository of regulatory decisions.
17. Require interagency sharing of regulatory submissions and reviews.
18. Invest in triage assisted by artificial intelligence (AI).
19. Tailor data requirements to risk.

Guidance and Bioliteracy

20. Require clear, consistent regulatory guidance.
21. Promote regulatory transparency.
22. Support early consultation between developers and regulators.
23. Train early career scientists in biotechnology product regulation.

Regulatory Agency Resources

24. Strengthen regulatory capacity.
25. Invest in training for regulators.
26. Establish a foundation to enable biotechnology commercialization.
27. Enable regulatory science to support efficient oversight.

International Coordination

28. Improve international regulatory coordination.
29. Form international data-sharing agreements.
30. Pilot reciprocal agreements with trusted countries.

Clear Regulatory Pathways

Clear, predictable regulation is essential for advancing emerging biotechnology. Stakeholders repeatedly noted that overlapping roles, inconsistent definitions, and outdated processes create confusion and waste resources.

1. **Establish federal coordination for biotechnology.** As the NSCEB described in its April 2025 report, the absence of coordination has resulted in scattered efforts across the federal government. This fragmentation is particularly evident for biotechnology product regulation, in which overlapping responsibilities and unclear processes delay innovation. To address this challenge, Congress should pass the bipartisan National Biotechnology Initiative Act of 2025 (H.R.2756 and S.1387) to establish a National Biotechnology Coordination Office (NBCO) within the Executive Office of the President. The NBCO would regularly convene federal regulators to identify and resolve processes that delay commercialization of biotechnology products. The NBCO would close key gaps in the U.S. Coordinated Framework for Regulation of Biotechnology by working with agencies to deduplicate regulatory processes and identify causes for regulatory delays.

2. **Require interagency agreements for clear regulatory pathways.** Biotechnology developers shared that they often face duplicative reviews and unpredictable timelines. Agencies have published some interagency agreements that help delineate regulatory pathways, though developers indicated that additional agreements would provide clarity across product types. Congress should instruct regulatory agencies to publish and regularly update interagency agreements that map clear regulatory pathways for each product type. These agreements would clarify existing processes or describe new processes, including to designate a lead agency, delineate agency roles, enable data sharing, and define timelines. Agreements should also set escalation procedures, including how agencies will resolve differences in interpretation and how developers can challenge unreasonable delays or overly burdensome requests for additional data. Congress should also instruct agencies to defer to the designated lead agency, while contributing relevant technical expertise where appropriate. For example, the EPA could defer to APHIS on non-target organism assessment, rather than conducting its own assessment. Clear regulatory maps would minimize regulatory burden and help deliver timely, coordinated decisions.

3. **Expand exemptions for familiar products and increase use of tiered, risk-based review.** Current regulations apply to many products that pose no new risks compared to conventional products. This results in disproportionate burden for biotechnology products, particularly for gene edited products with precise genetic changes that could otherwise have been produced without biotechnology. In recent years, agencies have taken steps to exempt or reduce scrutiny of such products.[6] However, stakeholders note that exemptions are inconsistent across agencies and limited in scope. Congress should direct agencies to reduce or remove regulatory hurdles for familiar products based on accumulated evidence and to use tiered, risk-based review frameworks that reserve intensive oversight for novel products. In addition, Congress should instruct agencies to conduct comparative risk assessments, and to consider potential risks of biotechnology products in the context of other human activities and comparable products that were not produced with biotechnology.

4. **Leverage information from prior reviews to speed review of similar products.** Biotechnology developers noted that regulators often require a full review even when a biotechnology product is nearly identical to other biotechnology products that regulators already deemed safe. Congress should require agencies to extend prior decisions to substantially similar products and to leverage post-market monitoring and other data from similar products to inform new risk assessments, where allowed by law. For example, the FDA could internally use data from a food safety review of a protein expressed in one plant species to inform assessment of the same protein in another plant species. Transparency on how prior reviews inform subsequent risk assessments would help developers better understand regulatory processes. For example, the EPA published documentation on how regulators leverage prior experience for ecological risk assessment of certain biotech plants.[7] This approach would reduce redundancy, speed market access, and free up resources for genuinely novel products.

5. **Adopt platform-based regulatory frameworks.** Current regulations often require agencies to review each biotechnology product as if it were entirely new, even when developers use the same, well-characterized organism or process to develop those

products. Congress should direct agencies to develop frameworks for regulating biotechnology products as platforms. Agencies should review unmodified organisms, such as a chassis microorganism, and other common components separately from engineered traits. Platform-based frameworks would better reflect development practices and enable faster review for subsequent modifications to the base organism or product.

6. **Incorporate risk-benefit analysis into regulatory decisions.**
   Many regulatory frameworks focus narrowly on risks, even when risks are manageable. Formal risk-benefit frameworks would enable more balanced decisions. Congress should encourage agencies to consider benefits of biotechnology products and to approve products when the benefits outweigh the risks , where appropriate. Such consideration should minimize requests for additional data. For example, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) instructs the EPA to consider "the economic, social, and environmental costs and benefits" of pesticides, and the EPA meets this requirement without requiring efficacy data in most cases.[8] Agencies should also consider potential benefits of replacing existing products with a product derived from biotechnology. Flexibility to consider well-supported benefits could support more balanced and transparent decision-making.

7. **Work with states to harmonize requirements.**
   In addition to federal regulation, developers shared that the patchwork of state requirements can add costs and delay commercialization of certain biotechnology products, such as food and feed ingredients, soil amendments, and pesticides. Stakeholders pointed to a successful agreement between the FDA and the Association of American Feed Control Officials (AAFCO) regarding shared terminology across industry, states, and the FDA, but this agreement expired in 2024.[9] For many products, lack of harmonization creates a resource-intensive regulatory environment that slows innovation and discourages manufacturers from bringing new products to market in the United States. Congress should direct federal agencies to collaborate with state counterparts to align key definitions, expectations, and labeling. Coordination would reduce duplicative requirements while preserving state authority.

Prepare for Future Products

In addition to improving regulatory pathways for today's biotechnology products, federal regulators must also ensure that oversight systems are equipped to handle what comes next. Forward-looking processes are essential to accommodate emerging technologies, novel product types, and uses that may not fit neatly within existing frameworks.

8. **Pilot new regulatory approaches for emerging products.**
   Existing regulatory pathways were designed for older technologies and often cannot easily accommodate novel traits, production methods, products, or uses. Congress should instruct agencies to create "regulatory sandboxes" and short-term pilots to develop new regulatory pathways for emerging products, then expedite updated regulations or guidance based on the results. Pilots are time-limited, controlled trials of a new regulatory approach that allows agencies to test requirements, data expectations, and review processes before broader implementation. Using pilots to build flexible, risk-based frameworks would reduce uncertainty and accelerate innovation while maintaining safety.

9. **Use conditional approvals to manage uncertainty.**
   Regulators sometimes need more information before allowing full commercialization of a biotechnology product. For example, developers may provide adequate data for a particular use or release in a particular location, but agencies may need more data about other uses or locations. Congress should instruct agencies to use conditional approvals with tools such as monitoring, usage restrictions, and staged or time-limited approvals to manage uncertainty through continued oversight. This would allow limited commercialization to proceed while developers gather additional data.

10. **Establish horizon scanning for emerging technologies and products.**
    Researchers noted that regulators are often unprepared for emerging biotechnology products that do not fit existing regulatory pathways. Congress should direct regulatory and research agencies to conduct joint horizon scanning to identify emerging risks and opportunities, with participation from industry, academia, and international partners. This

could include foresight exercises and preliminary risk assessments to help identify regulatory gaps and build familiarity with emerging products.

11. **Remove barriers for biotechnology research.** Federal research grants often prohibit use of funding for regulated activities, such as field trials, even when those activities are authorized by the appropriate regulatory agency and essential to the research objectives. These blanket restrictions slow innovation and disproportionately burden academic researchers. Congress should direct research funding agencies to remove categorical prohibitions on regulated activities and to coordinate with regulatory agencies to ensure compliance with applicable regulations. Aligning granting policies with regulatory oversight would accelerate research translation, improve interagency coordination, and ensure that federally funded research delivers timely, real-world benefits.

12. **Reduce duplicative requirements for biotechnology research.** In addition to biotechnology product regulation, the National Institutes of Health (NIH) provides oversight for organisms produced with recombinant DNA technology through the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Guidelines).[10] The NIH is currently undergoing a modernization process for the Guidelines.[11] Congress should encourage the NIH and regulatory agencies to work together on appropriate standards for containment and encourage the NIH to exclude products from the Guidelines if they are under another agency's regulatory oversight. This would reduce duplicative oversight for products that are already regulated by another agency and allow the NIH to provide risk-proportionate oversight for biotechnology research.

13. **Recognize voluntary consensus standards.** Developers stressed that agencies often develop standards much more slowly than industry and other organizations, leading to costly delays. Organizations such as the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) develop voluntary standards through expert-driven, transparent processes that are often more responsive to technological advances than agency rulemaking. Congress should instruct agencies to recognize voluntary consensus standards, when feasible, and to participate in domestic and international standard-setting bodies. For example, conforming to voluntary safety standards such as the Safe Strain Lineage could reduce downstream regulatory burden for engineered microbes.[12] For plants, the Global Stewardship Group facilitates development of a quality management system (QMS) and best management practices.[13] Adopting such standards could help satisfy regulatory requirements for containment of plants in field trials. Recognition of voluntary standards is consistent with longstanding federal policy and would harmonize approaches, align regulation with industry practices, and foster innovation while maintaining safety.[14]

14. **Conduct continuous regulatory improvement.** Biotechnology product regulation lags behind the science, and outdated requirements remain long after they lose value. Congress should require periodic assessment of regulations and guidance to ensure that oversight is current and risk proportionate. For example, agencies should update exemptions for familiar products and leverage information from prior reviews, as mentioned above. Agencies should report annually to Congress on regulatory targets, timelines, and performance, using outcome-based metrics to assess trends over time and to evaluate efforts to optimize regulatory processes. Regular review would align regulation with emerging technologies, reduce unnecessary burdens, and strengthen confidence in biotechnology product regulation.

Digital Infrastructure and Data

Fragmented portals, duplicative submissions, and paper-bound processes increase burden, slow reviews, and frustrate biotechnology product developers and regulators alike. Computational power constraints, including limited access to high-performance computing resources, prevent regulators from effectively analyzing complex data. By modernizing infrastructure and data practices, Congress can streamline oversight, increase efficiency, and improve transparency for American innovators.

15. **Establish a single point of entry for biotechnology regulation for non-medical products.** Developers expressed frustration that they must navigate multiple systems to submit applications, track progress, and receive feedback. Congress should direct agencies to develop a central portal for applications, data, reviews, and decisions for biotechnology products, excluding human medical products that are regulated solely by the FDA. The portal should enable coordinated responses and tracking of regulatory submissions. Developers

should be able to submit data on a rolling basis, with appropriate data protections.

16. **Create a public repository of regulatory decisions.** Prior regulatory decisions and reviews are often inaccessible or scattered across multiple government websites. Congress should direct agencies to develop a central repository that aggregates regulatory reviews and decisions for biotechnology products, with appropriate data protections. Using this repository, developers could learn from prior approvals to design better applications, agencies could apply precedents more consistently, and policymakers would gain insight into how statutes are being implemented.

17. **Require interagency sharing of regulatory submissions and reviews.** Developers shared that regulators often require submission of the same information to multiple agencies in slightly different formats, wasting resources and complicating reviews. Agencies have entered into some information sharing agreements, such as a now-expired 2011 agreement on sharing non-public information related to plants produced with biotechnology.[15] However, developers report ongoing uncertainty about the scope of permissible information sharing. Congress should require agencies to enter into agreements that allow interagency sharing of submissions and reviews, with appropriate data protections. Congress should also require agencies to move toward interoperable data management systems and standardized application formats, while defining elements unique to each agency, program, or product. These actions would lower burden for developers, improve efficiency, and provide more consistent review.

18. **Invest in triage assisted by artificial intelligence (AI).** Backlogs regularly delay approvals, with familiar products waiting in the same queue as novel products. Congress should support agencies in developing AI-assisted triage systems that prioritize submissions by risk, complexity, similarity to previously-approved products, and data completeness. AI systems should meet established criteria for trustworthiness.[16] By accelerating the review of familiar products and directing attention to more complex cases, AI tools could help make regulators more efficient and provide more predictable review timelines.

19. **Tailor data requirements to risk.** Regulator requests for additional data, beyond what is necessary to determine safety, can increase burden and slow reviews. Congress should require agencies to regularly review data requirements and eliminate requirements that are no longer needed. Congress should also instruct agencies to limit requests to data directly tied to identified risks and to use adaptive risk assessment approaches informed by decades of safety data. Agencies should justify additional data requests, ensuring that reviews focus only on information critical to safety, and reduce burden by allowing the submission of aggregate data. Each agency should request only the data needed to evaluate plausible risk pathways that fall within its regulatory authority. Congress should also instruct agencies to allow the submission of innovative data sources, such as shared reference data, new approach methodologies (NAMs), non-animal models, digital twins, and in silico simulations. Tailored, risk-based data requirements would reduce costs to developers and shorten review times without compromising safety.

Guidance and Bioliteracy

Regulatory processes are often more complex than they appear, in large part because agencies do not consistently provide clear guidance and often use terms and definitions that are not well-understood. Developers and investors need clear guidance so they understand how regulatory processes work, how long regulation will take, and what data is needed. Bioliteracy, meaning the ability to understand and engage with biology and biotechnology, directly affects how effectively developers, investors, and consumers can interact with and understand the regulatory system. By requiring agencies to improve communication and enabling early consultation with developers, Congress can strengthen regulatory bioliteracy and make biotechnology regulation more transparent, credible, and effective.

20. **Require clear, consistent regulatory guidance.** Developers and investors are often uncertain about regulatory processes, data requirements, timelines, and points of contact, especially when multiple agencies are involved. Congress should require agencies to issue and regularly update guidance to explain details such as risk tiers, data requirements, fee structures, decision trees, and interim checkpoints in language that is clear to a broad variety of stakeholders, including investors in the biotechnology sector and developers who are entering the regulatory system for the first time. When oversight overlaps, agencies should jointly develop guidance, align exemptions, and move toward standardized analytical

approaches. Agencies should also jointly develop and update terms and definitions that are consistent with those used by researchers and developers. These actions would strengthen interagency coordination and improve predictability for developers.

21. **Promote regulatory transparency.**
Regulators often use unclear terms that can be confusing for developers, consumers, and trading partners. For example, APHIS uses the term "nonregulated" to indicate when a review is complete,[17] but some people interpret this to mean a product was never regulated. Congress should require agencies to use plain-language terms that clearly signal when review is complete and what that means for market entry. Additionally, Congress should require that agencies publish plain-language summaries of regulatory reviews and conduct biotechnology education and outreach initiatives for developers, investors, and consumers. For example, some stakeholders suggested that regulators could increase transparency by documenting regulatory decisions and methodologies in peer-reviewed journals, following the model used by the European Food Safety Authority (EFSA).[18] Clear communication would reduce misinformation and strengthen public trust in regulation.

22. **Support early consultation between developers and regulators.**
Developers often wait to approach agencies until their formal submission is ready, resulting in extended review times and requests for additional data. First-time applicants particularly struggle with complex, multi-agency processes. Congress should encourage each agency to open voluntary pre-submission consultation programs, similar to FDA's Pre-Investigational New Drug meetings and Veterinary Innovation Program.[19] With appropriate staffing, agencies could designate "regulatory navigators" or case managers to guide developers of novel products through multi-agency processes. Early engagement would improve submission quality and completeness and reduce review timelines.

23. **Train early career scientists in biotechnology product regulation.**
Early-career researchers face a steep regulatory learning curve when they identify a product for commercialization. In 2017, the National Academies of Sciences, Engineering, and Medicine called on federal agencies to support efforts that build regulatory awareness among students whose research may lead to biotechnology products.[20] Stakeholders emphasized that regulatory training would help researchers design products with regulation in mind, reducing costly redesign and delays. Such training could spur innovation in regulatory science. Congress should encourage federal research agencies to explore mechanisms to support regulatory training and raise regulatory awareness for graduate students in biotechnology and related fields. Improved regulatory literacy would accelerate responsible innovation, reduce development bottlenecks, and strengthen the talent base of scientists prepared to commercialize products in the United States.

Regulatory Agency Resources

Effective biotechnology regulation requires the right people and expertise. Limited resources create bottlenecks and slow reviews. By strengthening workforce capacity, training, partnerships, and regulatory science, Congress can give agencies the tools they need to keep pace with biotechnology innovation.

24. **Strengthen regulatory capacity.**
Agencies cannot conduct timely, science-based reviews without adequate staffing. Congress should empower agencies to hire and retain domain-specific experts, with surge capacity for specific needs, such as major reviews, regulatory updates, or policy development. Agencies should convene, hire, or contract outside experts to supplement internal expertise and support short-term projects, with safeguards against conflicts of interest. Congress should also instruct agencies to formalize reimbursable and non-reimbursable detail agreements. For example, research agencies could detail scientific or policy experts to regulatory agencies.

25. **Invest in training for regulators.**
Regulators want and need to maintain their expertise to keep pace with emerging biotechnology. Congress should require that agencies provide regular technical upskilling for regulators on topics such as scientific advancements; risk assessment, risk management, and risk communication; and new regulatory systems and processes. Agencies should support professional development through scientific conferences and partnerships with academic institutions, industry, and other organizations. A regulatory fellowship program would allow regulators and other federal employees to rotate across agencies and build cross-functional understanding. With appropriate protections in place,

agencies should allow sponsored travel to increase access to professional development opportunities, including site visits, building on the FDA's Experiential Learning Program.[21]

26. Establish a foundation to enable biotechnology commercialization.
Independent, government-affiliated foundations provide a flexible, efficient way to supplement federal activities. For example, Congress established the Reagan-Udall Foundation in 2007 to facilitate stakeholder engagement and advance regulatory science for FDA-regulated medical products.[22] Congress should pass the bipartisan Foundation for Enabling Biotechnology Innovation Act of 2025 (S.2696) to establish a foundation focused on biotechnology commercialization. This foundation would promote public-private partnerships, expand market access and international cooperation, and support federal agencies in bringing safe biotechnology products to market.

27. Enable regulatory science to support efficient oversight.
Regulators often lack the data needed to evaluate emerging technologies, such as multi-season, multi-location studies that assess potential environmental impacts. Congress should pass the bipartisan National Biotechnology Safety Act of 2025 (S.2697) to generate the necessary scientific data to justify simplified regulatory pathways. This research could support baseline assessments, new analytical methods and detection tools, and predictive risk models. Public-private partnerships would further expand capacity for early safety and performance data, ensuring regulators are prepared to evaluate novel products.

International Coordination

Resolving regulatory challenges in the United States is essential, but domestic action alone is not sufficient to enable commercialization of American biotechnology products. Global coordination is critical for U.S. biotechnology to compete abroad. Misaligned processes, duplicative reviews, and slow approvals by trading partners create costly delays. By strengthening collaboration and pursuing reciprocal agreements, Congress could reduce trade barriers and maintain U.S. leadership.

28. Improve international regulatory coordination.
Delayed approval of biotechnology products by trading partners can block or delay commercialization in the United States. Congress should require that regulatory agencies share information with trade and diplomatic agencies about domestic regulatory processes and approvals, with appropriate data protections. Congress should also conduct oversight to ensure adequate U.S. participation in international organizations such as Asia-Pacific Economic Cooperation (APEC) and the Organisation for Economic Co-operation and Development (OECD), as well as standard-setting organizations, such as the International Organization for Standardization (ISO) and the Codex Alimentarius Commission. Better international coordination would help open markets for U.S. products, reduce trade disruptions, and maintain U.S. leadership in shaping global regulatory norms.

29. Form international data-sharing agreements.
International regulators often independently review large data packages and require developers to repeat costly trials, even when comparable, high-quality data already exist. This duplication delays approvals without improving safety. Congress should instruct agencies to negotiate reciprocal data-sharing agreements with foreign regulators, with appropriate data protections, and to enter into reciprocal agreements to accept relevant data collected in a partner country, when appropriate. These agreements would enable partner regulators to rely on high-quality data generated in the United States, and would reduce costs, accelerate reviews, and improve consistency across global supply chains.

30. Pilot reciprocal agreements with trusted countries.
Regulators often repeat assessments even when peer agencies abroad have already assessed the same product. For example, reviewers across 18 countries and the European Union issued 162 separate approvals for a single bacterial protein that can protect crops from insects.[23] Congress should direct agencies to pilot reciprocal agreements with foreign regulators that have comparable regulatory standards. Options include "Trusted Foreign Reviewer" programs where approval by one partner triggers fast-track review by the other, coordinated reviews where one partner leads a scientific assessment while the other issues its own determination, and mutual recognition agreements where partners agree to accept part or all of each other's reviews. Successful models, such as the collaborative assessment by Health Canada and Food Standards Australia New Zealand (FSANZ), show that these tools can work.[24] Reciprocal agreements with allies and partners would help to align expectations and speed products to market.

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Modernizing Plant Biotechnology Regulation

In its April 2025 report, the National Security Commission on Emerging Biotechnology (NSCEB) recommended creating simple pathways to market (Rec. 2.1a) and preparing regulatory agencies for novel products (Rec. 2.1b). Since the release of the report, the NSCEB conducted extensive stakeholder outreach to identify specific Congressional actions to achieve those outcomes. The NSCEB looks forward to working with Congress, federal agencies, and other stakeholders to implement these policy options, including through legislation, oversight activities, and other efforts.

American farmers already rely on biotechnology to help reduce land, water, and other inputs for over 90% of corn, cotton, canola, soybeans, and sugarbeets.[1] Developers are using biotechnology to create promising new plant varieties, but outdated regulatory frameworks slow their path to market. Redundant reviews, unclear processes, and inconsistent timelines create uncertainty for developers and discourage private investment in next-generation crops that could strengthen American agriculture.

Opportunities to Modernize Plant Biotechnology Regulation

The United States divides regulation of plants produced with biotechnology among three primary agencies working under multiple statutes.[2] Developers often must consult more than one agency before bringing a product to market.

- Under the Plant Protection Act (PPA), the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) oversees biotech plants that may pose a risk to plant health.
- Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) reviews the safety of ingredients in human and animal food, including from biotech plant varieties.
- Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) regulates pesticides and plants engineered to produce pesticidal compounds.

Future Plants Within Reach Today

Developers are using biotechnology to produce innovative plants that will benefit American farmers and consumers, such as:

Short-stature corn that can withstand storms and can deliver higher yields per acre.[3]

Thornless, seedless blackberries that are easier to harvest and easier to eat.[4]

Orange trees that can resist the devastating citrus greening disease and protect Florida's orange groves.[5]

Avocadoes that stay fresh for longer, including when bruised or cut, which reduces food waste.[6]

Regulatory complexity discourages developers from bringing new crops to market. For smaller developers in particular, navigating this complex system can be a significant barrier to market entry and pushes development overseas. For example, some companies noted that they are moving research to countries such as Argentina and Brazil, where common sense regulatory reform has already taken place.[7] Notably, these countries have taken steps to exempt gene edited crops that could have been produced with traditional breeding from more burdensome regulatory review. Further, U.S. regulators spend the majority of their limited time and resources re-reviewing previously approved traits instead of focusing on genuinely novel products. Without Congressional action and regulatory modernization, the United States risks ceding leadership in plant biotechnology innovation to other countries with more streamlined, science-based regulation.

American farmers have safely and successfully cultivated biotech crops the last three decades, demonstrating both the strength of existing regulation and the potential of modern plant breeding. The United States has many promising biotech plants ready for deployment, but outdated regulatory processes slow their path to market. Congress can modernize the relevant laws and equip agencies to review biotech plants more efficiently. The following policy options focus on streamlining existing pathways and establishing new ones that support innovation while protecting human health and the environment. If implemented, these policy options would streamline oversight for innovative plant products, strengthen U.S. competitiveness in agricultural biotechnology, and ensure that Americans benefit from the next generation of resilient, nutritious crops.

Overview

Policy Options for Modernizing Plant Biotechnology Regulation

Building on NSCEB's prior recommendations, this paper describes eight policy options across three key areas for modernizing oversight of plants produced with biotechnology: plant health, pesticides and related products, and food and feed safety. These should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for microbes, animals, and medical products, which are presented in separate discussion papers.

Policy Options for Plant Health

1. Focus APHIS regulation on plausible risks to plant health.
2. Provide risk-proportionate permitting processes for biotech plants.

Policy Options for Pesticides and Related Products

3. Clarify definitions and exemptions.
4. Streamline review for familiar plant products.
5. Eliminate unnecessary requirements for biological pesticides.

Policy Options for Food and Feed Safety

6. Focus FDA consultation on plausible risks to food safety.
7. Instruct the FDA to coordinate internally on food and feed safety review.
8. Address impacts of asynchronous approvals.

Policy Options for Plant Health

Well-understood biotech plants often face unnecessary review, taking time away from novel products that may warrant more attention. APHIS oversight of biotech plants hinges on "plant pest risk," an outdated interpretation of its statutory authority to protect plant health.[8] Under this framework, plant pests are organisms that can damage or cause disease in plants. APHIS's regulatory approach depends on whether a plant was engineered with DNA from a plant pest or with older transformation tools, rather than on potential risks. In 2020, APHIS adopted a new rule that successfully focused regulators on risks and reduced regulatory burden, but a federal court vacated the rule in 2024.[9] The court found, in part, that APHIS did not adequately consider its rulemaking record in the updated regulations.[10] By shifting toward a more risk-proportionate approach, Congress can focus oversight where it matters and reduce burden for safe, well-understood products.

1. **Focus APHIS regulation on plausible risks to plant health.**
   Stakeholders noted that APHIS should regulate biotech crops based on potential risks, not the method used to create them.[11] APHIS's current approach subjects well-understood plants to unnecessary review while diverting attention from genuinely novel products. Congress should instruct APHIS to build on its 2020 rule and regulate biotech plants based on plausible risks to plant health or the environment, reserving the highest scrutiny for novel products, such as plants that produce pharmaceuticals or industrial enzymes. Congress should ensure that APHIS has sufficient staffing and technical expertise to regulate plants under their plant health authority. Congress should also direct APHIS to use exemptions or fast-track review for plants with changes achievable through conventional breeding or that are similar to previously-approved plants. Replacing the outdated plant pest framework with tiered, risk-based review would allow APHIS to bypass full reviews for products that pose minimal risk to plant health or the environment, while maintaining oversight of novel products.

2. **Provide risk-proportionate permitting processes for biotech plants.**
   APHIS and the EPA both regulate outdoor field trials of biotech plants: APHIS regulates field trials under the PPA, and the EPA regulates larger field trials of biotech plants with pesticidal traits under FIFRA. Developers noted that compliance requirements for field trials and movement of biotech plants often emphasize documentation rather than real-world risk. Congress should instruct APHIS and the EPA to adopt performance-based permit standards that focus on plausible risk pathways, while reducing requirements for well-understood products. For pesticidal traits, Congress should direct APHIS and the EPA to collaboratively develop clear guidance for developers, and to share information as appropriate to ensure a harmonized permitting approach. These improvements would enable a smooth transition from small-scale to larger trials and appropriately focus APHIS and EPA resources, without imposing unnecessary barriers to innovation.

Policy Options for Pesticides and Related Products

Some biotech plant traits and biological products are regulated under the same frameworks as chemical pesticides. Small developers stressed that this adds unnecessary steps and slows review for safe, familiar products. The EPA has undertaken some regulatory streamlining and provided limited exemptions from pesticide registration, but additional improvements are needed.[12] Clearer definitions and right-sized data requirements would simplify review and allow safe products to enter the market more quickly.

3. **Clarify definitions and exemptions.**
   The EPA broadly interprets the definition of "pesticide" to include products such as plant incorporated protectants (PIPs) and plant growth regulators.[13] Developers emphasized that this creates unnecessary regulatory burden for plant traits that are not intended to function as pesticides, such as traits that affect plant growth. Congress should update definitions in FIFRA, building on the Plant Biostimulant Act of 2025 (S.1907 and H.R.3783), which the NSCEB previously endorsed in its December 2024 interim report. Congress should also instruct the EPA to clarify exemptions and remove ambiguity around which products are subject to pesticide regulation. Regulatory agencies, including APHIS, the FDA, and the EPA, should work collaboratively to shift non-pesticidal products to more appropriate regulatory pathways. Products that are exempt from pesticide regulation should also be exempt from requirements for pesticide residues, known as "tolerances," or should be covered by broad tolerance categories.

4. **Streamline review for familiar plant products.**
   The EPA requires developers to submit extensive data packages, even when a product is substantially

similar to a previously approved product. These data requirements are especially burdensome for smaller companies that do not have access to previously submitted data. Congress should instruct the EPA to expedite review for previously approved PIPs and familiar products, such as "stacks" built from previously approved traits, traits from related species, loss-of-function edits, and RNA interference (RNAi). Congress should also ensure that the EPA has appropriate, sufficient staffing and technical expertise to regulate plants that are intended for pest management. Modeled after the more efficient generic drug approvals process, this approach would reduce regulatory burden while maintaining safety.

5. **Eliminate unnecessary requirements for biological pesticides.**
   Biological pesticides, including PIPs, fundamentally differ from conventional chemical pesticides, yet the EPA evaluates them under the same framework. This mismatch imposes inappropriate requirements that slow market entry for safe, well-understood products. Congress should instruct the EPA to evaluate and reduce regulatory requirements for biological pesticides, when appropriate. Reducing unnecessary requirements would maintain safety while supporting innovation.

Policy Options for Food and Feed Safety

Food and feed safety reviews for biotech plants often apply to well-understood products, adding unnecessary regulatory burden. Overlapping responsibilities and unclear pathways can further slow approvals and create uncertainty for developers. A more focused and coordinated approach would maintain food and feed safety and improve public confidence in foods from biotech plants while lowering administrative hurdles.

6. **Focus FDA consultation on plausible risks.**
   The FDA regulates food safety of biotech plants through voluntary premarket consultation, with an option for voluntary premarket meetings for gene-edited plants.[14] This is a step in the right direction, but developers have noted that consultation has become a de facto requirement as nearly every biotech plant has gone through the process.[15] Congress should instruct the FDA to limit consultation to biotech plants with plausible food safety risks, such as meaningful changes in nutrients or toxins. Congress should also ensure that the FDA has sufficient staffing and technical expertise to regulate plants that are intended for food uses. Limiting consultations would reduce unnecessary burden and free up FDA resources for novel products while maintaining safety and consumer confidence.

7. **Instruct the FDA to coordinate internally on food and feed safety review.**
   Within the FDA, the Human Foods Program (HFP) oversees food for humans, while the Center for Veterinary Medicine (CVM) oversees food for animals. Developers noted that the HFP and CVM review many ingredients separately, including those derived from biotech plants, which can slow regulatory approvals. Some differences in risk assessment are appropriate, in part because animals typically have less varied diets than humans. Even so, the FDA could consolidate parts of the review, such as nutrient composition. Congress should require a coordinated FDA approach to ensure that the right expertise is applied without duplicative review.

8. **Address the impacts of asynchronous approvals.**
   Developers stressed that approval by U.S regulatory agencies is often insufficient for commercializing a biotech crop in the United States. Many other countries maintain separate regulatory approvals for domestic cultivation and imports. If a trading partner has not approved import of a biotech crop, shipments that include that crops could be rejected at foreign ports, creating trade disruptions and financial risk for farmers and developers. Consequently, American farmers often cannot plant a biotech crop until key trading partners approve importation. This situation, called asynchronous approval, occurs when one country has approved a biotech crop while others have not. Congress should direct regulatory agencies, along with trade-focused agencies such as the Department of State and the Office of the United States Trade Representative (USTR), to identify and implement strategies that would address asynchronous approvals and accelerate trading partner review of U.S. biotech crops for import.

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Modernizing Animal Biotechnology Regulation

In its April 2025 report, the National Security Commission on Emerging Biotechnology (NSCEB) recommended creating simple pathways to market (Rec. 2.1a) and preparing regulatory agencies for novel products (Rec. 2.1b). Since the release of the report, the NSCEB conducted extensive stakeholder outreach to identify specific Congressional actions to achieve those outcomes. The NSCEB looks forward to working with Congress, federal agencies, and other stakeholders to implement these policy options, including through legislation, oversight activities, and other efforts.

Modern biotechnology offers tools to develop animals with traits that address major challenges in agriculture, conservation, and beyond.[1] These innovations could help strengthen food security, revolutionize human medicine, produce new materials, and contribute to conservation efforts.

Although scientific advances in animal biotechnology began decades ago, well before comparable developments in crops, animal agriculture has seen little of the resulting benefit.[2] Only a few biotech animals have reached the market, primarily due to regulatory hurdles. These products face long, uncertain, and costly regulation that discourages investment and delays promising traits that could support U.S. farmers and ranchers.

Biotechnology developers working with animals describe several unique challenges compared to other biotechnology products, including that the United States is the only country that uses a drug authority to regulate animals.[3] This regulatory approach creates delays and uncertainty that developers say are out of step with both science and international practice. Ultimately, regulatory barriers prevent American farmers from accessing agricultural innovations and push developers overseas.

Innovations in Animal Biotechnology

Biotechnology offers tools to develop animals that provide major benefits across agriculture, medicine, and natural resources, such as:

Heat-tolerant cattle that maintain production of meat and milk in high temperatures.[4]

Chickens with resistance to avian influenza that could reduce devastating outbreaks.[5]

Pigs with transport-ready organs that can save lives and address the shortage of human donors.[6]

Resilient, disease-resistant coral that can support healthy ocean ecosystems.[7]

Silkworms that produce strong, stretchy fibers for parachutes, wound dressings, and more.[8]

Opportunities to Modernize Animal Biotechnology Regulation

Animals produced with biotechnology are currently regulated by the Food and Drug Administration (FDA) under the animal drug authority in the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA regulates each intentional genomic alteration (IGA) as a "new animal drug," regardless of whether the animals are intended for medical or agricultural purposes. After review is complete, the FDA imposes additional requirements, such as facility registration and post-approval monitoring.

Developers of certain IGAs, including animals raised for food, may seek an expedited process, called Enforcement Discretion. However, the FDA requires that developers label domestic shipments and exports of live animals, genetics, and cells regulated under Enforcement Discretion as containing an "unapproved drug," which carries significant stigma and creates trade barriers. American developers are at a further competitive disadvantage because animals developed abroad may be imported into the United States without a full drug review.

Two agencies within the U.S. Department of Agriculture (USDA) also have authority to regulate animals, including those produced with biotechnology. Under the Animal Health Protection Act (AHPA), the Animal and Plant Health Inspection Service (APHIS) oversees animal health, focusing on pests and disease. Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA), the Food Safety and Inspection Service (FSIS) oversees food safety for meat, poultry, eggs, and catfish. However, the FDA oversees food safety for milk and foods from other animals, including deer, rabbits, and most fish.

Regulation of biotech insects raises additional complexity. Like other animals, biotech insects face potential regulation by the FDA under its animal drug authorities in the FFDCA and APHIS under the AHPA. In addition, biotech insects may be regulated by the FDA under its food safety authorities, by APHIS under the Plant Protection Act (PPA), and by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These overlapping authorities create regulatory uncertainty for important applications of biotech insects, such as suppression of insect-borne diseases, agricultural pest management, and insect-based food and feed.

Outdated regulatory approaches have prevented animal biotechnology from meeting its full potential, and developers of promising biotech animal innovations will continue to move overseas without regulation that reflects modern science.[9] In 2017 and again in 2021, a bipartisan group of Members of Congress sent letters to the FDA and the USDA, instructing them to identify a path forward for coordinated, science-based regulation of biotech animals, but the agencies have made little progress due to remaining ambiguity in how to resolve overlapping regulatory authorities.[10] Congress must act to reduce unnecessary regulatory burden, empower and resource regulators to work more efficiently, and ensure safety and transparency for consumers. If implemented, the following policy options would streamline oversight for animal biotechnology applications, strengthen U.S. competitiveness, and enable these innovations to provide benefits to American farmers and consumers.

Policy Options for Modernizing Animal Biotechnology Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes ten policy options for modernizing oversight of biotech animals. These policy options should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for plants, microbes, and medical products, which are presented in separate discussion papers.

Policy Options for Livestock, Poultry, and Fish

1. Streamline current FDA processes for familiar animals.
2. Establish a clear pathway for APHIS animal health oversight of biotech animals.
3. Establish a clear pathway for FDA food safety oversight of biotech animals.
4. Establish clear pathways for biotech animals used for agriculture and medicine.
5. Ease regulatory barriers for research.
6. Provide consistent labeling of foods from animals produced with biotechnology.

Policy Options for Insects

7. Establish a clear pathway for EPA regulation of biotech insects for pest management.
8. Establish a clear pathway for APHIS animal health oversight of biotech insects.
9. Focus APHIS regulation of insects for biocontrol and sterile insect technique.
10. Provide a clear pathway for FDA food safety oversight of biotech insects.

Policy Options for Livestock, Poultry, and Fish

Livestock and poultry developers need clear, predictable regulatory pathways to bring safe, innovative biotech animals to market. In 2020, the USDA published an Advanced Notice of Proposed Rulemaking (ANPR) to modernize regulation of biotech livestock and poultry.[11] The USDA did not proceed with rulemaking, in part due to ongoing disagreement between the USDA and FDA over their respective jurisdictions and continued overlap of food safety authorities.[12] Developers emphasized that any regulatory approach should leverage each agency's expertise and statutory authority. For biotech plants, APHIS oversees plant health while the FDA oversees food safety. A similar approach for biotech animals, assigning animal health to APHIS and food safety to the FDA, would dramatically improve regulatory clarity, strengthen U.S. competitiveness in animal biotechnology, and align with international regulatory processes.

1. Streamline current FDA processes for familiar animals.
Current regulatory processes impose unnecessary burdens on developers of well-understood biotech animals, including animals engineered with traits that are already present in the species. These burdens slow review without improving safety. To provide interim relief while the USDA and FDA develop clear regulatory pathways, Congress should instruct the FDA to update existing guidance to reduce the burden associated with animal drug regulation that is not appropriate for regulating biotech animals. This should include to remove unnecessary data requirements, reduce excessive adverse event reporting, and simplify supplemental filing

obligations for minor facility changes. Congress should also instruct the FDA to remove the "unapproved drug" designation that comes with Enforcement Discretion for animals, genetics, and cells beyond the first generation. These actions would reduce some regulatory burden but would not resolve challenges associated with regulating biotech animals under an animal drug authority.

2. Establish a clear pathway for APHIS animal health oversight of biotech animals.
The absence of a clear pathway for animal health oversight has resulted in regulatory gaps and forced the FDA to use a regulatory authority that developers say is poorly suited for biotech animals. Building on USDA's ANPR, Congress should instruct APHIS to conduct expedited rulemaking for tiered, risk-based oversight of biotech animals under its animal health authority. Traits that could have been achieved with conventional breeding should be exempt from additional review. Congress should ensure that APHIS has sufficient staffing and technical expertise to regulate animals under their animal health authority. Congress should also clarify that APHIS's authority applies to both communicable disease and non-communicable conditions affecting productivity or welfare and to all animals used in agriculture or that may affect agriculture, including traditional and non-traditional livestock and poultry, fish and other aquatic animals, and wildlife. The FDA would continue to regulate animals raised exclusively in containment for non-agricultural purposes, such as human medicine and biomedical research, but these animals may be subject to APHIS permitting for interstate movement, imports, and exports. APHIS should consult with the FDA on traits related to human or animal disease and with the EPA on traits related to pest management. APHIS should also conduct its reviews in full compliance with applicable environmental laws and regulations, removing the need for the FDA to replicate that work. Together with FDA food safety oversight, APHIS animal health oversight would establish clear regulation for biotech animals and strengthen cross-agency collaboration for animals with overlapping considerations.

3. Establish a clear pathway for FDA food safety oversight of biotech animals.
At the same time, Congress should instruct the FDA to develop tiered, risk-based oversight of biotech animals under its food and feed safety authorities. Traits that could have been achieved with conventional breeding should be exempt from additional review. Congress should also ensure that the FDA has sufficient staffing and technical expertise to regulate animals under their food safety authority. Within the FDA, the Human Foods Program (HFP) oversees food for humans, while the Center for Veterinary Medicine (CVM) oversees food for animals. Congress should require a coordinated FDA approach to ensure that the right expertise is applied to biotech animals without duplicative review. In addition, the FDA should collaborate closely with the FSIS so that the FSIS can fulfill its regulatory responsibilities related to slaughter, processing, packaging, and labeling. Along with APHIS animal health oversight, FDA food safety oversight would further enable commercialization of biotech animals.

4. Delineate clear pathways for biotech animals used for agriculture and medicine.
Some developers are creating animals that are intended for both agricultural and biomedical uses, such as pigs with organs for transplantation into humans that can also be used for meat. These animals could be regulated by APHIS under the pathway described above and by the FDA under their animal drug authority. Congress should require the USDA and the FDA to establish a coordinated pathway for dual-purpose biotech animals. A lead agency should be designated based on objective criteria, such as projected market share, intended scope of deployment, or predominant use claims. Congress should also direct APHIS and the EPA to collaboratively develop clear guidance for developers and to share information as appropriate to ensure a harmonized approach.

5. Ease regulatory barriers for research.
The FDA's drug-based regulation of IGAs in biotech animals imposes inflexible requirements, onerous costs, and decades-long review timelines. Under current requirements, animals in research must receive approval from the FSIS prior to slaughter, and biotech animals must also receive food use approval from the FDA. Developers stressed that these hurdles are largely prohibitive for academic labs and discourage the use of biotechnology, including gene editing, in animal breeding programs.[13] Congress should instruct the FDA and FSIS to collaboratively develop research exemptions and expedited approval pathways that enable research. Agencies should communicate regulatory requirements clearly with small developers. The FDA should expedite food use approvals for meat and milk from biotech animals in research, and agencies should work with state regulators to reduce regulatory burden. In addition,

the FDA should not require food use approval for animals with traits that could have been achieved with conventional breeding. Easing these regulatory barriers would enable scientists to pursue breakthroughs with less red tape, accelerating innovation and delivering benefits to American farmers and to the American people more broadly.

6. **Provide consistent labeling of foods from animals produced with biotechnology.**
Under the Bioengineered Food Disclosure Law, USDA-regulated meat and poultry are exempt from "Bioengineered" labeling.[14] As a result, steak from a biotech steer would not be labeled, while stew containing pieces of the same steak would require the Bioengineered disclosure. Developers noted that this inconsistency can complicate marketing and confuse consumers. Congress should instruct the Agricultural Marketing Service (AMS), FSIS, and FDA to collaboratively investigate options for clear, consistent labeling for foods derived from organisms produced with biotechnology, including animals or animal cells, under their respective labeling authorities. Consistent food labeling across food sources would support consumer confidence.

Policy Options for Insects

As with livestock and poultry, developers of biotech insects need clear, predictable regulatory pathways. Developers expressed concern about duplicative processes and the lack of a clear commercialization pathway for biotech insects. In 2023, the EPA and FDA announced efforts to modernize regulatory oversight of biotech insects along with animal drugs and pesticides, but developers emphasized that problems remain.[15] Single-agency oversight of biotech insects would speed innovation and reduce unnecessary regulatory burden.

7. **Establish a clear pathway for EPA regulation of biotech insects for pest management.**
Developers stressed the importance of EPA pesticide registration to facilitate state regulation and to allow biotech insects to enter international trade. Developers also noted that the EPA has the strongest technical expertise for reviewing biotech insects. Accordingly, Congress should instruct the EPA to delineate a clear regulatory pathway for biotech insects intended for pest management. Congress should also ensure that the EPA has sufficient staffing and technical expertise to regulate such insects. When conducting regulatory review, the EPA should consult with the FDA for traits related to human disease, and with APHIS on insects that are plant or animal pests related to animal disease. Additionally, EPA-regulated insects may require APHIS permitting for interstate movement, imports, and exports. Clarifying EPA's lead role in regulating pest management traits in biotech insects would reduce ambiguity for innovators.

8. **Establish a clear pathway for APHIS animal health oversight of biotech insects.**
Insects intended for purposes other than pest management, such as conservation, need a clear regulatory pathway outside of animal drug and pesticide registration. Congress should instruct APHIS to include biotech insects that are not intended for pest management in its expedited rulemaking for tiered, risk-based oversight of biotech animals under its animal health authority. APHIS regulation should include all non-pest management traits relevant to animal health, including those intended to reduce pathogen load or transmissibility of disease. Along with EPA pesticide registration and FDA food safety oversight, APHIS animal health oversight would provide clear pathways for biotech insects and strengthen cross-agency collaboration for insects with overlapping considerations.

9. **Focus APHIS regulation of insects for biocontrol and sterile insect technique.**
Biocontrol, short for biological control, is a pest management strategy that aims to reduce pest populations by introducing natural predators or other organisms to control the pest, such as using ladybugs to control aphids.[16] A subset of biocontrol, sterile insect technique (SIT), involves the release of sterile insects as a way to reduce insect populations; when the sterile insects mate with wild insects, the resulting eggs are not viable and will not hatch.[17] APHIS Plant Protection and Quarantine (PPQ) currently regulates non-biotech insects for biocontrol, including SIT, but developers noted that PPQ does not provide any documentation to indicate that review is complete. Congress should instruct APHIS to provide developers with documentation for non-biotech biocontrol insects that they have reviewed, with the goal of meeting state and international requirements prior to release. Congress should also instruct APHIS to provide oversight for non-biotech biocontrol insects based on intended use, not the presence of biocontrol properties in the scientific literature. Such insects would not undergo extensive

review but may require APHIS permitting for interstate movement, imports, and exports. These changes would better align APHIS regulation with international norms for scientific risk assessment.

10. Provide a clear pathway for FDA food safety oversight of biotech insects.
Insects can be an efficient, nutritious source of human and animal food, and developers are increasingly using biotechnology in this space.[18] Insects are also key elements of circular bioeconomy strategies that focus on the recycling of food waste and agricultural residues. Congress should instruct the FDA to develop tiered, risk-based oversight of these biotech insects under its food and feed safety authorities. Traits that could have been achieved with conventional breeding should be exempt from additional review. As with livestock, the FDA's HFP and CVM should coordinate on products that are intended for both food and feed. The FDA should consult with APHIS on insects that are plant or animal pests. Additionally, FDA-regulated insects may require APHIS permitting for interstate movement, imports, and exports. The FDA should also consult with EPA on insects with pest management traits, which may be subject to pesticide registration.

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Modernizing Microbial Biotechnology Regulation

In its April 2025 report, the National Security Commission on Emerging Biotechnology (NSCEB) recommended creating simple pathways to market (Rec. 2.1a) and preparing regulatory agencies for novel products (Rec. 2.1b). Since the release of the report, the NSCEB conducted extensive stakeholder outreach to identify specific Congressional actions to achieve those outcomes. The NSCEB looks forward to working with Congress, federal agencies, and other stakeholders to implement these policy options, including through legislation, oversight activities, and other efforts.

Humans have relied on microorganisms for thousands of years, long before scientists understood their existence. Foods such as bread and yogurt are among the earliest examples of humans putting microorganisms to work, and scientists have used biotechnology to improve microorganisms since the 1970s.[1] Today, biotechnology is enabling the development of microorganisms with incredible potential to help the United States defend, build, nourish, and heal.

Applications of genetically engineered microorganisms (GEMs) can be broadly divided into two categories: contained use and environmental release. Acting as tiny factories, GEMs in contained biomanufacturing systems can produce products such as biofuels, chemicals, enzymes, food, and medicines. GEMs can also serve as environmental tools, performing specific functions such as mining rare elements, adding nutrients to soil, and detecting toxins. For both categories, scientists enlist a variety of microorganisms, such as bacteria, yeast, and microalgae.

GEMs in Action

Developers are applying GEMs in a wide range of current and emerging uses, such as:

Biomanufacturing enzymes that allow detergents to clean clothes better at lower water temperatures.[2]

Producing the materials, food, and medicines that astronauts need on long missions.[3]

Providing nitrogen directly to crops, reducing the need for costly imported fertilizer.[4]

Serving as biological sensors that alert military divers of potential toxins in ocean water.[5]

Recovering critical minerals from mining waste and reducing dependence on overseas mines.[6]

Opportunities to Modernize GEM Regulation

The United States divides oversight of GEMs across three primary agencies: the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).[7] However, depending on the product, oversight may involve multiple offices and programs operating under different statutes, some of which are shown in the following table.

Selected Agencies and Authorities for GEM Regulation

Agency	Office or Program	Statutory Authority	Products
Animal and Plant Health Inspection Service (APHIS)	Biotechnology Regulatory Services (BRS)	Plant Protection Act (PPA)	GEMs that may pose a plant pest risk
	Veterinary Services (VS)	Animal Health Protection Act (AHPA)	GEMs that may pose an animal health risk
Food and Drug Administration (FDA)	Human Foods Program (HFP)	Federal Food, Drug, and Cosmetic Act (FFDCA)	GEMs in human food, supplements, & cosmetics
	Center for Veterinary Medicine (CVM)		GEMs in animal food
Environmental Protection Agency (EPA)	Office of Pesticide Programs (OPP)	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	GEMs in pesticides
	Office of Pollution Prevention and Toxics (OPPT)	Toxic Substances Control Act (TSCA)	Intergeneric GEMs that are not regulated by another agency

Fragmented regulation discourages investment, development, and commercialization of GEMs in the United States. Developers often face review by more than one agency, and each agency regulates similar GEMs under different criteria.[8] Unlike the decades of precedent for plant biotechnology, GEM developers have few commercial case studies to guide them. At the same time, emerging technologies such as synthetic genomes and multi-species microbial communities do not fit neatly within existing risk assessment frameworks. Synthetic genomes involve designing and assembling genetic material at a scale beyond traditional genetic modification, while multi-species microbial communities rely on interactions among a group of multiple microorganisms rather than the behavior of a single, well-characterized strain.[9]

Developers are using new gene editing tools, high-throughput automation, and artificial intelligence (AI) to design microorganisms with unprecedented precision. The next generation of GEMs will feature advanced genetic techniques that allow fine-tuned control of microbial behaviors, including production of complex materials on demand. Developers are also exploring new microbial platforms, such as extremophilic microorganisms that can function under harsh conditions and with less water and energy. These scientific advancements underscore the need for a modern regulatory system with flexible but predictable oversight. Without Congressional action to streamline and modernize microbial biotechnology regulation, the United States risks losing global leadership to countries that are building more agile regulatory systems.

Although scientific understanding of GEMs has advanced significantly over the past fifty years, outdated laws and regulations prevent regulatory agencies from fully leveraging these developments. Congress can modernize the relevant laws and equip agencies to review GEMs more efficiently. The following policy options focus on streamlining existing pathways and establishing new ones that support innovation while protecting human health and the environment. If adopted, these policy options would strengthen U.S. leadership in microbial biotechnology and ensure that Americans benefit from new tools for defense, industry, agriculture, medicine, and beyond.

Overview

Policy Options for Modernizing GEM Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes 13 policy options for modernizing oversight of GEMs in containment and in the environment. These policy options should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for plants, animals, and medical products, which are presented in separate discussion papers.

Policy Options for GEMs in Containment

1. Focus EPA regulation on plausible risks of GEMs in containment.
2. Streamline EPA regulation of GEMs in containment.
3. Delineate agency responsibilities for GEMs used in animal feed.
4. Clarify FDA regulation of GEMs used in food.
5. Instruct the FDA to internally coordinate on food and feed safety review.
6. Clarify processes for importing GEMs into the United States.

Policy Options for GEMs in the Environment

7. Focus APHIS regulation on plausible risks to plant health.
8. Delineate clear pathways for GEMs in the environment.
9. Instruct EPA offices to coordinate on pesticide intermediates.
10. Streamline EPA regulation of GEMs for pest management.
11. Clarify FIFRA definitions for pesticide regulation.
12. Provide risk-proportionate permitting for GEMs.
13. Instruct APHIS programs to coordinate on GEMs for plant health.

Policy Options for GEMs in Containment

GEMs are used widely in biomanufacturing to produce a broad range of products. In biomanufacturing, biofuels production, and similar activities, GEMs are contained within closed systems, such as fermentation tanks and closed processing equipment, which are designed to prevent their release into the environment. Advances in metabolic engineering have improved production of desired substances in contained systems by integrating synthetic metabolic pathways into microorganisms. Developers have also transformed industrial enzyme production through advanced genetic techniques. These innovations support sustainable manufacturing processes by increasing the production of desired substances but can present unique regulatory challenges.

1. Focus EPA regulation on plausible risks of GEMs in containment.
Under federal policy known as the Coordinated Framework for Regulation of Biotechnology, the EPA regulates GEMs that are not regulated by other agencies under the Toxic Substances Control Act (TSCA).[10] The EPA applies its authority under TSCA to regulate certain GEMs that are intergeneric, meaning GEMs that have been engineered with DNA from a different type of microorganism.[11]

Developers noted that regulation based on whether a GEM is intergeneric is outdated and overbroad, because microorganisms naturally exchange DNA with one another.[12] Congress should instruct the EPA to regulate GEMs based on plausible risks to human health and the environment, and to reserve the highest scrutiny for novel products such as synthetic genomes. For example, well-understood strains of microorganisms with a history of safe use in biofuels production should face minimal regulation. Congress should ensure that the EPA has sufficient staffing and technical expertise to regulate GEMs based on plausible risks.

2. Streamline EPA regulation of GEMs in containment.
The EPA requires that developers submit a Microbial Commercial Activity Notice (MCAN) before manufacturing, importing, or commercially using certain GEMs. The EPA provides risk-based exemptions based on the organism's characteristics, genetic modifications, use conditions, and containment.[13] Tier I covers the lowest-risk activities with the least oversight, while Tier II allows somewhat broader activities with additional oversight. Together, these two tiers are intended to focus full MCAN review on higher-risk cases while enabling faster pathways for well-understood, low-risk GEMs. Some developers noted that MCANs work well and that the EPA often provides fast responses, but others expressed concerns about costly requirements for low-risk products. Congress should instruct the EPA to work with developers to make minor improvements to the MCAN process and exemptions, which would reduce burden for both developers and regulators, while maintaining safety. Specifically, the EPA should:

- Publish a standard form for MCAN submissions and update guidance with a list of recommended data to reduce the need for additional data requests;
- Establish performance-based standards for maintaining containment during transport and allow transport of GEMs under Tier I if they otherwise meet Tier I requirements;
- Update guidance to allow minor genetic changes within existing MCANs, including parameters for what constitutes a minor change and a notification process that allows developers to update an MCAN when changes meet those parameters; and
- Allow greater consolidation of similar GEMs in one MCAN and update guidance with set criteria for similarity, in recognition that modern strain development programs require testing of 20 to 30 similar strains.

3. Delineate agency responsibilities for GEMs used in animal feed.
Regulatory pathways for GEMs in animal feed depend on whether the GEM is intended to provide nutritional benefits, improve animal health, or provide environmental benefits. Developers noted that this can lead to overlapping jurisdictional issues and unnecessary delays. Congress should pass the Innovative FEED Act of 2025 (S.1906 and H.R.2203), which would create a new regulatory category for animal feed ingredients that do not improve nutrition and direct the FDA to regulate these ingredients as food additives rather than animal drugs. Congress should further clarify that the FDA should regulate GEMs intended to provide nutritional or animal health benefits under its animal food authorities and instruct the FDA to establish a notification-based pathway for well-known probiotic chassis used in animal feed. Congress should also direct the FDA, EPA, and APHIS to establish an interagency agreement outlining regulatory roles and responsibilities for GEM feed additives with claimed environmental benefits, such as reducing methane emissions or improving nutrient utilization. Together, these options would provide a non-drug pathway for animal feed additives and speed commercialization of safe products.

4. Clarify FDA regulation of GEMs used in food.
The FDA requires that food additives undergo premarket review and approval but provides a notification-based pathway for additives that are well-characterized and recognized as low risk. Developers noted that this notification pathway is not clearly defined for GEMs. Congress should clarify that the FDA has the authority to establish streamlined, risk-based review pathways for well-characterized, low-risk GEMs and the food ingredients they produce, consistent with the agency's long-standing approach for other low-risk food substances. Congress should ensure that the FDA has sufficient staffing and technical expertise to regulate GEMs under their food safety authority. The FDA should issue clear guidance defining when premarket notifications are appropriate and publish a list of ingredients for which developers submitted a notification. The FDA should also provide simplified review or exemptions for well-understood GEMs that are not eligible for notification. These actions would reduce uncertainty for developers and allow the FDA to focus resources on products that raise novel or higher-risk safety questions.

5. Instruct the FDA to internally coordinate on food and feed safety review.
Within the FDA, the Human Foods Program (HFP) oversees food for humans, while the Center for Veterinary Medicine (CVM) oversees food for animals. The FDA implements notification-based pathways differently for human and animal food, even though the risk considerations are similar. In addition, different parts of the FDA may review many food ingredients separately, including those derived from GEMs. While there are some differences in risk assessment – for example, animals typically have less varied diets than humans – there are opportunities to consolidate parts of the review. Developers noted that duplicative review can delay approvals. Congress should require a coordinated FDA approach to ensure that the right expertise is applied without duplicative review.

6. Clarify processes for importing GEMs into the United States.
Stakeholders identified inconsistent coordination between APHIS and Customs and Border Protection (CBP) on processing GEM imports into the United States, leading to inappropriate holds of GEMs and non-engineered microorganisms at U.S. ports of entry. Delays or destruction of imported samples can halt experiments, disrupt production timelines, and slow research and development. Congress should instruct APHIS to provide training to CBP to ensure that permitted and permit-exempt microorganisms are not inappropriately held at the border. By directing APHIS to provide targeted training to CBP personnel, Congress can reduce unnecessary delays at ports of entry and support American development of GEMs while maintaining biosecurity.

Policy Options for GEMs in the Environment

Current regulations are poorly suited for GEMs intended for environmental release, creating regulatory dead-ends in which no agency provides a viable pathway to commercialization. Both APHIS and the EPA have authority over some GEMs intended for environmental release, but their oversight relies on outdated frameworks. To date, the only GEMs EPA has approved for environmental release are microbial pesticides. APHIS lacks a commercialization pathway for environmental release altogether. As a result, developers confine work indoors or move projects offshore. Solutions to these regulatory gaps are increasingly important as developers pursue beneficial products such as GEMs that capture rare earth metals from mining waste or that pull pollutants from water and soil.[14]

7. Focus APHIS regulation on plausible risks to plant health.
APHIS oversight of GEMs hinges on "plant pest risk," an outdated interpretation of its authority in the Plant Protection Act (PPA) to protect against plant pests, which are organisms that can damage or cause disease in plants.[15] APHIS's regulatory approach depends on whether a GEM itself is a plant pest, or if it is engineered with DNA from a plant pest, rather than any actual risks. Congress should instruct APHIS to regulate GEMs based on plausible risks to plant health or the environment, and to reserve the highest scrutiny for novel products, such as synthetic genomes or multi-species groups of GEMs that are intended for release into the environment together. Congress should ensure that APHIS has sufficient staffing and technical expertise to regulate GEMs under their plant health authority. Congress should also direct APHIS to use exemptions or fast-track review for well-understood or low-risk GEMs, such as microorganisms that do not replicate in the environment or that are closely related to well-characterized strains. Replacing the outdated plant pest framework with tiered, risk-based review would allow APHIS to bypass full reviews for products that pose minimal risk to plant health or the environment, while maintaining oversight of novel products.

8. Delineate clear pathways for GEMs in the environment.
As mentioned above, the EPA regulates intergeneric GEMs that are not regulated by other agencies under TSCA. Specifically, the EPA regulates GEMs that are intended for uses other than food, food additives, drugs, cosmetics, medical devices, tobacco, nuclear material, firearms, or pesticides. Developers emphasized that chemical risk assessment frameworks can be poorly suited to microorganisms, which replicate, evolve, and interact with ecosystems in ways that chemicals do not. As APHIS establishes a clear pathway for GEMs through the policy option described above, some GEMs could fall under both APHIS and EPA oversight. In addition to instructing the EPA and APHIS to regulate GEMs based on plausible risks, Congress should direct the agencies to collaboratively determine which GEMs would be regulated by each agency, and to avoid duplicative oversight. Congress should also direct APHIS and the EPA to collaboratively develop clear guidance for developers and to share information as appropriate to ensure a harmonized approach.

9. Instruct EPA offices to coordinate on pesticide intermediates.
The EPA regulates pesticides, including those produced by GEMs, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). However, the EPA regulates pesticide intermediates under TSCA. Developers expressed concern that GEMs used for pest management consequently often face regulation under both FIFRA and TSCA. Although chemical pesticides and intermediates can also face regulation under both statutes, developers emphasized that applying both FIFRA and TSCA to pesticidal GEMs results in greater complexity and burden than is warranted by their risk profile. Congress should instruct the EPA's Office of Pesticide Programs (OPP) and Office of Pollution Prevention and Toxics (OPPT) to provide coordinated review for products that are regulated by both offices. Congress should also direct the OPP and OPPT to collaboratively develop clear guidance for developers, and to share information as appropriate to ensure a harmonized approach.

10. Streamline EPA regulation of GEMs for pest management.
Microorganisms provide innovative opportunities for pest management, such as GEMs engineered to target specific plant diseases.[16] Congress should instruct the EPA to establish a streamlined regulatory pathway for microbial pesticides that do not replicate in the environment, use well-characterized, low-risk strains, or use well-understood modes of action. Streamlining the review of low-risk microbial pesticides would accelerate access to safer, more sustainable pest control options and align with the EPA's ongoing efforts to modernize regulation of microbial pesticides.

11. Clarify FIFRA definitions for pesticide regulation.
The EPA broadly interprets the definition of "pesticide" to include products such as biostimulants – biological substances that can stimulate natural processes in plants, such as faster growth or defense mechanisms against pests and disease.[17] Developers emphasized that this creates unnecessary regulatory burden for GEMs that are not intended to function as pesticides. Congress should update definitions in FIFRA, building on the Plant Biostimulant Act of 2025 (S.1907 and H.R.3783), which the NSCEB previously endorsed in its December 2024 interim report. Congress should also instruct the EPA to clarify exemptions and remove ambiguity around which products are subject to pesticide regulation. In addition, the EPA and APHIS should work collaboratively to shift non-pesticidal products to more appropriate regulatory pathways. Products that are exempt from pesticide regulation should also be exempt from requirements for pesticide residues, known as "tolerances," or should be covered by broad tolerance categories.

12. Provide risk-proportionate permitting processes for GEMs.
APHIS and the EPA collectively regulate outdoor field trials of GEMs under three statutes: APHIS regulates GEM field trials under the PPA, the EPA regulates small-scale trials of GEMs under TSCA, and the EPA regulates larger field trials of pesticidal GEMs under FIFRA. Developers stressed that it is often unclear which agency should regulate GEMs with multiple uses or at different stages of development. Developers also noted that containment requirements often do not reflect actual environmental risk. Congress should instruct APHIS and the EPA to adopt performance-based permit standards that focus on plausible risk pathways, while reducing requirements for well-understood products. Congress should also direct APHIS and the EPA to collaboratively develop clear guidance for developers and to share information as appropriate to ensure a harmonized approach. Guidance should outline a stepwise approach, with smaller trials under an APHIS permit or an EPA TSCA Environmental Release Application (TERA), transitioning to an EPA Experimental Use Permit (EUP) under FIFRA for large-scale pesticidal uses. These improvements would streamline permits and appropriately focus APHIS and EPA resources, without imposing unnecessary barriers to innovation.

13. Instruct APHIS programs to coordinate on GEMs for plant health.
Within APHIS, two programs have overlapping oversight for microorganisms used in agricultural products. The Biotechnology Regulatory Service (BRS) regulates GEMs that may pose a plant pest risk while Plant Protection and Quarantine (PPQ) regulates unmodified microorganisms. However, developers noted that BRS and PPQ maintain separate plant pest lists to determine which pests call for increased regulatory scrutiny. In addition, developers noted that BRS and PPQ have inconsistent processes for assessing whether a product is exempt from regulation, causing duplication and delays. Congress should require a coordinated APHIS approach to ensure that the right expertise is applied without duplicative review.

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Modernizing Medical Biotechnology Regulation

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The United States has been the global leader in medical biotechnology since the 1970s and must modernize its medical biotechnology regulations to maintain its leadership. China's share of the global drug development pipeline has risen to 30%, up from just 6% a decade ago.[1] Developers are increasingly shifting medical research, development, and manufacturing overseas, in part due to slow, unpredictable regulation in the United States. This weakens U.S. competitiveness and delays new treatments for American patients.

Opportunities to Modernize Medical Biotechnology Regulation

Preserving and strengthening American biotechnology leadership will require the Food and Drug Administration (FDA) to modernize its approach to cutting-edge medical products. The FDA divides oversight of medical products across three centers: the Center for Drug Evaluation and Research (CDER) regulates drugs, biosimilars, generics, and over-the-counter products; the Center for Biologics Evaluation and Research (CBER) regulates biologics, vaccines, cell and gene therapies, and blood; and the Center for Devices and Radiologic Health (CDRH) regulates medical devices and radiation-emitting products. This structure has largely been successful for traditional products but is increasingly inefficient when applied to innovative medical products.

Current regulatory frameworks were built for well-characterized, small-molecule drugs. The FDA struggles to adapt to biotechnology-enabled medical products, such as cell and gene therapies.[3]

The FDA's Hybrid Funding Model

In fiscal year 2024, the FDA received about $3.6B in annual appropriations and $3.3B from industry user fees.[2] This hybrid funding model balances stable appropriations with user fees that directly support product review.

- Annual appropriations are not tied to product review. Instead, they fund broader functions, such as outreach and interagency coordination, along with salaries, facilities, and information technology systems. Regular, sustained funding is essential for agency independence and for cross-cutting public-health functions.
- User fees are negotiated by the FDA and industry every five years, then codified by Congress. They establish specific industry fees and regulatory timelines for each process. User fees must be spent on work that is directly linked to product review, such as reviewer staffing, outside consults, and related infrastructure.

In addition, while the FDA's hybrid funding model provides flexibility, it also limits long-term, systemic regulatory improvements and modernization.

The United States now has advanced scientific and regulatory tools to evaluate innovative new medicines produced with biotechnology, but Congress needs to unlock them. Congress must act to reduce unnecessary regulatory burden for medical biotechnology products, and empower and resource regulators to work more efficiently. Adopting these policy options would speed medical product reviews, bolster U.S. competitiveness in global health innovation, and bring safe treatments to American patients faster.

Overview

Policy Options for Modernizing Medical Biotechnology Regulation

Building on the NSCEB's prior recommendations and extensive stakeholder input, this paper describes 22 policy options across five key areas to improve the regulation of biotechnology medical products: ensuring predictable and transparent reviews; conducting faster, fairer clinical trials; hiring, training, and retaining regulators; building a connected FDA; and promoting efficient manufacturing. These policy options should be considered alongside the NSCEB's overarching policy options for modernizing biotechnology product regulation. The NSCEB also developed detailed policy options for microbes, plants, and animals, which are presented in separate discussion papers.

Ensure Predictable and Transparent Reviews

1. Finalize and expand the platform technology designation.
2. Help developers meet data expectations.
3. Align evidentiary standards and review practices.
4. Establish a regulatory sandbox for medical biotechnology products.
5. Validate modern testing methods.

Conduct Faster, Fairer Clinical Trials

6. Require centralized review for multi-site trials.
7. Allow trial designs for small populations.
8. Align endpoints and biomarkers across the FDA.
9. Remove barriers to speedy Phase I trials.
10. Remove barriers to insurance cost sharing.

Hire, Train, and Retain Regulators

11. Target workforce gaps with existing tools.
12. Tie career progression to continuing education.
13. Rebuild the FDA's internal policy capacity.

Build a Connected FDA with Modern Integrated Systems

14. Build a single FDA enterprise system.
15. Leverage FDA data to support innovation and safety.
16. Implement AI-assisted review.
17. Harmonize terminology across agencies.
18. Support strong participation in international standard setting.

Promote Efficient Manufacturing

19. Expand risk-based inspections overseas.
20. Clarify manufacturing requirements.
21. Coordinate country-of-origin labeling.
22. Expand domestic manufacturing capacity and workforce.

Ensure Predictable and Transparent Reviews

Predictable review processes and clear regulatory milestones are essential for securing investment, scaling up manufacturing, and keeping trial sites and patients engaged. Biotechnology developers face uncertainty from uneven timelines, opaque decisions, shifting expectations, and inconsistent processes. These challenges raise the cost of product development, prolong the regulatory process, and delay patient access to new therapies.

1. **Finalize and expand the platform technology designation.**
   Biotechnology enables developers to rapidly build multiple therapies from the same well-characterized platform. However, inconsistency across the FDA limits the reuse of validated components, assays, and manufacturing methods. Additionally, current FDA policy restricts a developer from referencing their own previously submitted information for biologics, resulting in a full review even when a platform has already been evaluated. Congress should instruct the FDA to finalize its draft platform technology guidance and establish a cross-center platform technology designation with uniform criteria, explicit carryover of validated data, and shared standards. This would reduce repetitive testing and review, lower costs, and speed scale-up of medical biotechnology products.

2. **Help developers meet data expectations.**
   Developers lack clear guidance on data expectations and common deficiencies, which leads to delays and multiple rounds of revisions. The FDA has made some efforts to provide clarity, such as by releasing Complete Response Letters that describe why a submission was rejected. However, these letters are heavily redacted, which signals risk to investors while providing little usable guidance to developers. Congress should direct the FDA to publish aggregated, de-identified reports of common deficiencies and to standardize deficiency letters into a four-part structure: what was submitted, why it was insufficient, what is required, and the scientific rationale.[4] Clearer expectations would reduce back and forth between developers and reviewers and shorten the time to approval.

3. **Align evidentiary standards and review practices.**
   Varying standards of evidence and review practices across the FDA result in inconsistent timelines and decisions. Congress should require that the FDA develop uniform definitions for key terms, such as "reasonably likely to predict clinical benefit" and "serious condition." Congress should also require that the FDA develop cross-center guidance that applies these definitions consistently to standardize decisions and reduce uncertainty for developers.

4. **Establish a regulatory sandbox for medical biotechnology products.**
   FDA regulators lack a structured way to test new oversight approaches before applying them across the agency. Congress should direct the FDA to create a "regulatory sandbox" for time-limited trials of new regulatory processes for emerging biotechnology products. These efforts would allow the FDA to evaluate and refine updated workflows, guidance, and regulations before broader implementation. The FDA should then expedite final regulations or guidance based on the results. A regulatory sandbox would also encourage iterative experimentation with digital tools under regulatory supervision, while accelerating learning and de-risking innovation before broader adoption.[5]

5. **Validate modern testing methods.**
   New approach methodologies (NAMs), including predictive tools such as digital twins and organ-on-a-chip systems, can generate safety and efficacy data faster and at lower cost than traditional animal studies. However, these methods lack consistent validation and acceptance across the FDA, limiting their use in regulatory submissions. Congress should direct the FDA and the National Institutes of Health (NIH) to establish clear, science-based validation pathways for NAMs and other predictive tools. The FDA should consistently accept validated methods to reduce redundant studies and support innovation while maintaining a high bar for safety.

Conduct Faster, Fairer Clinical Trials

The FDA's clinical trial expectations are centered on large, randomized trials with thousands of patients. These expectations are increasingly out of step with the realities of modern medicine. Advances in diagnostics and genomics now allow researchers to define diseases more precisely, dividing patients into smaller groups. Large-scale clinical trials with thousands of patients are not possible for ultra-rare diseases that affect only a handful of people in the United States. Rigid regulatory standards that demand traditional trial designs are unworkable in these contexts. This misalignment between regulatory expectations and

clinical realities disproportionately affects rare disease communities and undercuts the very promise of precision medicine. Regulatory flexibility, including alternative endpoints, adaptive trial designs, and conditional approvals, is essential to ensure that scientific progress can translate into patient impact, even when the patient population is measured in dozens rather than thousands.

Operational constraints further undermine clinical trial efficiency. Layered bureaucracy significantly slows clinical trials in the United States and pushes developers to conduct clinical trials abroad. Stakeholders report that recruitment of trial participants continues to be a challenge, despite federal efforts. Other countries, such as Australia and China, are attracting developers due to investigator-initiated pathways and faster patient recruitment. Modern digital health tools can increase patient access to trials, but uptake is slow. Developers also report inconsistent application of standards for endpoints, biomarkers, and data requirements, despite FDA guidance on adaptive trial designs and alternative pathways. The United States needs risk-based, science-driven reforms to accelerate clinical trials and ensure that cutting-edge medical products are available to American patients first.

6. **Streamline multi-site trials.**
   Large, multi-site clinical trials are often delayed because each trial location must go through its own ethics review. This creates repetitive paperwork rather than improving patient protections. The Federal Policy for the Protection of Human Subjects, referred to as the Common Rule, encourages the use of a single Institutional Review Board (IRB) for multi-site studies, but provides exemptions for FDA-regulated trials.[7] Although the FDA has proposed alignment with the Common Rule, the lack of a clear mandate has resulted in inconsistent implementation, and stakeholders report that too few trials use a single IRB. Congress should instruct the Department of Health and Human Services (HHS) to require centralized IRB review for FDA-regulated multi-site trials, with limited exceptions. The FDA and the HHS Office for Human Research Protections (OHRP) should create a clear framework for designating one independent IRB of record for each multi-site trial, with modular consent language to address site-specific needs. Ancillary committees such as pharmacy, radiation safety, biosafety, and conflict of interest could remain local to each site, but run in parallel. Congress should also instruct the HHS to finalize its "Use of a Single Institutional Review Board for Cooperative Research" guidance, and the HHS should provide practical guidance on topics such as insurance, onboarding, and training. This framework and guidance would facilitate central contracting with trial sites to reduce administrative burden and decrease timelines. In addition, Medicaid patients often face barriers in receiving care across state lines. This can prevent eligible patients from enrolling in clinical trials, particularly when trials for rare diseases are offered only at a limited number of sites nationwide. State Medicaid programs should implement pathways, such as expedited or provisional enrollment for clinical trials, to allow residents to participate in out-of-state clinical trials.[8] Together, these actions would speed patient enrollment, reduce the administrative burden of standing up trial sites, and expand the geographic distribution of trials so more people can participate, even if they live far from a major medical center.

Clinical Trials Ensure Safety and Efficacy

Before a medical product can reach patients, it must go through a multi-step process to ensure it is safe and effective. Developers begin with early research and laboratory testing, followed by animal studies to assess safety. If results look promising, the product is tested in several phases of clinical trials. Each phase builds on the previous step to reduce risk, gather stronger evidence, and protect patients.[6]

1. **Early Testing:** Identifies promising compounds through laboratory and computational studies to assess basic function and feasibility.
2. **Animal Testing:** Evaluates safety, dosing, and potential side effects before testing in humans. This could take place in animals or new-approach methodologies.
3. **Phase 1:** Tests safety in a small group of patients or healthy volunteers (15 to 30).
4. **Phase 2:** Explores whether the product works and identifies appropriate dosage in a small group of patients (50 to 100).
5. **Phase 3:** Confirms safety and efficacy in a larger group of patients (hundreds or more), using a randomized controlled trial design in which participants are randomly assigned to receive either the new treatment or a comparison treatment.
6. **FDA Review:** The FDA evaluates all data to decide whether the developer can bring the product to market.
7. **Phase 4:** Post-market monitoring identifies rare or long-term effects.

7. **Allow trial designs for small populations.** Promising therapies often stall not because they are unsafe or ineffective, but because the required trial structure is mathematically or logistically impossible when only a small number of patients exist. The FDA instituted Rare Disease Evidence Principles (RDEP) to support more flexible trial designs, but developers still face inconsistent acceptance by reviewers, unnecessary meetings, and additional paperwork. Congress should clarify that developers can meet the requirement for "substantial evidence" through other scientifically valid trial designs when large trials are not feasible. Congress should also require that the FDA use formal notice-and-comment rulemaking for the recently-announced Plausible Mechanism Pathway, and, if it proves to have merit, take steps to ensure consistent implementation. These changes would allow more rare disease treatments to become available faster.

8. **Align endpoints and biomarkers across the FDA.** Endpoints and biomarkers are the measurable outcomes and biological indicators used in clinical trials to determine whether a medical product is safe and effective. Inconsistent acceptance of endpoints and biomarkers across the FDA creates confusion for developers and delays clinical trials.[9] Congress should direct the FDA to create a cross-center process for issuing harmonized guidance and to convert relevant review frameworks into binding resources with uniform definitions and expectations for evidence.[10] These actions would standardize expectations and provide the necessary consistency and predictability to speed up trials.

9. **Remove barriers to speedy Phase I trials.** Some countries, including Australia, have a streamlined process for Phase I trials, in which the developer provides a 30-day notice to the regulator, then the trial proceeds unless the regulator objects.[11] In the United States, the Federal Food, Drug, and Cosmetic Act (FFDCA) similarly specifies that a trial may begin 30 days after notice to the FDA, and that the FDA may place a clinical hold if there are safety concerns.[12] However, stakeholders noted that delays in the initiation of Phase I trials are common in the United States, especially compared to some countries such as Australia and China. In fact, some stakeholders reported that they were unaware that current U.S. law already allows trials to begin 30 days after notification. Congress should direct the FDA to apply a risk-based approach to clinical holds for Phase I trials and to limit holds to cases where credible safety concerns are identified. The FDA should also provide clear information to developers about its 30-day notice for Phase I trials. This would enable timely initiation of Phase I trials while maintaining patient safety.

10. **Remove barriers to insurance cost sharing.** Current law requires insurers to pay for the routine costs of care for enrollees in clinical trials, though stakeholders reported that this is a challenge in practice. Specifically, when patients need a treatment and there is no standard of care for the disease, or the experimental treatment is not building upon a standard, insurers cannot easily assess if the treatment is routine or not. The result is that developers bear a disproportionate share of costs to care for trial enrollees. According to stakeholders, cost sharing is particularly important for early trials, when funding is tighter. Stakeholders suggested that other payment models may be more helpful for Phase I trials. Congress should consider new payment models as well as ways to ensure that the existing laws are being implemented to best serve patients and further innovation. Congress should also instruct the Office of the Inspector General (OIG) for the Centers for Medicare & Medicaid Services (CMS) to evaluate the ease of clinical trial enrollment for rare and chronic disease patients in a selection of state Children's Health Insurance Program (CHIP) and Medicaid programs, and challenges in paying for the costs of care for these patients. State Insurance Commissioners should also consider how state requirements may affect this issue. Together, these actions would lower costs for early-stage trials, improve predictability for developers, and support continued innovation in medical biotechnology.

Hire, Train, and Retain Regulators

Persistent staffing shortages and knowledge gaps limit the FDA's ability to review emerging technologies. Review teams often lack needed expertise in rare diseases, cell and gene therapy, and data science. High rates of staff turnover drain institutional knowledge and shift work to less experienced staff. The FDA has piloted training initiatives, such as Accelerating Rare disease Cures (ARC), Rare Disease Evidence Principles, and Support for clinical Trials

Advancing Rare disease Therapeutics (START), but these remain small in scale. Training opportunities are limited, workforce planning is opaque, and capacity for cross-functional policy has eroded.

11. **Target workforce gaps with existing tools.** Persistent staffing shortfalls limit the FDA's ability to review applications efficiently and keep pace with scientific advancements. Congress should direct the FDA to implement a workforce plan with detailed benchmarks and public dashboards that track vacancies, time-to-hire, and retention. The FDA should deploy existing authorities to strengthen its talent pipeline, such as direct-hire, special salary rates, and recruitment and retention incentives. Clear staffing targets would ensure that hiring efforts translate into increased review capacity.

12. **Tie career progression to continuing education.** The FDA struggles to compete with industry for talent, and reviewers often lack experience with the latest scientific advances. Congress should require that the FDA establish a continuing education framework, similar to Continuing Medical Education, that links verified learning credits to promotions, proficiency pay, and leadership eligibility. The FDA should set minimum annual requirements and define eligible activities, such as scientific conferences, workshops, certifications, and interagency rotations. The FDA should also evaluate and expand programs such as its Cell and Gene Therapy Interactive Site Tours and CDRH's Experiential Learning Program. A structured, incentivized training system would strengthen reviewer expertise, improve retention, and close knowledge gaps.

13. **Rebuild the FDA's internal policy capacity.** Critical policy development initiatives such as CDER's Office of New Drugs and the FDA's Rare Disease Council are under-resourced, despite their role in maintaining consistency across the FDA. Reductions in policy staff have slowed guidance updates and constrained activities such as stakeholder outreach and international harmonization efforts. Congress should restore and resource the FDA's policy offices and cross-center councils to accelerate guidance development and improve consistency across programs.

Build a Connected FDA with Modern, Integrated Systems

Fragmented information technology systems and manual workflows slow FDA review, create inconsistencies, and complicate coordination between CDER, CBER, and CDRH. Advances in artificial intelligence and machine learning (AI/ML) offer opportunities to automate routine tasks, strengthen data quality, and streamline review, but only if the FDA has modern, connected infrastructure. Terminology differences across the FDA and other agencies pose further barriers to consistent review. Without concerted efforts, legacy systems and fragmentation will continue to delay reviews and prevent the United States from using the FDA's clinical and manufacturing data as a strategic asset.

14. **Build a single FDA enterprise system.** The FDA has taken steps to standardize and consolidate submissions, but these initiatives remain siloed and incomplete. Congress should require the development of a single FDA enterprise system that unifies its cloud submission infrastructure and integrates AI/ML tools, shared application interfaces, consistent data access controls, and cross-Center analytics. The platform should support machine-readable standards and enable secure operations, such as audit trails and role-based access. A clear transition plan would include staff training, developer outreach, data sharing, timelines, and escalation procedures. By providing resources for an FDA enterprise system, Congress would accelerate reviews and enable data assets to be fully leveraged across the product life cycle.

15. **Leverage FDA data to support innovation and safety.** The FDA holds valuable troves of data from decades of regulatory reviews and post-market monitoring. Stakeholders proposed several ways to make better use of this information to improve oversight and support innovation, including fee-based access models to monetize certain data. For example, the FDA could expand academic access to Sentinel, its active surveillance system for post-market safety. The FDA could create a fee-based platform that allows industry, academics, and others to access aggregated and de-identified data from product submissions. In addition, combining data from the FDA and CMS could dramatically strengthen early detection of safety issues and help inform coverage decisions or label expansions for approved products.

16. **Implement AI-assisted review.**
The FDA is taking steps to adopt AI/ML tools, but capabilities are limited and uneven across the agency. AI could support tasks such as summarizing documents, validating data quality, and checking cross-submission consistency. For example, submissions often arrive as static PDFs, forcing manual processing that introduces errors and delays review, but AI could extract structured data and check for completion. Congress should instruct the FDA to implement AI-assisted review with human-in-the-loop controls, validated models, continuous monitoring, and regular audits. Congress should also establish a dedicated, well-resourced FDA AI task force to accelerate implementation, train FDA reviewers, and coordinate adoption across the FDA. Careful AI implementation would accelerate drug-approval timelines and make staff more efficient.

17. **Harmonize terminology across agencies.**
Center-specific definitions and data fields within the FDA make it difficult to combine and compare regulatory and medical data. For example, the terminology used to describe a cancer diagnosis can either facilitate or hinder comparison between patients.[13] Inconsistencies extend to the NIH and other agencies within the HHS. Congress should direct the HHS to develop a "common terminology service" to provide standardized, centralized definitions across systems, building on the NIH's efforts toward common data elements.[14] Harmonized terminology would support data sharing across the HHS and accelerate the translation of research into needed medical treatments.

18. **Support strong participation in international standard setting.**
Mismatched global standards complicate multi-country regulatory submissions, increasing costs and delaying patient access to new therapies. Congress should direct the FDA to strengthen participation in international standards development. Specifically, the FDA needs dedicated staff to lead International Council for Harmonisation (ICH) working groups. Because international regulatory agencies adopt ICH guidelines as binding, stronger participation would give the United States direct influence on regulatory requirements in other countries, including China. Shared international standards would also reduce duplicative trials and ease multi-country approvals.

Promote Efficient Manufacturing

Ensuring that novel products can be manufactured domestically is a matter of national strategic importance. Conventional, small-molecule medicines are shelf-stable and can be mass-produced overseas. In contrast, cell and gene therapies must be manufactured on-demand or in small batches to be delivered quickly. The United States must enact policies for modernized, domestic manufacturing to support American innovation and safeguard critical supply chains.

19. **Expand risk-based inspections overseas.**
The FDA has already implemented a risk-based approach to inspections, in which inspection history, safety signals, and other factors help the FDA prioritize inspections. The FDA often conducts domestic inspections with little advance notice, but surprise inspections of manufacturers overseas are all but impossible due to international agreements. This leaves domestic manufacturers at a disadvantage. Congress should instruct the FDA to consider options to enforce parity in inspection frequency between domestic and foreign facilities. The FDA should evaluate and consider expansion of its Foreign Unannounced Inspection program pilot to help level the playing field for U.S. manufacturers. Expanding mutual recognition agreements to cover pre-approval inspections would reduce duplication and accelerate approvals. In addition, domestic policy incentives such as fee waivers, exclusivity extensions, and priority inspections would help attract investment back to the United States and rebuild critical development and manufacturing capacity.

20. **Clarify manufacturing requirements.**
The FDA sets manufacturing requirements for products in development and on the market. These Current Good Manufacturing Practice (CGMP) regulations cover issues from the cleanliness of the workspace to potency and purity testing to record keeping. While the FDA does not require full compliance with Good Manufacturing Practice (GMP) for Phase I trials, many developers believe they must comply at this stage. Congress should instruct the FDA to clearly communicate manufacturing requirements and issue a roadmap so that developers are aware of validation requirements. This would help correct the widespread misconception that full GMP compliance is required prior to human trials.

21. Coordinate country of origin labeling.
Under existing law, all products that are imported into the United States must be marked with their country of origin, and the container that reaches the consumer must have this information.[15] U.S. Customs and Border Protection (CBP) is responsible for enforcement at the port. Many FDA-regulated products are shipped in large, multi-unit packages and individual products are not typically marked with their country of origin, even though each product typically includes FDA-approved labeling. Congress should instruct the FDA, CBP, and Federal Trade Commission (FTC) to coordinate enforcement and ensure each individual product is labelled appropriately. This would allow consumers to understand the sources of medical products and consider the country of origin when making purchasing decisions.

22. Expand domestic manufacturing capacity and workforce.
Particularly for emerging companies, the capital investment needed for a stand-alone manufacturing facility can be a major barrier in developing a viable therapy. Even when facilities are available, a fully-trained workforce is needed. Stakeholders discussed a variety of options to address these concerns. For example, Congress could consider opportunities to license private platforms to national labs and to enable entities such as academic medical centers to manufacture emerging products like personalized gene therapies. Stakeholders also discussed the potential for incentives, such as priority reviews, vouchers, or tax incentives, for products manufactured in the United States. These actions would enable more companies to manufacture advanced therapies in the United States and accelerate patient access to innovative treatments.

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Acronyms

AAFCO: Association of American Feed Control Officials

AHPA: Animal Health Protection Act

AI: artificial intelligence

AI/ML: artificial intelligence and machine learning

AMS: Agricultural Marketing Service

ANPR: Advanced Notice of Proposed Rulemaking

APEC: Asia-Pacific Economic Cooperation

APHIS: Animal and Plant Health Inspection Service

ARC: Accelerating Rare disease Cures

ASTM: American Society for Testing and Materials

BRS: Biotechnology Regulatory Services

CBER: Center for Biologics Evaluation and Research

CBP: Customs and Border Protection

CDER: Center for Drug Evaluation and Research

CDRH: Center for Devices and Radiologic Health

CGMP: Current Good Manufacturing Practice

CHIP: Children's Health Insurance Program

CMS: Centers for Medicare & Medicaid Services

CVM: Center for Veterinary Medicine

EFSA: European Food Safety Authority

EPA: Environmental Protection Agency

EPIA: Egg Products Inspection Act

EUP: Experimental Use Permit

FDA: Food and Drug Administration

FFDCA: Federal Food, Drug, and Cosmetic Act

FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act

FMIA: Federal Meat Inspection Act

FSANZ: Food Standards Australia New Zealand

FSIS: Food Safety and Inspection Service

FTC: Federal Trade Commission

GEMs: genetically engineered microorganisms

GMP: Good Manufacturing Practice

HFP: Human Foods Program

HHS: Department of Health and Human Services

ICH: International Council for Harmonisation

IGA: intentional genomic alteration

IRB: Institutional Review Board

ISO: International Organization for Standardization

MCAN: Microbial Commercial Activity Notice

NAMs: new approach methodologies

NBCO: National Biotechnology Coordination Office

NIH: National Institutes of Health

NSCEB: National Security Commission on Emerging Biotechnology

OECD: Organisation for Economic Co-operation and Development

OHRP: Office for Human Research Protections

OIG: Office of the Inspector General

OPP: Office of Pesticide Programs

OPPT: Office of Pollution Prevention and Toxics

PIPs: plant-incorporated protectants

PPA: Plant Protection Act

PPIA: Poultry Products Inspection Act

PPQ: Plant Protection and Quarantine

QMS: quality management system

R&D: research and development

RDEP: Rare Disease Evidence Principles

RNAi: RNA interference

SIT: sterile insect technique

START: Support for clinical Trials Advancing Rare disease Therapeutics

TERA: TSCA Environmental Release Application

TSCA: Toxic Substances Control Act

USDA: U.S. Department of Agriculture

USTR: Office of the United States Trade Representative

VS: Veterinary Services

Staff at the National Security Commission on Emerging Biotechnology authored this paper with input from the NSCEB Commissioners. The content and recommendations of this paper do not necessarily represent positions officially adopted by the NSCEB.

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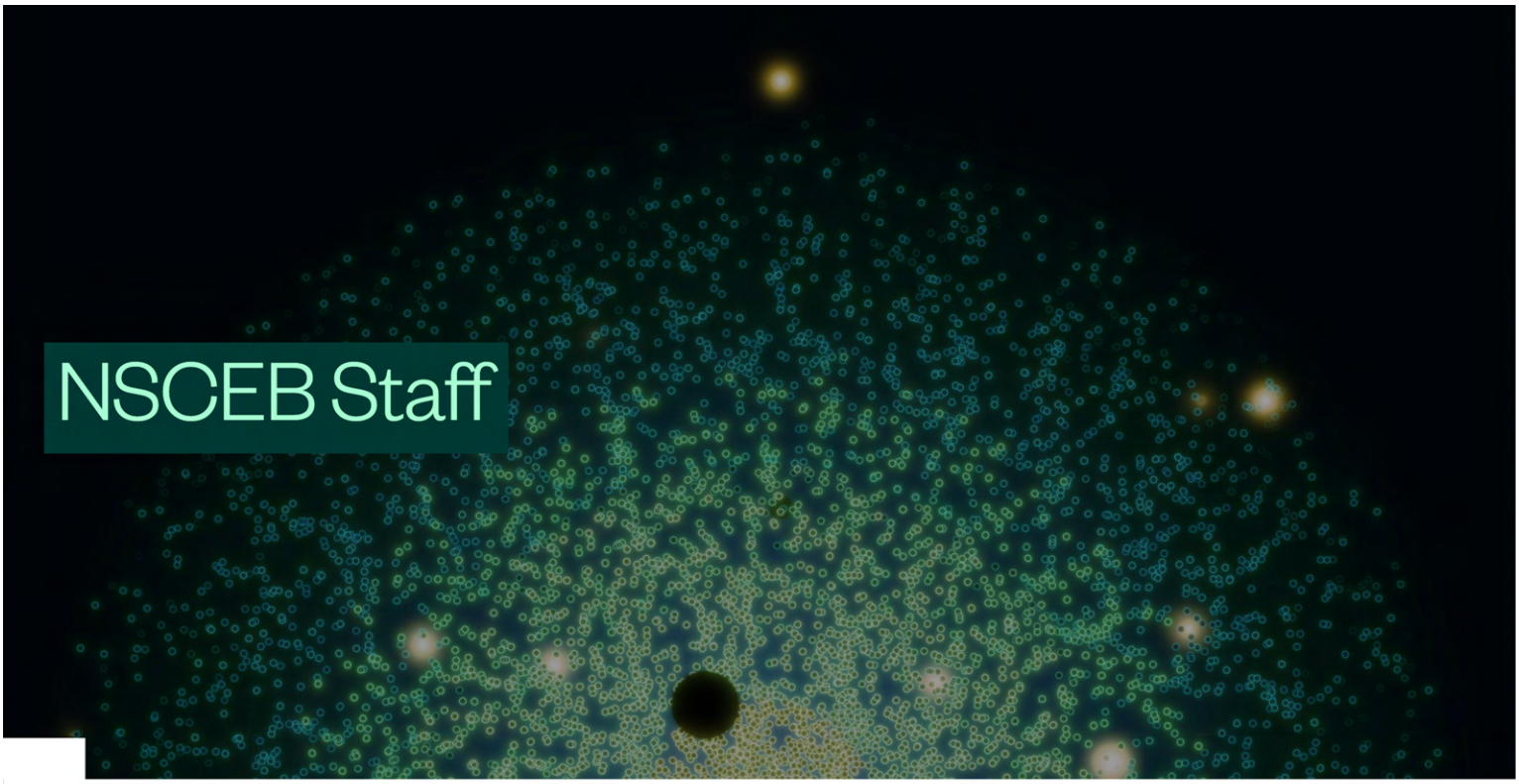

Appendix B

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** This list includes Commissioner staff designees from April 2025 to December 2025.

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Cara Tenenbaum
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* This list includes Commission staff, fellows, detailees, and interns from March 2023 through April 2025.