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Office of Science and Technology Policy
725 17th St, NW
Washington, DC 20500

For electronic submission

Re: BIO Comments on ID OSTP-TECH-2025-0100

Dear Ms. Murphy:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments on the Office of Science and Technology Policy (OSTP) Request for Information on federal policies that can accelerate the American scientific enterprise. BIO appreciates this RFI as it demonstrates the Administration's focus on ensuring that the United States maintains its leadership in biomedical innovation, which contributes to our nation's health, economic and national security. Through our comments BIO emphasizes that a stable and predictable policy environment is essential to sustaining public-private collaboration and long-term investment in biomedical innovation. Drug discovery and development require extended time horizons and significant capital commitments, and uncertainty in federal research priorities or funding disrupts effective partnership planning and execution.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 35 other nations. BIO membership includes vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovation and life-saving vaccines for all individuals.

Below please BIO's responses to a selection of the proposed questions.

(i) What policy changes to Federal funding mechanisms, procurement processes, or partnership authorities would enable stronger public-private collaboration and allow America to tap into its vast private sector to better drive use-inspired basic and early stage applied research?

Modernize federal funding mechanisms to align with biomedical innovation

To fully leverage America's private-sector innovation capacity, federal funding mechanisms must better reflect the realities of biomedical research and development.

First, federal investments should place greater emphasis on use-inspired basic and translational research, particularly in areas where scientific risk remains high but public health impact is significant. Sustained, multi-year funding that supports early target validation, platform technologies, and enabling science would provide a stronger foundation for downstream private investment.

Second, funding structures must be more flexible and milestone-driven, allowing resources to support early proof-of-concept work, IND-enabling studies, and scalable manufacturing approaches. Programs that permit industry partners to contribute expertise, infrastructure, and capital alongside federal funds—without unnecessary restrictions—will accelerate translation and improve outcomes.

Finally, federal funding should be designed to de-risk early-stage innovation and crowd in private capital. Expanded and predictable R&D tax incentives, combined with co-investment and blended-finance models, would strengthen incentives for companies to engage in collaborative research with federal laboratories and academic institutions.

Taken together, these changes would modernize federal funding mechanisms, reduce early-stage risk, and enable more effective public-private collaboration to advance high-impact biomedical innovation.

Establish a predictable, long-term policy environment to support public-private collaboration

Federal agencies should commit to multi-year funding frameworks that provide continuity across fiscal years and administrations, particularly for programs supporting use-inspired basic and early-stage applied research. Clear articulation of national research priorities—aligned with public health needs, biosecurity, and U.S. competitiveness—would further enable industry, academic, and government partners to coordinate investments and capabilities more effectively.

In addition, consistent and transparent policy signals regarding partnership authorities, intellectual property protections, and regulatory expectations are critical to reducing perceived risk and encouraging private-sector engagement. Harmonizing approaches across agencies and maintaining durable partnership models would strengthen trust, improve efficiency, and support sustained collaboration.

A predictable and coherent policy environment would enable the biopharmaceutical industry to plan and invest with confidence, reinforce the effectiveness of public-private partnerships, and help ensure that federal research investments translate into meaningful advances for patients and public health.

Further operationalize the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to strengthen the MCM Enterprise

The United States has built powerful but fragmented authorities for medical countermeasure (MCM) research, development, and procurement across the Administration for Strategic Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), Strategic National Stockpile (SNS), Department of War (DoW), National Institutes of Health (NIH), and the U.S Food and Drug Administration (FDA). Project BioShield and BARDA's advanced research and development programs exemplify that long-term, public investment and predictable markets can incentivize companies to continue to participate in high-risk, low-commercial-return MCM areas. Strengthening the nation's MCM enterprise directly advances the Administration's goals of making America safer, more secure, and more prosperous by ensuring that the United States can rapidly detect, prevent, and respond to chemical, biological radiological and nuclear (CBRN) threats. When MCM development, procurement, and interagency activities are aligned, it enables the government to leverage private-sector innovation more effectively and sustain the readiness needed to protect the American people.

In the context of MCM development, the "valley of death" refers to the critical transition period between preclinical evaluation of a candidate and the initiation of more costly Phase-2 clinical trials. During this phase, technologies must be sufficiently derisked to justify larger scale investment. This challenge is particularly acute for MCMs, where commercial markets are often limited, or uncertain and private capital alone is frequently insufficient to support progression through early development.

Bridging this transition requires not only targeted and sustained funding of ASPR's programs, but also coordination across agencies responsible for MCM research, advanced development, procurement, and deployment to ensure continuity, clarity of requirements, and alignment around potential downstream pathways.

The PHEMCE was designed to address this challenge by coordinating Federal roles across research, development, procurement, and deployment. Building on this existing framework, further operationalizing PHEMCE could help ensure that early stage, use inspired research is better connected to later stage development and acquisition decisions.

To systematically engage the broader private sector for MCM development and procurement, BIO recommends several policy changes:

- Using PHEMCE processes to improve alignment across NIH, BARDA, DoW, and ASPR by connecting early MCM research investments to clearly articulated development objectives, transition criteria, and potential procurement considerations, consistent with each agency's mission and authorities. This approach reflects the direction set forth in section 2811–1 of the Public Health Service Act (42 U.S.C. § 300hh–10a), which establishes PHEMCE to coordinate Federal medical countermeasure research, development, procurement, and deployment, and would be strengthened by the leadership and coordination of a dedicated White House official to provide continuity, visibility, and convening leadership for the enterprise, consistent with statutory intent and prior practice.

- Engaging industry through targeted, recurring PHEMCE-convened meetings focused on priority MCM areas, to improve mutual understanding of development timelines, readiness benchmarks, and transition challenges, and to help ensure that Federal research, development, and procurement activities are informed by real-world scientific and manufacturing considerations.

By strengthening continuity across the MCM lifecycle, PHEMCE can help reduce the risk that promising MCM candidates stall at key transition points, enabling the Federal government to leverage private sector innovation more effectively to sustain readiness and protect national security.

Reinforce predictable demand signals to sustain private sector engagement and readiness
In areas where commercial markets are limited or uncertain, predictable government demand signals play a critical role in sustaining private-sector engagement and preserving capabilities essential to national security. Existing Federal programs, including Project BioShield and BARDA, demonstrate the value of stable funding and procurement commitments in enabling industry participation in high-priority MCM areas that would otherwise struggle to attract sustained private investment.

Predictability across funding and acquisition timelines allows companies to make long-term investments in MCM research and development, reducing risk during early development and supporting continuity across the innovation lifecycle. These dynamics are particularly important where the marketplace for MCMs is driven primarily by Federal procurement through BioShield or the Strategic National Stockpile.

To build on these models, BIO recommends the following changes:

- Expanding the use of the PHEMCE Multi-Year Budget (MYB) and procurement authorities, including mechanisms that allow for greater flexibility across fiscal years, to provide continuity and reduce disruption across research, development, and acquisition phases.

- Utilizing a range of market-shaping tools, such as advance market commitments, volume guarantees, and warm-base manufacturing agreements, to sustain readiness, preserve manufacturing capability, and enable rapid scale-up and surge capacity when needed.

- Pairing procurement strategies with lifecycle management and replenishment planning, ensuring that investments support the long-term effectiveness and readiness of the Strategic National Stockpile rather than one-time acquisitions.

Together these considerations would reinforce alignment across research, development, and procurement; support sustained private-sector engagement; and strengthen the nation's ability to advance MCM research and development in support of biodefense and broader national security objectives.

(ii) How can the Federal government better support the translation of scientific discoveries from academia, national laboratories, and other research institutions into practical applications? Specifically, what changes to technology transfer policies, translational programs, or commercial incentives would accelerate the path from laboratory to market?

BIO and our biotechnology company, academic institution, state biotechnology center, and related organization members assess that there are currently three key opportunities for the Federal government to better support the translation of scientific discoveries from academia, national laboratories, and other research institutions into practical applications: (1) Empowering U.S. contract manufacturing; (2) Modernizing intellectual property (IP) management and streamlining administrative processes for federal research; and (3) Enhancing FDA as Global Gold Standard.

Empower U.S. contract manufacturing

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

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

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

- Provide incentives for biotech companies to choose U.S. contract manufacturers or move existing contract pipelines to the U.S. Incentives could include targeted tax credits for the incremental costs of transferring technology from one facility to another, access to other forms of capital, patent term.

extensions, additional exclusivity, federal procurement commitments, etc. Technology transfers between facilities, including from international facilities to the U.S., require significant spend, such as on production batches, equipment upgrades, labor, validation, and regulatory documentation. Incentives reduce barriers to commercialization, encourage U.S. domestic scaling, and derisk capital commitment from investors.

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

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

A series of commercial incentives would supercharge the biotechnology ecosystem.

- Incentivize Servicing Low-Volume Contracts. Apply preferential tax rates for contract manufacturers serving low-volume contracts or orphan sponsors. Implement accelerated depreciation for qualifying capital expenditures and expand interest deductibility for biotech infrastructure investments. These policies reduce cost barriers, improve cash flow, and make it financially attractive to prioritize smaller U.S. innovators while expanding domestic capacity.
- Lower Barriers to Making Capital-Intensive Investments. Offer financial incentives, such as tax credits, targeted grants, or partial loan forgiveness for capital-intensive investment. These could include greenfield facility builds, buildouts of existing sites, purchasing of specialized equipment and upstream materials, etc. Greenfield builds, site expansions, and capital investments carry high upfront risk but deliver resilient, future-ready facilities. Incentives de-risk private investment and anchor long-term capacity in the U.S.
- Encourage Integrated End-to-End Facilities. Explicitly reward fully integrated contract manufacturing campuses that bring end-to-end capabilities (from the creation of drug substance through to final drug product) under one roof. Incentives may include preferential tax treatment and grants. End-to-end integration reduces friction, eliminates the need for tech transfer across multiple contract manufacturers, lowers regulatory burden, and strengthens supply chain security. End-to-end models speed time-to-market and increase U.S. competitiveness.
- Ensure Manufacturing Equipment and Raw Materials are Available. Establish funding mechanisms and tax credits for upstream suppliers of critical biotechnology equipment and materials, including raw inputs, prioritizing domestic production. Reliable access to specialized equipment and inputs is essential. Domestic support reduces reliance on international vendors, secures U.S. supply chains, and ensures timely access to essential equipment.
- Prioritize Long-Lead Equipment and Materials. Create a National Strategic Biomanufacturing Priority List for long-lead equipment and critical materials, with incentives for domestic sourcing and priority procurement under federal oversight. Key equipment often has 18–24 month lead times. Federal prioritization shortens timelines and strengthens long-term security.
- Encourage Public-Private Manufacturing Clusters. Promote development of regional contract manufacturer-anchored biotechnology manufacturing clusters through incentives for shared infrastructure, workforce, and collaborative innovation. Clusters lower capital burdens, foster collaboration, and strengthen regional economies through localized supplier networks and talent pools. They accelerate product development by providing shared access to advanced facilities, expertise, and supply chains.
- Facilitate Access to Land and Infrastructure. Work with state and local governments to offer land grants, infrastructure support, and site development incentives in underutilized industrial or economic development zones. Subsidizing land and infrastructure attracts biotech investment, creates jobs, and revitalizes regions while aligning with national innovation goals.

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

- Advance policies to improve utilities and transportation networks critical to biotech manufacturing operations. Stable utilities and efficient logistics are essential. Coordinated State, Local, and Federal

investment reduces risk and increases competitiveness of U.S. biotech hubs. Examples of utilities include power grid reliability, water and sewage systems, etc.

- Work with state and local governments to simplify and expedite environmental review processes for biotechnology facility construction, while maintaining safety standards. Long review timelines delay build-out and deter investment. Streamlining accelerates expansion and enhances public health readiness.

Modernize intellectual property (IP) management and streamlining administrative processes

- Modernization of IP and licensing management would stimulate more investment:
    - Simplify Licensing Agreements: Create standardized, plain-language, non-exclusive license templates for early-stage technologies to speed up initial adoption by small businesses and startups. This reduces the time and cost associated with complex legal negotiations.
    - Increase Flexibility in the Bayh-Dole Act: While the Bayh-Dole Act has been critical, the Federal government could provide more clarity and flexibility, particularly for inter-institutional collaborations and for research involving federally-funded databases or software, ensuring its application doesn't create unintended barriers to open access or commercialization.
    - Shift from "Patent and License" to "Business Building": Encourage Technology Transfer Offices (TTOs) at universities and national labs to focus less on passive IP management (licensing revenue, patent numbers) and more on active startup incubation, including mentorship, access to early-stage funding, and facilitating the formation of viable commercial entities.
    - Withdraw Biden administration Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.
    - Withdraw or modify NIH licensing guidance “NIH Intramural Research Program Access Planning Policy.”
    - Consider creation of tax incentives for inventions that are made and commercially developed in the United States, in order to encourage domestic R&D investment and to incentivize businesses to locate or repatriate their IP to the United States (patent box-type ideas).
    - Assess if U.S. patent law currently affords sufficient protection for technologies such as diagnostic tests, personalized medicine, AI-enabled processes, computer- or network-implemented inventions, and related cutting-edge technologies. Consider **reforms to the scope of patent-eligible subject matter** (35 USC 101) to ensure that US patent law is commensurate with the patent laws of our major trading partners with respect to the patentability and transferability of such technologies.

- Streamlining administrative processes will speed research partnerships:
    - Faster Review and Approval: Mandate accelerated timelines for reviewing and executing key agreements like Cooperative Research and Development Agreements (CRADAs) and Material Transfer Agreements (MTAs), which are essential for research collaboration between federal labs/academia and industry partners.

- AI Transformation: Invest in digital platforms and centralized communication hubs to manage the tech transfer process, making it faster, more transparent, and easier for external partners to identify and access federal technologies.

Strengthening FDA as the global gold standard

The cost and complexity of early drug development must be reduced by taking a number of steps.

- Support opportunities to reduce the administrative burden associated with the conduct of clinical trials by standardizing documents and processes. This may include uniform clinical trial contracts, streamlined Form 1572 reporting requirements, and standardized informed consent. Processes associated with opening sites and conducting clinical programs are inefficient and costly.
- Explore expansion of single IRB policies both within the FDA and across HHS and leverage new technologies for centralizing document collection and coordination. Use of local IRBs can take much longer than central or single IRBs slowing down the opening of new study sites.
- Outline expectations in guidance and support collaborative efforts to reduce animal testing with the goal of enabling New Approach Methods (NAMs). NAMs have the potential to more accurately model human biology and substitute for traditional animal models while accelerating the initiation of clinical trials.
- Clarify toxicology data requirements minimally necessary to initiate clinical testing and expand the use of risk-based approaches that can be scaled based on modality, mechanism of action, and clinical risk profile. A full IND-enabling toxicology data package can take 6 to 9 months to collect, and a risk-based approach may shorten this timeline while still ensuring patient safety.

- Support efforts to fulfill PDUFA meeting management goals and continue to evolve meetings best practices. Explore the potential for existing meeting types to be used more effectively to resolve urgent drug development questions. Drug sponsors need reliable and efficient mechanisms to engage with the FDA to reduce regulatory uncertainty and advance innovation.
- Support the application of Quality Risk Management to CMC to accelerate the start of INDs and ultimately product approval. Streamlining CMC data requirements may help address the US lag in first in human clinical trials.

FDA regulatory review must be strengthened so that it is more predictable and efficient to ensure the U.S. system for clinical development remains a distinctive and global competitive edge.

- Ensure predictability and consistency in regulatory reviews by conducting them according to the PDUFA "Enhanced Review Program". Key components of the application review process are occurring late in the review cycle contributing to last-minute decision making and growing numbers of CRLs.
- Streamline the manufacturing inspection process by expanding the use of Remote Interactive Evaluations, the use of Drug Master Files, and reliance on inspections by other health authorities. Facility inspections create a significant bottleneck that hinders timely product launch and discourages domestic investment.
- Evolve PDUFA regulatory science pilot programs into common practice (e.g., Complex Innovative Designs, Real World Evidence, Model Informed Drug Development) by updating guidance, training reviewers, and increasing transparency about the use of more efficient methodologies. Innovative clinical trial designs can reduce patient burden and increase overall trial efficiency.
- Partner with external stakeholders to evaluate the root causes and potential solutions for the lack of validated endpoints for use in clinical trials in many unmet medical needs. A persistent translational gap exists between biomarker discovery and regulatory acceptance that may be driven by an inconsistent qualification process, unclear evidentiary standards, and poor resourcing.
- Advance the use of Platform Technology Designations (PTD) with the goal of streamlining regulatory review by leveraging well-characterized technology that can be used across multiple drug products. Work to date to advance PTD has not resulted in drug development efficiencies. Existing guidance should be updated to clarify eligibility criteria, evidentiary requirements, and procedural efficiencies.
- With a focus on chronic diseases, explore the use of expedited drug development tools and innovative approaches with the goal of managing the high cost/risks associated with investments in these diseases. Consider the overall public health impact and apply a risk-based regulatory framework when determining when/how these tools may be utilized. Investment and innovation in drug research and development for highly prevalent chronic diseases has stalled in recent decades despite half of all Americans living with at least one chronic disease.
- Support efforts to fulfill PDUFA meeting management goals and evolve meetings best practices. Explore the potential for existing meeting types to be used more effectively to resolve urgent drug development questions. Sponsors need reliable and efficient mechanisms to engage with the FDA to reduce regulatory uncertainty and advance innovation.

New models for external engagement and transparency must be supported.

- Evolve the use of Advisory Committees (AC) to focus on questions of science rather than questions about the regulations and ensure proper training for AC members. Modernize conflict of interest requirements to ensure appropriate participation. ACs are critical to augment FDA expertise on emerging science and innovation, but their utilization has been fraught with accusations of misuse, lack of appropriate expertise, conflicts of interest, and underutilization of public/patient input.
- Support common platforms for shared learning across the innovation ecosystem. Fill FDA positions focused on consistently advancing the vision for regulatory science and ensuring consistent implementation/process. FDA leadership have publicly stated their focus on the value and urgency of regulatory innovation. However, regulatory science advances continue to be applied inconsistently across review divisions.

(iii). What policies would encourage the formation and scaling of regional innovation ecosystems that connect local businesses, universities, educational institutions, and the local workforce - particularly in areas where the Federal government has existing research assets like national laboratories or federally funded research centers?

Create an accelerated ecosystem

Policies and programs that directly support accelerated ecosystem creation serve as excellent opportunities to connect local businesses, universities, education institutions, and the local workforce. By providing incentives for stakeholders to collaborate on key projects, relationships and ecosystems may develop much faster than if they were left to organically grow.

Regional Technology and Innovation Hubs:

The EDA took significant steps towards forming and scaling local ecosystems with the Regional Technology and Innovation Hubs (Tech Hubs) program. Continued operation of this program including funding of existing Tech Hubs and designation of additional hubs in the United States will encourage further formation and scaling of local ecosystems.

- By design, Tech Hubs require consortia to consist of key stakeholders and support projects in workforce development, startup support, technology maturation, infrastructure, and governance. Consortia that receive Tech Hub designation also become eligible for further technical assistance, network-expansion, and additional funding opportunities through the EDA, the Department of Commerce, and other federal agencies.
- At present, 12 of the 31 Tech Hubs have received Implementation Awards. In September of 2025 a new NOFO opened to the remaining 19 Hubs that have not yet received an Award. The Tech Hubs program, established under the CHIPS and Science Act of 2022, was authorized to receive $10 billion over five years. To date, Congress has appropriated approximately $1 billion to the program. Continued appropriations for the Tech Hubs program to enable the EDA to continue providing Designated Tech Hubs with Implementation Awards, and Tech Hub applicants with Strategy Development Grants (SDG) that serve as a key local, strategic investment.

ARPANET-H Health Innovation Network:

- ARPANET-H is a nationwide innovation network that supports the Advanced Research Projects Agency for Health (ARPA-H). The Investor Catalyst Hub, based in Boston, MA, is the Hub of the hub-and-spoke model utilized by the program. With nearly 700 spoke members, the Investor Catalyst Hub was created with the goal of speeding up the transition of ideas into solutions by connecting institutions such as investors, incubators, accelerators, and researchers, with needed resources that others may have.

Invest in workforce training models

Biosciences workforce training is an excellent vehicle for further ecosystem creation and scaling. Existing federally funded programs and initiatives target high schools, vocational schools, community colleges, and universities, making Americans with all levels of education aware of the opportunities that exist within the biosciences sector. These programs share some common strategic goals to address gaps:

- Expanding the Pipeline: Building awareness of biotechnology careers in K-12 education, fostering links between high schools, community colleges, and four-year institutions, and recruiting talent from diverse populations, including veterans, and underemployed individuals.
- Industry Alignment: Ensuring training is based on industry-validated competencies and skills (e.g., in bioprocessing, quality assurance, bioinformatics) to directly meet employer needs.
- Alternative Credentials: Promoting alternatives to traditional four-year degrees, such as industry-validated certifications, certificate programs, and apprenticeships, to standardize competency assessment and increase the pool of skilled technicians.

Public-Private Partnerships:

The public-private partnership model for workforce training facilitates collaboration between the government, industry, and academia. By developing curricula in concert with industry members, non-profits, and educational institutions, local ecosystems are strengthened. The institutes below, established to accelerate advanced manufacturing play a significant role in workforce development for biomanufacturing and should be expanded to increase workforce capabilities around the country.

- The Bioindustrial Manufacturing and Design Ecosystem (BioMADE) is the DOD's Manufacturing Innovation Institute that focuses on advancing bioindustrial manufacturing. Its mission includes building a competitive workforce by creating partnerships with K-12 schools, community colleges, and universities to align education with industry needs and provide workshops and training.

- National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL): This public-private partnership is focused on accelerating biopharmaceutical innovation and provides extensive workforce development through curriculum creation, training programs, and resources for industry employees.

Other Supportive Workforce Training Programs:

In addition to current public-private partnership models, continued support and investment in workforce training programs such as the efforts below from the National Science Foundation are needed. Like the public-private partnership model, continued funding for training and educational programs at local educational institutions provides significant opportunities for industry and academia to collaborate and expand the ecosystem.

- InnovATEBIO National Biotechnology Education Center: Funded by the NSF's Advanced Technological Education (ATE) program, this is a national network that supports biotechnology workforce education. It includes numerous college programs offering degrees and certificates in biotechnology and biomanufacturing, and it actively collaborates with industry members to ensure curricula are relevant.
- Experiential Learning for Emerging and Novel Technologies (ExLENT) Program: This program is designed to scale hands-on, work-based learning opportunities in emerging technology areas like biotechnology, helping to prepare students from both traditional and non-traditional backgrounds for skilled technical jobs. The biosciences is a dynamic and rapidly changing field, and the hand-on or “learning by doing” opportunities enabled by the ExLENT program provides Americans with the experience needed to retain a competitive edge through reskilling and upskilling.

(iv) How can Federal policies strengthen the role played by small- and medium-sized businesses as both drivers of innovation and as early adopters of emerging technologies?

Small- and medium-sized biotechnology companies play a critical role in the U.S. innovation ecosystem, serving both as primary drivers of early scientific breakthroughs and as early adopters of emerging technologies across drug discovery, development, and manufacturing. Federal policies can strengthen this role by reducing barriers to participation, improving access to capital and infrastructure, and aligning incentives with the unique risk profile of biotech innovation.

First, federal funding and contracting mechanisms should be tailored to the scale and constraints of small- and medium-sized biotech firms. Renewing, expanding, and modernizing programs such as SBIR and STTR—through larger award sizes, faster decision timelines, and greater flexibility in eligible costs—would enable smaller companies to advance high-risk, high-impact research. Streamlined application, reporting, and compliance requirements would further reduce administrative burdens that disproportionately affect smaller organizations.

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

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

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

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

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

(v) What empirically grounded findings from metascience research and progress studies could inform Federal grantmaking processes to maximize scientific productivity and increase total return on investment? Please provide specific examples of evidence-based reforms that could improve funding allocation, peer review, or grant evaluation.

BIO supports efforts to improve productivity and returns from investments in scientific research. Both the lack of speed and lower levels of risk tolerance in the Federal grantmaking process can have a direct impact on scientific productivity, and there are opportunities to improve this process to drive greater societal returns from investments in research. BIO supports greater experimentation with a wider variety of funding models to assess whether there are opportunities to assess the comparative impact of different models. The ultimate goal of such programs should be to create lessons that can inform future reforms and maximize the long-term value of the scientific output from federally funded research.

(vii) How can the Federal government support novel institutional models for research that complement traditional university structures and enable projects that require vast resources, interdisciplinary coordination, or extended timelines?

The traditional university structure for federally funded research has been an enormous boon to American patients and patients around the world in advancing the scientific knowledge needed to create new cutting-edge therapies. In addition to this structure, which the federal government should continue to robustly fund and support, new models can help advance research that may be ill-suited for the traditional university-based approach. This can include certain projects that require industrial-scale coordination across multiple enterprises, or that come from non-university research organizations formed to address specific scientific problems.

There are examples from biomedical research of multi-disciplinary, cross-cutting research consortia that are worth emulating and expanding. For example, the Accelerating Medicines Partnership (AMP) program is a public-private partnership among NIH, FDA, multiple life sciences companies, and nonprofit and other organizations. This cross-sector partnership enables agencies and partners to share expertise and assembled resources beyond that of any one individual entity. As a specific example, the Bespoke Gene Therapy Consortium is part of AMP, and works to establish platforms and standards to speed the development of “bespoke” or customized gene therapies. Another set of examples are the multiple disease-specific consortia which FDA fund at the Critical Path Institute, where FDA works with academic researchers and industry to pursue data sharing and other pre-competitive research initiatives. Funding such programs directly is a great example of how federal funders can support non-traditional projects that allow for greater coordination on longer time horizons, to address specific problems.

Regarding new collaborations, BIO also recommends that NIH seek to understand the root cause of shortcomings of previous collaborative models, such as the Helping to End Addiction Long-term (HEAL) initiative. The HEAL initiative demonstrated success at the preclinical stage. However, challenges emerged when the program moved into Phase I/II clinical development programs. BIO believes it would be worth investigating if this is due to 1) lack of volume in the pipeline, 2) legal/IP issues, or 3) if there is a loss of control over trial design, enrollment, or patient data that lead companies resist these partnerships at later stages. BIO believes that understanding why there was less collaboration at the clinical stage will allow NIH to develop new collaborative models with enhanced partnering between government, academia, and industry.

(viii) How can the Federal government leverage and prepare for advances in AI systems that may transform scientific research—including automated hypothesis generation, experimental design, literature synthesis, and autonomous experimentation? What infrastructure investments, organizational models, and workforce development strategies are needed to realize these capabilities while maintaining scientific rigor and research integrity?

Next-generation technologies like artificial intelligence, automation, and molecular engineering are poised to revolutionize biotechnology innovation. These tools enable faster drug discovery, more efficient manufacturing, real-time data analysis in clinical trials, and the design of novel therapeutics that were previously unimaginable. The nation that leads in deploying these technologies will not only dominate the future of biotech but also shape the trajectory of adjacent strategic sectors - such as defense, agriculture, energy, and advanced materials. To secure U.S. leadership, the federal government should invest in smart manufacturing infrastructure, create national centers of excellence to accelerate innovation, and cultivate a skilled workforce equipped to apply these technologies. Strong intellectual property protections will also be essential to safeguarding U.S. innovation and maintaining a competitive edge.

The use of artificial intelligence and machine learning (together: “AI”) tools is becoming increasingly common, though not yet ubiquitous, among BIO’s member companies, who deploy this technology to assist in drug discovery, clinical or field trial design, manufacturing process improvements, and a range of other applications. BIO applauds the Administration’s interest in developing national policies for sustaining and enhancing America's AI preeminence in order to promote human flourishing, economic competitiveness, and national security. To that end, we would like to offer a few high-level recommendations.

Maintain flexibility to account for specific needs of different business models and industry sectors.

BIO members regard AI as an important and powerful addition to their arsenal of tools with which they create and accelerate innovation in an already comprehensively regulated space. When BIO members use AI (or other tools) to augment, for example, the discovery of new therapeutic molecules, they already must ensure compliance with highly specific regulatory schemes designed to ensure that new biotechnology products are researched, developed, and deployed safely, reliably, lawfully, and responsibly. We trust that the Administration will ensure that any new national AI policies will map smoothly onto existing sector-specific regulatory frameworks. This should be done in ways that draw on the experience and ongoing work of specialized regulatory agencies and their regulated industries, and that enhance, rather than encumber, the efficient operation of these regulatory frameworks.

Develop national uniformity.

Increasing commercial use of AI tools and the related collection, use, and dissemination of consumer data is already generating significant legislative and regulatory activity at the state level. There is a risk that new national AI policies could stand in tension with a patchwork of state health data privacy and consumer protection laws in ways that create nonuniformity, business uncertainty, and unrealistic compliance and reporting burdens. While much can be learned from ongoing state efforts in AI safety, accountability, and transparency, the Administration should push for harmonization across different developing state frameworks and consider whether certain aspects of AI governance should be reserved exclusively to the United States.

Maintain the ability of US businesses and researchers to responsibly collect, use, and aggregate data across state lines and international borders.

AI tools cannot be developed or deployed without access to large and high-quality data sets. As the Administration considers the development of national AI policies, it should ensure that biotechnology firms can access and utilize the most robust and comprehensive data sets, not just for research but as part of the development of accurate AI systems. Ability to access data in a timely and efficient manner drives biotechnology innovation that is critical to our success in the life sciences industry. The Administration should work with our global allies to protect private sector access to the best genomic, genetic and biologic data. Should key nations take steps to block their data from inclusion in public databases, U.S. AI systems may not be as accurate or efficient and could slow our industry’s ability to innovate and compete.

At the same time, the Administration should ensure that proprietary or sensitive data sets are given adequate protection to guard against not only data theft, but IP theft or duplication of products. Open AI models have the potential to expose large or sensitive data sets, which are under threat of theft by adversarial foreign actors especially for the health sector. BIO encourages any AI policy to consider public sector data sets, those that belong to private industry, and those developed within academia and the specific, nuanced steps needed for each individually. To maintain U.S. dominance in AI and biotechnology, AI inputs must be given the same protections as AI products.

Considerations of AI use in drug development.

As a transformative tool, AI will soon span the full range of drug development activities – from discovery and preclinical testing to post- approval studies, pharmacovigilance, and manufacturing. The FDA's current regulatory framework ensures the safety and efficacy of products approved for U.S. patients, guided by the principle of assessing the benefit of a medical product against its potential risks to patients. Accordingly, the risks of incorporating AI across drug discovery and development should be considered on a use-case basis. This would include a consideration of the AI model influence (the weight of the model in the totality of evidence for a specific decision) and decision consequence (the potential consequences of a wrong decision).

BIO agrees with the FDA that the potential patient risk related to the use of AI in drug discovery is low. Patients will generally benefit from reductions in research time for the discovery of molecules for further investigation. When it comes to clinical trials, AI has the potential to be useful in, for example, site selection, recruitment, and demographic balancing of control and treatment groups. However, as AI becomes more integrated in the actual design of clinical trials, the assessment of endpoints, and the manufacturing of approved therapies, the associated risks may increase.

In every phase of drug development, industry and regulators should work collaboratively to establish best practices for AI development and use and the type and amount of evidence adequate for the FDA to accurately assess whether AI is fit for purpose for the specific context of use. Evidence requirements will vary based on use, and industry and regulators should work together to create clear expectations. As AI and machine learning has increased in salience over the past decade, the FDA has already set forth a number of guidance documents and other publications. These materials provide a valuable beginning and a basis for refinement.

BIO has encouraged FDA to consider the following recommendations for further engagement between industry and regulators:

(i) Clarify the scope of regulatory oversight to increase stakeholder understanding. The primary focus should be on areas where FDA has regulatory authority.
(ii) Strive for consistent terminology, such as the FDA's Digital Health and Artificial Intelligence Glossary. We believe the FDA could take a leading role in further defining terms critical to the regulatory process.
(iii) Adapt "Good Machine Learning Practices" (GMLP) to the use of AI in drug development, using medical device practices as a starting point. The adapted Practices should include considerations for AI model design, development, testing, and performance. The standards should specify the degree of transparency required for the Agency to evaluate regulatory submissions.
(iv) Draft a risk assessment and credibility framework for AI for different contexts of use, such as clinical research and manufacturing. New frameworks should build on established ones when possible.
(v) Clarify regulatory expectations for validation of AI models. Detailed expectations for testing, evaluation, verification, and validation will enable better understanding among developers.
(vi) Clarify requirements for regulatory submissions and commercially confidential information. Clear and detailed enumeration of FDA expectations on information to include in dossiers is essential. Transparency needs to be balanced with the protection of innovation for drug and technology developers.
(vii) Adopt an agile approach to regulatory oversight to ensure it is responsive to changing technology. Given the early stage of AI use in drug development and the emergence of new technologies and best practices, BIO has recommended that the FDA consider principles-based recommendations, Q&As, and discussion papers rather than formal guidance.
(viii) Step up discussions with appropriate foreign drug regulatory authorities about harmonizing regulatory principles applicable to AI use.

Maintain the ability to leverage Intellectual property (IP).

BIO members use AI as a tool to augment a wide range of research and development activities, and it is critical that innovative products that were discovered and developed with the use of AI remain eligible for IP protection. However, troubling questions have been raised about the patentability of inventions where the inventor’s discovery was facilitated in important ways by the use of an AI tool. Current examination guidance in the U.S. Patent and Trademark Office (USPTO) grapples with these questions and seems to offer a workable framework for now, but it applies U.S. patent law concepts such as “conception” and joint inventorship in new, unfamiliar, and ill-fitting ways. It will be important to carefully monitor how well these historic tests will work to account for the impact of AI and other computational tools on the patentability of resulting inventions.

It will also be important to monitor whether the United States may be deviating in important and unnecessary ways from how foreign patent systems address similar questions about the use of AI and other computational tools in the invention process. The USPTO Guidance implicitly but clearly casts doubt upon the substantive patentability of inventions that result from the use of AI. It suggests that even where there has been some human involvement, there may be no patentable invention because no natural person contributed “enough” -- and the specter of unpatentability is there even if the invention is otherwise perfectly novel, unobvious, and properly described. Foreign patent offices that have confronted the question, in contrast, don’t seem to view the involvement of computational tools as a potentially patentability-destroying event in the way the USPTO Guidance implies.

Finally, BIO has cautioned the USPTO and public policymakers against premature and reflexive actions in response to the increasing adoption of AI and other computational tools among US innovators. There is nothing inherently harmful or problematic about novel and unobvious inventions just because they were generated with the help of AI tools. In fact, public discourse should celebrate the emergence of efficiency-enhancing tools that allow more US innovators, including in biotechnology, to make more inventions more quickly, cheaply, and efficiently.

(ix) What specific Federal statutes, regulations, or policies create unnecessary barriers to scientific research or the deployment of research outcomes? Please describe the barrier, its impact on scientific progress, and potential remedies that would preserve legitimate policy objectives while enabling innovation.

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Incentivizing Small Biotech Investment: Angel Investor Tax Credit

Modeled after numerous state programs, a federal Angel Investor Tax Credit would provide an incentive for high-net-worth individuals to invest in emerging biotech companies. To be eligible for this credit, investors would have to make an investment in a company with fewer than 500 employees performing qualifying research. The credit would be equal to 50% of their investment, thus providing an important tax incentive for investment in innovative research-intensive industry.

Stimulating Private Capital for Biotechnology: R&D Partnership Structures

Due to the drawn-out nature of the drug development process, small biotechnology companies often have difficulty obtaining early-stage financing for their research and development. Given that smaller biotech companies are not yet profitable, they are unable to immediately use their tax assets to offset income. New partnership structures wherein biotech companies would enter into a joint venture with high-net-worth investors and flow through certain tax assets (i.e., tax credits and losses) from the biotech company or its projects to the investors would provide more immediate benefits by allowing investors to offset their income with the company's tax assets, thus stimulating private investment.

Reducing Time, Cost and Complexity of Drug Development

One of the most promising areas to reduce barriers to critical research is to reduce the time, cost, and complexity of drug development, especially preclinical and Phase 1 development. BIO has been in communication with FDA on this topic, and we look forward to having the opportunity to continue to engage with the agency. Policies to address in this space include:

- Reducing administrative burdens in clinical trials (e.g., streamline Form 1572 reporting requirements, standardize informed consent forms, etc.);
- Supporting single Institutional Review Boards (sIRBs);
- Advancing the development and use of New Approach Methods (NAMs) to reduce animal testing and increase the efficiency and accuracy of preclinical testing;
- Clarifying toxicology data requirements minimally necessary to initiate clinical testing;
- Furthering the application of Quality Risk Management in manufacturing; and
- Ensuring rapid/frequent communications with sponsors; especially during pre/early-IND period.

(x) How can Federal programs better identify and develop scientific talent across the country, particularly leveraging digital tools and distributed research models to engage researchers outside traditional academic centers?

Federal investment in the current and future workforce is critical to better identifying and developing U.S. scientific talent and supporting advanced biotechnology and biomanufacturing operations. A strong domestic biomanufacturing ecosystem requires a diverse set of skills - from manufacturing operations and quality control to biomanufacturing construction and R&D. These roles span a wide range of educational backgrounds, including technical certifications, associate and bachelor's degrees, and terminal degrees such as PhDs. CDMOs and biopharmaceutical companies often face difficulties recruiting skilled workers to non-traditional biotech hubs. Federal and state governments can play a vital role by offering targeted incentives to attract and retain talent in diverse geographic regions across the country. We would like to offer a few high-level recommendations.

Education and Training Pathways

- Establish Standardized Educational Pathways for Biomanufacturing Careers. Create a nationally coordinated framework for biomanufacturing education, including two-year degree programs, modular training, and micro-credentialing aligned with current Good Manufacturing Practice (cGMP) standards. A standardized credential system ensures consistent training quality, accelerates workforce readiness, and enables mobility across biotech hubs. Flexible, stackable pathways will meet industry demand while expanding access to high-value careers for diverse learners.
- Fund Workforce Development for Institutions and Learners. Provide federal and state funding for accredited biomanufacturing training programs, including tuition grants, earn-and-learn apprenticeships, and institutional support for curriculum development and infrastructure. Millions of Americans without college degrees represent an untapped workforce. Funding incentives reduce barriers to entry, promote inclusive economic growth, and empower educational institutions to build capacity and meet urgent labor needs.
- Expand Cross-Training for Science and Technology Professionals. Support accelerated certificate and retraining programs that equip current science and technology professionals with hands-on biomanufacturing and regulatory skills. Retraining leverages existing technical talent and shortens time to workforce

deployment. Applied coursework and apprenticeships provide industry-ready skills, strengthening the talent pipeline and maximizing return on prior education investments.

- Enhance STEM Education. Expanding graduate fellowships and increasing investment in two- and four-year degree programs would help strengthen the pipeline. A stronger emphasis on science and associated trades in the U.S. education system is essential for building long-term capacity.
- Leverage Community College Programs. Investments can be used to establish targeted training centers to efficiently prepare a skilled workforce, especially in manufacturing operations and quality control. Special attention should be given to two-year programs at community colleges. Models like Ireland's National Institute for Bioprocessing Research and Training (NIBRT), and its counterpart K-NIBRT in South Korea, have been very effective. For instance, since its founding in 2011, NIBRT has trained over 50,000 individuals.[1]

Incentives and Support Mechanisms for Workforce Growth and Development

- Encourage the use of employer incentives such as tax credits for companies offering tuition coverage or in-house training programs and bonus payroll tax credits for workforce development activities would encourage employers to increase workforce growth and development.
- Increase federal and state Investments by expanding public grants and public-private partnerships for terminal degrees (M.D./Ph.D.) in critical fields, targeting loan forgiveness programs to attract students into biomanufacturing and life sciences, and providing NIH funding for private-sector postdoctoral positions.

[1] **National Institute for Bioprocessing Research and Training.** (2025, April 11). *NIBRT publishes Annual Report 2024*. Retrieved from https://www.nibrt.ie/nibrt-publish-annual-report-2024/

(xi) How can the Federal government foster closer collaboration among scientists, engineers, and skilled technical workers, and better integrate training pathways, recognizing that breakthrough research often requires deep collaboration between theoretical and applied expertise?

To bolster the biotechnology ecosystem, which relies on experts in theory through application, the Federal government can foster closer collaboration among scientists, engineers, and skilled technical workers, and better integrate training pathways, by incentivizing the creation of regional biomanufacturing hubs. These centers can anchor ecosystems of innovation, workforce development, and local supply chain resilience. An example of a program that could be leveraged for building additional biotechnology manufacturing capacity is the Tech Hubs Program through the U.S. Economic Development Administration.[1] Six of the thirty-one sites are already designated for biotechnology manufacturing, and the knowledge and best practices learned through the development of these hubs could be used to build out additional infrastructure. To further incentivize investment, the Administration could consider designating specific regions as biomanufacturing zones - similar to the Opportunity Zones framework from President Trump's first term - tailored specifically to the needs of the biotechnology industry.

[1] U.S. Economic Development Administration. (n.d.). Regional Technology and Innovation Hubs (Tech Hubs). Retrieved May 6, 2025, from https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs

(xiii) How can the Federal government strengthen research security to protect sensitive technologies and dual-use research while minimizing compliance burdens on researchers?

The biotechnology sector strongly supports biosafety and biosecurity practices that protect sensitive technologies and mitigate risks associated with dual-use research, while ensuring that legitimate scientific work critical to national security, preparedness, and innovation can proceed without unnecessary barriers. Effective research security policies must be risk-based, scientifically grounded, and designed to focus enhanced oversight where it is most warranted.

A foundational element of this approach is maintaining clear, precise definitions that distinguish between categories of dual-use research. ***Dual-use research*** broadly refers to life sciences research conducted for legitimate scientific, medical, or public health purposes that could, in theory, be misapplied. This category encompasses a wide range of essential research activities that underpin vaccine development, diagnostics, therapeutics, and other medical countermeasures.

By contrast, ***dual-use research of concern (DURC)*** represents a defined subset of dual-use research that meets specific criteria indicating that the work could reasonably be anticipated to generate knowledge, products, or technologies that pose a significant risk to public health or national security if misused. OSTP policy has historically limited DURC to research involving a small number of high-consequence pathogens and a defined set of experimental outcomes that could meaningfully increase risk.

Maintaining this distinction in future OSTP guidance documents is critical. Conflating dual-use research with dual-use research of concern risks subjecting low-risk, high-value research to heightened scrutiny, increasing compliance burdens without improving security outcomes and potentially discouraging work that is essential to national preparedness.

These same principles of clarity, proportionality, and scientific grounding should also guide Federal approaches to emerging biosecurity safeguards, including ***gene synthesis screening***.

As synthetic nucleic acid technologies become more accessible, consistent, and risk-based gene synthesis screening standards represent an important opportunity to strengthen biosecurity without impeding legitimate research and development. Many U.S. providers already conduct voluntary sequence and customer screening, but uniform Federal expectations can reduce uneven practices, clarify responsible conduct, and reinforce U.S. leadership in biosecurity. To be effective and sustainable, gene synthesis screening frameworks should be narrowly scoped to sequences with plausible biosafety or biosecurity significance, operationally feasible for providers of different sizes, and designed to protect proprietary data and sensitive information. Overly broad definitions or prescriptive requirements risk increasing costs, slowing research timelines, and unintentionally driving sensitive work to less regulated jurisdictions, undermining both security and competitiveness.

A research security framework grounded in clear definitions, targeted oversight, and practical safeguards can protect sensitive technologies and address dual-use risks while minimizing unnecessary compliance burdens. This approach preserves the strength of the U.S. research enterprise, sustains innovation critical to biodefense, and ensures that security measures enhance, rather than impede, national preparedness and scientific leadership.

Conclusion:

BIO and our member companies share the Administration's commitment to the development and implementation of policies that will encourage robust scientific advancement in the biotechnology sector. We stand ready to work closely with the OSTP to continue to create a clear, sustainable and predictable environment at both the federal and state level that will encourage increased scientific advances in health for all Americans. We would be pleased to meet with the Office to further discuss our recommendations.

Sincerely,

Phyllis A. Arthur
EVP & Head, Healthcare Policies and Programs