July 13, 2026

Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503
Re: Docket No. OMB-2026-0034

Dear Sir/Madam:

The Council of State Bioscience Associations (CSBA) Board of Directors thanks the Office of Management and Budget (OMB) for the opportunity to submit comments on the proposed rule *Regulation for Federal Financial Assistance*.[1]

The CSBA is a coalition of state and territory-based life sciences trade associations that advocate for public policies to support development and delivery of innovative medical, agricultural, and bioindustrial products. The collective CSBA voice represents a nationwide grassroots network of innovators, researchers, manufacturers, and accelerators. Our member companies employ 2.3 million people in more than 149,000 businesses across the U.S. and Puerto Rico. The total economic impact of the bioscience industry on the U.S. economy totaled $3.2 trillion dollars in 2023.[2]

CSBA acknowledges the Administration's objective of strengthening accountability and effectiveness in federal financial assistance. However, as drafted, we are concerned that the proposed rule would weaken U.S. competitiveness, disrupt essential research, and slow innovation. Ultimately, it will negatively impact scientists' ability to bring innovation to patients. If finalized, this rule could impact the U.S. biotechnology ecosystem by:

- **Creating instability within the research ecosystem and delay patient access to innovative medicines.**
- **Reducing both public and private sector investment into the high-risk development pipeline.**
- **Restricting the expansion of the skilled biotechnology workforce.**
- **Reducing the translation and transfer of research into innovation.**

America's innovation ecosystem, including CSBA's own industry members, rely on federal assistance to develop the next generation of life changing and saving biotechnology innovations. Support from a variety of federal government agencies plays a key role in the ability to take breakthrough innovations from basic scientific research through multi-year development processes before finally reaching an approved therapy American patients can benefit from. Standard estimates indicate that it can take as long as 15 years for a new therapy to receive approval and

[1] 91 Fed. Reg. 32189 (May 29, 2026).
[2] TEConomy/Biotechnology Innovation Organization. (2024). *The U.S. Bioscience Economy: Driving Economic Growth and Opportunity in States and Regions*. https://www.bio.org/csba-resources-and-reports

reach a patient.[3] Federally funded biomedical research often provides initial insights that enable future drug development. For example, a recent study found that NIH-funded research contributed to 354 of 356 (99.4%) drugs approved by FDA between 2010 and 2019.[4]

Continued federal investment in America's biotechnology industry is critical to ensuring U.S. leadership in the global biotechnology industry. This is especially critical now as China is emerging as another global center for biotechnology innovation. Those key sources of federal financial support, which are central to maintaining U.S. leadership in biotechnology, include:

- **National Institutes of Health (NIH) grants and cooperative agreements:** As the world's largest public funder of biomedical research, NIH provides foundational scientific support that advances drug discovery and development.
- **Small Business Innovation Research (SBIR) program support:** SBIR provides critical non-dilutive funding to early-stage biotechnology companies and helps attract private-sector investment for high-risk research and development.
- **Small Business Technology Transfer (STTR) program support:** STTR provides important non-dilutive funding that helps generate foundational intellectual property for licensing to small businesses or other STTR-eligible companies.
- **National Science Foundation (NSF) support:** NSF programs, including the Advanced Technological Education (ATE) program, expand participation in the biotechnology talent pipeline to help build and sustain a skilled workforce across the full innovation lifecycle, from research and development to commercial biomanufacturing.
- **United States Department of Agriculture (USDA) National Institute of Food and Agriculture (NIFA) grants and interagency programs:** USDA NIFA programs such as the Agriculture and Food Research Initiative (AFRI) support research in food and agricultural sciences from both animal and plant health and production to bioenergy and agricultural technology while also ensuring the United States addresses projected shortfalls of qualified graduates in agricultural, food, forestry, and energy resources sectors.
- **Department of Energy (DOE) Office of Science (OIS) grants and cooperative agreements:** The Biological and Environmental Research (BER) program supports research and facilities with the goal of advancing the nation's energy and infrastructure security. Research supported by BER helped map the human genome and continues to make considerable advances in the energy sector with the production of biofuels and other biomass products.
- **Department of Energy (DOE) Alternative Fuels and Feedstocks Office (AFFO) grants and cooperative agreements:** AFFO enables research, development, and demonstration to accelerate commercialization of alternative fuels, fertilizers, chemicals, and feedstocks, further establishing a secure domestic supply chain and lowering costs for these products.
- **Defense Advanced Research Projects Agency (DARPA) Biological Technologies Office (BTO) grants and cooperative agreements:** BTO supports research and commercialization of biological properties and processes to protect and enhance our nation's warfighters. Additionally, through Ag x BTO Program, BTO supports the

[3] Biotechnology Innovation Organization, *Drug Development, Review & Lifecycle Management*, BIO, https://www.bio.org/policy/human-health/drug-development-review-lifecycle-management

[4] Cleary et al., Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019, JAMA Health Forum, 2023 Apr 7;4(4):e230511.

development of innovative agricultural defense solutions and the creation of resilient domestic infrastructure.

- **Advanced Research Projects Agency for Health (ARPA-H) grants and cooperative agreements:** ARPA-H supports novel, high-impact research designed to accelerate progress in priority areas of biomedical innovation.
- **Centers for Disease Control and Prevention (CDC) grants and cooperative agreements:** CDC funding supports public health research across disease areas and strengthens the surveillance systems, data infrastructure, and implementation capacity needed to evaluate and deploy medical innovations in real-world settings.
- **Biomedical Advanced Research and Development Authority (BARDA) support:** BARDA partners effectively with the private sector to advance pharmaceutical innovations that help protect Americans from natural and human-made chemical, biological, radiological, and nuclear threats.

These forms of financial support are not only critical to maintaining U.S. biotechnology leadership but have also contributed to countless innovations that have improved the way patients are treated and cured of disease, food is grown, and fuel is created.

This proposed rule threatens to disrupt federal funding by imposing mid-award program terminations or suspensions, which will cause irreversible disruptions to ongoing work in advancing biomedical innovation. Terminating or suspending funding, or even the threat of such action will result in systemic uncertainty that discourages private sector investment in biomedical research and development. That in turn will cause delays to treatments and cures that patients depend on. Beyond the irreversible disruption that losing these federal funding streams would impose on the biotechnology ecosystem, additional provisions of the proposed rule would place added pressure on small start-up biotechnology companies that are ill-equipped to absorb the financial impact this proposed rule would cause.

As outlined in our comments above, the CSBA opposes the proposed rule. As drafted, OMB-2026-0034 would introduce significant uncertainty, reduce flexibility, and impose constraints that will hinder and increase costs for the biomedical research ecosystem. The provisions contained in the proposed rule would destabilize critical research and weaken U.S. leadership in biotechnology innovation. Federal policy should support, not impede, the systems that drive discovery and deliver innovation. Therefore, the CSBA urges OMB to either withdraw the proposed rule or revise it, in collaboration with stakeholders, in a manner that ensures the continued stability, predictability, and success of the biotechnology sector in the United States.

Thank you for your consideration. Please contact CSBA Board Chair, Mike Guerra at mguerra@califesciences.org should you have any questions.

Sincerely,

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