July 8, 2026

Director Russell Vought
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: Comments on Proposed Rule – Regulation for Federal Financial Assistance (OMB-2026-0034)

Dear Director Vought:

On behalf of **MichBio**, Michigan's statewide biosciences industry association, I appreciate the opportunity to comment on the Office of Management and Budget's proposed revisions to the Guidance for Federal Financial Assistance (OMB-2026-0034).

MichBio represents more than 3,300 organizations spanning Michigan's life sciences ecosystem, including biotechnology and pharmaceutical companies, medical device manufacturers, diagnostics developers, digital health innovators, contract research organizations, manufacturers, research universities, academic medical centers, health systems, venture investors, suppliers, and patient advocacy organizations. Together, these organizations comprise one of Michigan's most research-intensive and innovation-driven industries, advancing discoveries that improve patient care, strengthen domestic manufacturing, enhance national security, and contribute significantly to both Michigan's economy and America's global leadership in science and technology.

Michigan's biosciences sector employs nearly 48,000 highly skilled professionals and is anchored by nationally recognized research universities, world-class health systems, independent research institutes, and innovative startup and established life sciences companies. Collectively, these institutions secure well over $1 billion annually in competitive NIH funding alone, in addition to substantial support from the National Science Foundation (NSF), Department of Defense (DoD), Department of Energy (DOE), Advanced Research Projects Agency for Health (ARPA-H), Biomedical Advanced Research and Development Authority (BARDA), USDA, and other federal agencies.

These investments are far more than research expenditures—they are the foundation of America's innovation economy. Federal support has helped launch and grow Michigan companies whose technologies now improve patient care around the world. **Accuri Cytometers**, born from engineering and biomedical research at the University of Michigan, developed affordable, high-performance flow cytometry technology before its acquisition by BD Biosciences, dramatically expanding global access to sophisticated cell analysis. **HistoSonics**, founded upon University of Michigan research and supported through federal research and commercialization programs, has pioneered histotripsy - a revolutionary, non-invasive platform for destroying liver tumors and other targeted tissues without surgery or radiation. **Akadeum Life Sciences** leveraged NIH-supported innovation and SBIR funding to commercialize its proprietary buoyancy-based cell separation technology, enabling advances in cell therapy, diagnostics, and biomedical research. Likewise, **Tetra Therapeutics**, emerging from federally funded neuroscience research, advanced novel therapeutics for cognitive disorders before its acquisition

by Shionogi, demonstrating how federally supported discoveries evolve into globally significant pharmaceutical innovation.

These examples represent only a small fraction of the innovations emerging from Michigan's research ecosystem. They illustrate how federal investments extend well beyond individual laboratories—creating startup companies, attracting private capital, supporting advanced manufacturing, generating high-paying jobs, and delivering lifesaving therapies and technologies to patients. Policies that introduce uncertainty into the administration of federal research funding therefore have consequences extending across the entire innovation economy.

MichBio shares the Administration's commitment to responsible stewardship of taxpayer resources, transparency, and accountability in the administration of federal financial assistance. However, we are deeply concerned that several provisions within the proposed rule would fundamentally alter the predictability and integrity of the federal research enterprise. In doing so, they risk discouraging scientific innovation, weakening public-private partnerships, reducing private investment, and delaying the development of new therapies, diagnostics, medical technologies, and manufacturing innovations that benefit patients and strengthen the American economy.

For nearly half a century, the United States has built the world's preeminent life sciences innovation ecosystem through a deliberate partnership among federal agencies, research universities, entrepreneurs, investors, and private industry. Federal investment in basic and translational research, coupled with the commercialization framework established by the Bayh-Dole Act, has enabled discoveries arising from federally funded laboratories to become lifesaving medicines, advanced medical technologies, and entirely new industries. As the Bayh-Dole Coalition recently observed in its comments to OMB, introducing unnecessary uncertainty into this proven system threatens the confidence upon which successful commercialization depends.

Broad Discretionary Termination Authority Would Undermine Research Stability

Our principal concern is the proposed authority permitting federal agencies to terminate financial assistance whenever continuation is determined to be "in the interest of the Federal agency" or "no longer in the Federal Government's interests." As currently drafted, these standards are extraordinarily broad, subjective, and lack objective criteria or procedural safeguards. As many other thought leaders and organizations have noted, such language risks politicizing federally funded research and undermining confidence in America's innovation system.

Biomedical research differs fundamentally from most other federally funded activities. Developing a new therapeutic, medical device, diagnostic platform, biologic, or advanced manufacturing technology routinely requires a decade or more of sustained scientific investigation, regulatory development, clinical validation, and private-sector investment. Federal research awards frequently represent the foundational investment that enables venture financing, strategic partnerships, manufacturing expansion, and commercialization.

Even if exercised infrequently, broad discretionary termination authority fundamentally changes the investment calculus for universities, startup companies, investors, manufacturers, and strategic partners. Increased uncertainty at the earliest stages of discovery reverberates throughout the innovation continuum, reducing private investment, slowing commercialization, and delaying patient access to transformative technologies.

Preserving the Integrity of Scientific Peer Review

As MichBio's President & CEO, I also offer the perspective of having served for decades as a scientific peer reviewer for the National Institutes of Health, including numerous NIH SBIR and STTR review panels. That experience has provided firsthand insight into the rigor, objectivity, and integrity with which federal research investments are evaluated and managed.

Applications undergo independent scientific review by nationally recognized subject matter experts operating under strict conflict-of-interest requirements and comprehensive program oversight. Funding recommendations are based upon scientific merit, innovation, feasibility, investigator qualifications, and potential public benefit - not shifting policy priorities or subjective interpretations.

The credibility of this system depends not only upon objective award decisions but also upon confidence that awards, once made, will be administered under transparent, predictable, and consistently applied standards. Researchers devote years developing proposals. Universities invest in specialized facilities. Entrepreneurs launch companies. Investors commit capital. Patients enroll in clinical studies. Each does so because they trust the integrity and stability of the federal research enterprise.

This principle is particularly important for the SBIR and STTR programs. For many emerging Michigan biotechnology, medical device, diagnostics, and digital health companies, an initial SBIR or STTR award provides the independent scientific validation necessary to attract follow-on investment and advance innovations toward commercialization. Akadeum, HistoSonics, and numerous other Michigan companies exemplify this pathway from federally supported research to globally competitive enterprises. Weakening confidence in the administration of these programs threatens not only academic research, but also startup formation, manufacturing investment, and America's innovation leadership.

Michigan's Innovation Economy Depends on Stable Federal Partnerships

Federal research investments create impacts extending well beyond individual grant recipients. The commercialization pathways followed by HistoSonics, Akadeum Life Sciences, Accuri Cytometers, and Tetra Therapeutics illustrate how biomedical innovation actually occurs. Breakthroughs rarely move directly from laboratory bench to patient bedside. Rather, they progress through years of federally supported research, competitive peer review, SBIR and STTR awards, technology transfer, venture investment, regulatory development, manufacturing scale-up, and commercialization. Each stage depends upon confidence that the federal government will administer research investments through objective, transparent, and predictable processes.

Interrupting that innovation continuum affects far more than principal investigators. It influences entrepreneurs launching companies, manufacturers expanding facilities, investors allocating capital, students pursuing scientific careers, and ultimately the patients who depend upon continued medical innovation.

America's Global Leadership Depends on Predictability

The proposed rule arrives during a period of unprecedented international competition in biotechnology, artificial intelligence, precision medicine, advanced manufacturing, and other strategically important technologies.

America's global leadership has never depended solely upon the amount invested in research. Rather, it has depended upon the confidence that researchers, institutions, entrepreneurs, and investors place in the stability, integrity, transparency, and predictability of the American research enterprise.

At a time when geopolitical competitors are investing aggressively to surpass American scientific leadership, policies that inject unnecessary uncertainty into our innovation system risk weakening one of the nation's greatest strategic advantages.

Recommendations

Accordingly, MichBio respectfully urges OMB to:

- Remove or substantially narrow provisions permitting discretionary termination of awards based upon broad determinations that continuation is "in the interest of the Federal agency" or "no longer in the Federal Government's interests."
- Establish clear, objective, transparent, and consistently applied standards governing any discretionary termination authority.
- Preserve independent, merit-based scientific peer review as the primary basis for awarding and continuing federally funded research.
- Provide meaningful procedural protections, including written justification, notice, opportunity to respond, and independent administrative review before discretionary termination of research awards.
- Recognize the unique characteristics of biomedical research and commercialization, where continuity of funding, long-term collaboration, and regulatory certainty are essential to translating federally funded discoveries into products that improve patient health, strengthen domestic manufacturing, and enhance America's global competitiveness.

Conclusion

Michigan's bioscience community strongly supports responsible stewardship of federal resources. Accountability, transparency, and effective oversight are indispensable to maintaining public confidence in federally funded research. However, accountability should reinforce - not undermine - the qualities that have made the United States the world's leader in biomedical innovation: scientific excellence, objective peer review, stable public-private partnerships, and predictable administration of research funding.

The United States did not become the world's innovation leader by accident. It did so by establishing a research ecosystem founded on scientific excellence, institutional integrity, strong intellectual property protections, public-private collaboration, and confidence that federal research investments would be administered consistently and fairly. Companies such as HistoSonics, Akadeum Life Sciences, Accuri Cytometers, and Tetra Therapeutics demonstrate what is possible when that system functions as intended. Each represents years of federally supported research, entrepreneurial risk-taking, private investment, and sustained collaboration between academia and industry. Their success has generated not only economic returns and high-quality American jobs, but also medical innovations that improve - and in many cases save - patients' lives.

For these reasons, MichBio respectfully urges OMB to withdraw or substantially revise those portions of the proposed rule that would inject unnecessary uncertainty into the nation's research enterprise while

preserving appropriate mechanisms for oversight, accountability, and fiscal responsibility. By doing so, OMB will help ensure that future generations of innovators can build the next life sciences unicorn and that American patients continue to benefit from discoveries made possible through a stable, merit-based, and globally respected federal research enterprise.

Thank you for your consideration of these comments.

Respectfully submitted,

Stephen Rapundalo, PhD
President and Chief Executive Officer