Conservatives
for
Property Rights

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National Institutes of Health
VIA EMAIL: SciencePolicy@od.nih.gov

RE: Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing thousands of Americans, writes in response to the National Institutes of Health's (NIH) request for comments in connection with the "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

CPR acknowledges NIH's taking stock of "policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries." We recognize that NIH has a "role in the broader biomedical research enterprise in promoting the application of knowledge to enhance human health." In NIH's consideration of "how NIH, as a research institution, approaches the patenting and licensing of biomedical inventions," CPR cautions the agency to consider what is working and keep in mind how shifts away from what is working are likely to be steps backward, causing unintended consequences. Failing to proceed with caution in this exercise would have serious, counterproductive effects that harm patients, weaken our economy, and even give adversarial competitors such as China an advantage in technological leadership.

NIH's Sweet Spot

NIH has an important role in biomedical research as a funder of basic research. NIH grants and its in-house biomedical research advance understanding of scientific and biomedical concepts and relationships. While some may be patentable, these initial discoveries are typically not readily translatable and certainly not ready for commercialization. Rather, NIH's or NIH-funded discoveries require orders of magnitude greater funding in applied research and development (R&D) to have a prospect for a commercial product.

The latter stages appropriately rely on private investment because the failure rate is approximately 9 out of 10. One study reported it "underscore[d] that the development of basic discoveries requires substantial additional investments, partnerships, and the shouldering of financial risk by the private sector if therapies are to materialize as FDA-

approved medicine."[1] For NIH to assume the enormous risk of failure that comes with development of the basic research discoveries, where its investment is more fertile, would be the height of misuse of taxpayer money.

NIH should stay in its lane underwriting basic research. This is NIH's most effective, efficient means of transforming discoveries into products. NIH's core competency (grantmaking) seeds basic scientific discoveries, which in turn hold promise for more technology, whose patents and intellectual property (IP) are held by grantees (universities and research institutions), to transfer. More embryonic technologies actively being commercialized means more products and more competition. More consumer choice and competition constrain product price increases, even before patent expiration. This indirect role on NIH's part in product and market development make the best use of taxpayer dollars and produce the best prospects of technology transfer and commercialization efforts succeeding.

IP and Bayh-Dole

IP ownership and having more IP-protected technology incentivize institutions to transfer inventions to willing entities capable of attempting commercialization. The key to this success is secure, reliable IP rights.

The 40-plus year experience of the Bayh-Dole Act of 1980 bears recounting. Bayh-Dole solved the problem of wasted expenditure of taxpayer money. Prior to Bayh-Dole, federally funded research led to many discoveries. The U.S. government owned 28,000 patents from research it funded. But only 5 percent were commercialized. Taxpayers received no practical benefit from all the research for which their taxes paid.

Pre-Bayh-Dole, the government tightly controlled the IP from its funded research in Washington, D.C. Some 26 agencies' rules controlled commercial use of federally owned IP. Grantees often were not allowed to take title of their discoveries. The government only gave nonexclusive licenses to patents. Thus, very little new knowledge was ever transformed into products.

This success-story law changed all that failure. It has facilitated commercialization by providing reliable property rights. Bayh-Dole has unleashed thousands of inventions that otherwise would have never moved to commercial application.

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[1] Duane Schulthess, Harry P. Bowen, Robert Popovian, Daniel Gassull, Augustine Zhang, and Joe Hammang, "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals," Therapeutic Innovation & Regulatory Science, January 2023; 57(1):160-169.

For instance, university inventions bring about more than two new products and two jobs every single day.[2] Bayh-Dole made possible the creation of the biotech industry. Its decentralized tech transfer has contributed $1 trillion to U.S. GDP from 1996-2020. Its patent licensing is responsible for about $2 trillion of industry gross output and supports 6.5 million jobs.[3] In the 1970s, most medicines Americans used were developed in Europe; since Bayh-Dole, the United States leads the world in drug discovery, R&D, commercialization, and the development of new innovative medicines.[4]

The stark contrast between the pre-Bayh-Dole barriers and central command-and-control policies, resulting in radically stunted benefits from the millions and millions of taxpayer dollars poured into research over four decades, and the post-Bayh-Dole democratization of ownership and IP decisionmaking by grant recipients over the fruits of their labors, must not be missed. The difference is night and day. Bayh-Dole spurs widespread invention; efficient, smart technology transfer and commercialization; and the outpouring of new products, startup companies, new jobs, invigorated innovation ecosystems across the country, and even new industries.

The Bayh-Dole Act provides the government "march-in" rights in certain narrow, extraordinary circumstances. March-in would require the patent owner or exclusive licensee to issue a license to the patented invention. The statute specifies the grounds for such march-in licensing: when the contractor has failed timely to pursue commercialization of the invention, has not reasonably satisfied public health or safety needs, has failed to ensure the invention is substantially made in the United States, or can't meet or hasn't met specified federal requirements for public use. None of these extremely limited exceptions for "march-in" relates to product prices. In more than 40 years, march-in has never been exercised despite a number of petitions requesting it. In denying march-in petitions, NIH has always acted appropriately and in accord with the statute. NIH has repeatedly, consistently declined the requested misuse of march-in. CPR commends this fidelity to the spirit and letter of this important law. We urge NIH to resolve to continue doing the right thing as the agency has heretofore done.

Catalyzing Technology Transfer

Again, NIH has far less involvement in technology transfer, where decisionmaking was revolutionized when Bayh-Dole democratized technology transfer decisionmaking to the grantee institutional level and away from Washington. Because

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[2] Eagle Forum Education & Legal Defense Fund, summary of remarks by Joseph P. Allen, "Benefiting from Federal Research Funding: Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society," Proceedings of Capitol Hill Briefing, Oct. 18, 2018, p. 5.

[3] AUTM and BIO, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020," June 14, 2022.

[4] Stephen Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System," Information Technology & Innovation Foundation, March 4, 2019.

of the localized prerogative to decide whether to obtain IP protection and how best to license it, this now properly locates and brings about the most effective, informed commercialization decisions.

As discussed, the benefits of the Bayh-Dole regime could hardly be clearer. Thus, NIH's (or any other federal government agency's) interference in or imposition of inadvisable conditions on IP, technology transfer, or commercialization would cause tremendous damage to the turning of discoveries into products and beyond.

NIH's policy levers to catalyze tech transfer include licensing commercially promising discoveries made by NIH researchers. This should be done efficiently, with minimized red tape, in keeping with Bayh-Dole's framework. In that context, NIH could seek to ensure that its policies and practices are user-friendly, "speed-of-business" for federal agency tech transfer processes and procedures. The agency should make certain that any such levers enable partnerships for translational R&D, technology maturation, and commercialization under existing partnership mechanisms (e.g., SBIR/STTR, CRADA).

With respect to CRADAs and other licensing vehicles and in light of the vast majority of public participants given speaking slots at the workshop, it is imperative that NIH remember and not forget the lesson of its Cooperative Research and Development Agreement (CRADA) experience in the 1990s. In 1989, NIH began requiring a "reasonable pricing" provision in its CRADAs as a condition for an exclusive license to NIH-developed technologies. That price-control clause injected uncertainty, diminished intellectual property value, and undermined property rights over eventual products.

The "reasonable pricing" requirement caused a significant drop in NIH CRADAs, which fell from 42 in 1989 to an average of 32 the next six years. This dramatic fall-off led NIH to eliminate the provision. CRADAs with NIH immediately rose to about 90 agreements in 1996 and more than 160 in 1997. The agency confirmed this lesson in 2021.[5]

When the government price control was removed, NIH Director Harold Varmus said "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. . . . Eliminating the clause will promote research that can enhance the health of the American people." New price controls today would do the same harm. Instead of catalyzing tech transfer or turning discoveries into products, NIH would repeat the failures of the past and radically diminish the stated aim of this exercise.

In closing, CPR applauds the successes NIH has had in technology transfer, particularly by funding research at research institutions and universities and respecting the

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[5] NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," Nov. 15, 2021. https://www.techtransfer.nih.gov/sites/default/files/CRADA Q&A Nov 2021 FINAL.pdf

boundaries of Bayh-Dole. We urge NIH to stay true to its lane and abide by the law. We urge rejection of the siren song of government price controls, "reasonable pricing," abuse of march-in, and any other scheme that would violate the provisions of the Bayh-Dole statute and ignore the clear lessons of secure IP held by grantee institutions, inventors, or licensees.

Sincerely,

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