December 23, 2025

Michael Kratsios
Director, U.S. Office of Science and Technology Policy
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: Office of Science and Technology Policy's Notice of Request for Information; Accelerating the American Scientific Enterprise

Dear Director Kratsios,

The Bayh-Dole Coalition, a group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act and informing policymakers and the public of its many benefits, appreciates the opportunity to respond to the OSTP's Request for Information on accelerating the American scientific enterprise.

For decades, the United States has led the world in scientific research and innovation. That's thanks, in large part, to the academic-industry collaborations made possible by the Bayh-Dole Act, which ensures that publicly funded discoveries can attract private investment, move from the lab to the marketplace, and ultimately deliver value to the American people. The law also allows entrepreneurial small companies to accept federal research contracts without fearing that the government will give away resulting inventions. Finally, Bayh-Dole allows federal laboratories to license their inventions to U.S. industry — something which rarely happened before the law's enactment.

The Bayh-Dole Act has been enormously successful — before its passage in 1980, the government licensed less than 5% of the 28,000 patents that it held. In the decades since, the Bayh-Dole Act has facilitated increased licensing that has contributed $1 trillion to the U.S. GDP — about $40 billion each year — and supported 6.5 million jobs. Federally-funded research has helped to launch over 19,000 startups.

However, several current proposals and initiatives risk weakening the system that has served us well for nearly half a century. Undermining Bayh-Dole would set back our long-term competitiveness with China, jeopardize American leadership in scientific discovery, and erode the innovation ecosystem that powers our economy and national security.

(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?

Preserving and reinforcing the Bayh-Dole framework — which has driven decades of public-private collaboration — remains the single best lever for mobilizing private capital and expertise around basic research and early-stage applied research.

This idea is reinforced by a 2018 report from the National Institute of Standards & Technology, initiated by the first Trump Administration. The report states that strong intellectual property rights are "often necessary" to bring discoveries "from the laboratory to the marketplace," noting that such rights enable "partnerships with industry for commercial adoption." The report describes the Bayh-Dole Act as "transformational" legislation that has "provid[ed] clarity of intellectual property ownership for the public good, and incentiviz[ed] the commercial development of inventions for U.S. economic impact."

Agencies should also support practical solutions that bridge the gap between universities and private partners — approaches that are already proving effective on a small scale. For example, at Boston University, engineer and entrepreneur Vinit Nijhawan worked to "maximize collisions" and "minimize friction" between researchers and companies through showcasing events, newsletters, and a more accessible tech-transfer website. Those efforts helped launch eight spin-off companies that collectively raised more than $350 million.

Federal agencies can take similar steps at scale, working to maximize collisions and minimize friction across the broader innovation ecosystem. This would include harmonizing IP and licensing practices across portfolios, streamlining contracting and reporting requirements, and adopting consistent, transparent rules that reduce transaction costs and uncertainty for industry partners.

Earlier this year, the Bayh-Dole Coalition alerted President Trump to several serious violations of the law under the Biden Administration, which should be repealed. That has not happened yet, but it would represent an important step in meeting your stated objective. We identify these policies in Section IX of our comments below.

(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?

The federal government can accelerate the path from laboratory to market by creating a publicly accessible database of U.S. manufacturers and their capabilities. Such a database would be organized by industry, and include appropriate contact information so licensees of federally-funded inventions can easily identify domestic manufacturers.

The government can also streamline inter-agency reporting and collaboration rules so private investors and small firms can move federally funded discoveries to market more quickly. And aligning agency IP and licensing practices could reduce transaction costs for academic-industry deals.

Finally, the government can amend current domestic manufacturing requirements to reduce barriers to commercialization. This includes changing guidelines for waiver requests, as the system currently creates major delays and risk for businesses that deters commercialization. For example, the government ought to require agencies to clearly respond to waiver petitions within 60 days, or otherwise automatically approve the petition. Such a requirement would reduce wait times and increase accountability. Similarly, agencies should be permitted to grant conditional waivers as needed.

(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?

The federal government should ensure that intellectual property rights are clear and predictable, giving businesses the confidence to invest the time and energy to bring a discovery to market.

Agencies should support research centers and federal laboratories in conducting outreach to nearby companies about technology transfer opportunities, while also streamlining communication among federally supported institutions, local universities, and industry to expand technology transfer collaboration.

The federal government can further support the ecosystem that Bayh-Dole created by backing regional collaboration efforts — such as the Southeast Venture Summit or Duke University's "Venture Day" — that attract investors to startups built around university technologies. It should invest in programs and infrastructure that foster sustained collaboration between startups, established firms, and investors.

(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?

Federal policy can strengthen the role of small- and medium-sized businesses by creating simpler, faster pathways for them to collaborate with federally funded research institutions and to adopt emerging technologies.

Currently, about 70% of university patent licenses go to small businesses and emerging startups under the Bayh-Dole Act. Safeguarding this licensing pathway is vital for small businesses, as it provides the confidence and stability required to turn early-stage research into market-ready innovations.

Additionally, Congress must renew the Small Business Innovation Research (SBIR) program, which provides crucial federal funding for small businesses, and the Small Business Technology Transfer (STTR) program, which supports companies developing technologies originating in universities and other research institutions.

(vi) What reforms will enable the American scientific enterprise to pursue more highrisk, high-reward research that could transform our scientific understanding and unlock new

technologies, while sustaining the incremental science essential for cumulative production of knowledge?

Reinforcing the Bayh-Dole Act — by officially rescinding Biden-era draft guidance that would have radically expanded the government's march-in powers, and in fact issuing new guidance, such as the regulation proposed towards the end of President Trump's first term, that further clarifies that objections over the price of commercially available products is not a valid trigger for exercising march-in rights — would help encourage the high-risk, high-reward research that propels the country forward.

The Bayh-Dole tech transfer framework has produced major breakthrough products and medicines, from the Google search algorithm to multiple AIDS therapies developed by Emory scientists, CAR T-cell cancer treatments pioneered across the University of Texas System, and a cattle vaccine developed at Louisiana State University that could save the U.S. cattle industry $1 billion per year. It has also supported the steady, incremental scientific progress that often yields enormous returns. Decades of university research on mRNA technology, for example, enabled companies like Pfizer and Moderna to rapidly develop Covid-19 vaccines when the pandemic struck.

(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 Bayh-Dole Act remains central to stimulating new institutional models for research. It established a framework in which universities receive federal funding, can patent their inventions, and partner with the private sector to commercialize those discoveries.

That model has helped create regional innovation hubs and research parks, entrepreneurship programs, and consortia that foster collaboration across universities. In Georgia alone, university tech transfer generates tens of billions of dollars in annual economic impact. Across other states, innovations similarly support hundreds of startups, thousands of jobs, and life-saving inventions — from water purification technologies developed at the University of Utah to life-saving vaccines from St. Jude Children's Research Hospital in Tennessee. It is therefore essential that the federal government support and strengthen the Bayh-Dole Act and the system it created.

(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.

A recent Commerce Department proposal for the government to claim royalties on university inventions supported by federal funding represents a major potential barrier. Most university tech transfer offices already barely break even or operate at a loss. Royalty-sharing would reduce universities' ability to manage technology transfer, decreasing their willingness to invest in patenting and licensing inventions. Fewer licensing deals would mean fewer partnerships with startups and local businesses — ultimately slowing the translation of research into products that benefit the public. Such proposals should be immediately withdrawn.

A set of licensing guidelines from the National Institutes of Health took effect in October 2025. These guidelines require industry licensees to submit continuous, burdensome access-planning reports on their commercialization efforts to meet vague objectives, including the price of a resulting product. It also requires licensees to submit publicly available information about their plans, something which was expressly forbidden by Congress when enacting Bayh-Dole. If the bureaucracy feels that an objective has not been met, even after a new drug has been approved, the guidelines allow the NIH to revoke the license so the product can be made available to copiers. Such a policy undermines the administration's goal of accelerating medical progress, and should be rescinded.

Similarly, the Department of Energy's Nuclear Research Program has mandated that inventions supported by its funding be "made freely available to the public with few or no intellectual property restrictions," so they can be given away, even to foreign competitors. This requirement directly violates Bayh-Dole and undermines the administration's ambitions for U.S. energy leadership. It should be rolled back.

The 2023 "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" would likewise impede scientific research and commercialization and must be withdrawn. The draft would permit the government to "march in" and relicense a patent if the resulting product's price is deemed "unreasonable." This is a profound misinterpretation of the Bayh-Dole Act and the specific instances in which march-in rights can be invoked. In fact, under the first Trump administration, the National Institute of Standards and Technology called march-in a "last resort" that has "never been exercised" in a 2018 green paper on potential policies to increase federal returns on R&D investment. The threat of march-in as a price control would chill private sector investment in federally-funded research, slowing the commercialization of research into useful products. The government should rescind the framework and reaffirm that march-in remains an exceptional remedy for non-use or failure to commercialize — not a tool for regulating prices.

The National Science Foundation's proposed "Intellectual Property Options," which would dictate how university inventions developed through industry partnerships must be licensed, exceeds the agency's authority. Bayh-Dole intentionally delegated to universities — handing back micromanagement of the licensing process to agencies would disrupt the Bayh-Dole system. These guidelines should be withdrawn.

The DOE has also issued a policy that requires all inventions developed with taxpayer funds through its Science and Energy Programs to be "substantially manufactured" in the United States. This policy creates major restrictions on manufacturing that go far beyond those established by Congress when enacting the Bayh-Dole Act's domestic manufacturing provisions, which aim to balance the noble goal of domestic manufacturing with facilitating commercialization. It would create major barriers for companies attempting to commercialize federally-funded discoveries, and ought to be rescinded.

(xii) What policy mechanisms would ensure that the benefits of federally-funded research — including access to resulting technologies, economic opportunities, and improved quality of life — reach all Americans?

Assuring universities, federal laboratories, investors, and private industry that the Bayh-Dole Act remains secure and protected would ensure federally-funded research continues to be commercialized into products available to all Americans. The fruits of the Bayh-Dole system range from brain-injury blood tests and anti-counterfeiting technologies that originated at universities in Florida to agricultural innovations from Montana academics and breakthrough medical therapies discovered at schools in Texas.

Furthermore, renewing federal programs like SBIR and STTR funding would help ensure commercialization and collaboration opportunities extend to small businesses across the country, not just in development hubs like Silicon Valley. This in turn would expand Americans' access to new products and the economic benefits of technology transfer.

Thank you again for the opportunity to provide information on this critical issue. The Bayh-Dole Coalition remains ready to assist you and your office in your work to accelerate America's great scientific enterprise.

Sincerely,

Joseph P Allen

Joseph P. Allen
Executive Director
Bayh-Dole Coalition