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.

Overview

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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Acronyms

- AAFCO: Association of American Feed Control Officials
- AI: artificial intelligence
- APEC: Asia-Pacific Economic Cooperation
- APHIS: Animal and Plant Health Inspection Service
- ASTM: American Society for Testing and Materials
- EFSA: European Food Safety Authority
- EPA: Environmental Protection Agency
- FDA: Food and Drug Administration
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- FSANZ: Food Standards Australia New Zealand
- HHS: Department of Health and Human Services
- ISO: International Organization for Standardization
- 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
- QMS: quality management system
- R&D: research and development
- USDA: U.S. Department of Agriculture

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.

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 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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Acronyms

- APHIS: Animal and Plant Health Inspection Service
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- FDA: Food and Drug Administration
- FFDCA: Federal Food, Drug, and Cosmetic Act
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- HFP: Human Foods Program
- NSCEB: National Security Commission on Emerging Biotechnology
- PIPs: plant-incorporated protectants
- PPA: Plant Protection Act
- RNAi: RNA interference
- USDA: U.S. Department of Agriculture
- USTR: Office of the United States Trade Representative

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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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Acronyms

- AHPA: Animal Health Protection Act
- AMS: Agricultural Marketing Service
- ANPR: Advanced Notice of Proposed Rulemaking
- APHIS: Animal and Plant Health Inspection Service
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- EPIA: Egg Products Inspection Act
- FDA: Food and Drug Administration
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- FMIA: Federal Meat Inspection Act
- FSIS: Food Safety and Inspection Service
- HFP: Human Foods Program
- IGA: intentional genomic alteration
- NSCEB: National Security Commission on Emerging Biotechnology
- PPA: Plant Protection Act
- PPIA: Poultry Products Inspection Act
- PPQ: Plant Protection and Quarantine
- SIT: sterile insect technique
- USDA: U.S. Department of Agriculture

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.

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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Acronyms

- AHPA: Animal Health Protection Act
- AI: artificial intelligence
- APHIS: Animal and Plant Health Inspection Service
- BRS: Biotechnology Regulatory Services
- CBP: Customs and Border Protection
- CVM: Center for Veterinary Medicine
- EPA: Environmental Protection Agency
- EUP: Experimental Use Permit
- FDA: Food and Drug Administration
- FFDCA: Federal Food, Drug, and Cosmetic Act
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- GEMs: genetically engineered microorganisms
- HFP: Human Foods Program
- MCAN: Microbial Commercial Activity Notice
- NSCEB: National Security Commission on Emerging Biotechnology
- OPP: Office of Pesticide Programs
- OPPT: Office of Pollution Prevention and Toxics
- PPA: Plant Protection Act
- PPQ: Plant Protection and Quarantine
- TERA: TSCA Environmental Release Application
- TSCA: Toxic Substances Control Act
- USDA: U.S. Department of Agriculture
- VS: Veterinary Services

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Modernizing Medical 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.

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 Predicatable 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.

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.

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.

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

- AI/ML: artificial intelligence and machine learning
- ARC: Accelerating Rare disease Cures
- 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
- FDA: Food and Drug Administration
- FFDCA: the Federal Food, Drug, and Cosmetic Act (FFDCA)
- FTC: Federal Trade Commission
- GMP: Good Manufacturing Practice
- HHS: Department of Health and Human Services
- ICH: International Council for Harmonisation
- IRB: Institutional Review Board
- NAMs: new approach methodologies
- NIH: National Institutes of Health
- NSCEB: National Security Commission on Emerging Biotechnology
- OHRP: Office for Human Research Protections
- OIG: Office of the Inspector General
- RDEP: Rare Disease Evidence Principles
- START: Support for clinical Trials Advancing Rare disease Therapeutics

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.