

On July 31, 2023, the National Institutes of Health hosted a virtual workshop to “discuss policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries. Goals [included] discussing how NIH, as a research institution, approaches the patenting and licensing of biomedical inventions. There [was] also discussion on the agency’s role in the broader biomedical research enterprise in promoting the application of knowledge to enhance human health.”

Both pre- and post-workshop, pro-IP advocates submitted comments on the subject. Below are some excerpts from these submissions:



Joseph P. Allen

Executive Director, Bayh-Dole Coalition (BDC)

“Perhaps the easiest way for the NIH to continue promoting successful technology transfer is to uphold the agency’s longstanding commitment and respect for the Bayh-Dole Act of 1980. Partnerships under Bayh-Dole have made the U.S. the unquestioned leader in the life sciences.”



Brian O’Shaughnessy

Senior V.P., Public Policy, Licensing Executives Society (USA & Canada)

“The greatest potential for public benefit derived of federally funded discoveries resides in our patent system, and in reliable and durable license agreements under the Bayh-Dole Act and the Federal Technology Transfer Act. The prospect that those agreements will be unilaterally altered or revoked after the fact will only drive industry away and deprive the public of the benefits of that research.”



Kate Hudson, Lizbet Boroughs, & Robert Hardy

Kate Hudson, JD, Associate Vice President and Counsel, AAU

Lizbet Boroughs, MSPH, Associate Vice President of Federal Relations, AAU

Robert Hardy, Director of Research Security & Intellectual Property Management, COGR

“The Bayh-Dole Act, combined with sustained government support for research at NIH, has helped to ensure U.S. competitiveness in biomedical research and technology. It remains critical that this existing policy apparatus and federal support be maintained and strengthened...We strongly believe that building upon existing NIH programs, as well as cross-collaboration with other federal agencies to improve and streamline the research, regulatory, and approval processes, will bring the best outcomes in catalyzing technology transfer efforts by the NIH overall.”



Stephen Susalka

Chief Executive Officer, AUTM

“The Bayh-Dole Act has been in existence for more than 40 years now and, for most of those years, the Act has been faithfully executed...Efforts to weaken technology transfer should be rejected. The Act’s march-in provisions were not designed to (and would not) lower drug prices. The same is true of efforts to weaken patents or burden technology licenses with provisions directed to reference pricing. Such efforts will harm innovation and will not have the desired effect of lowering drug prices.”



Karen Kerrigan

President & Chief Executive Officer, Small Business & Entrepreneurship Council

“Rather than protect and build on critical IP rights, some [workshop] panelists suggested reforms that would erode these protections — threatening the small business-led innovation ecosystem economy in the process...Small businesses and startups are advancing the next generation of innovative treatments. We urge the NIH to continue supporting and promoting the system of robust and assured intellectual property protections that make it all possible.”



Yale Office of Cooperative Research

Jon Soderstrom

Managing Director, Yale University’s Office of Cooperative Research (OCR), 1996-2021

Director of Program Development, Oak Ridge National Laboratory, 1994-1996

Director of Technology Licensing, Martin Marietta Energy Systems, 1984-1994

“Absent the Bayh-Dole Act and a technology transfer framework that leverages intellectual property rights, medicines like Zerit — along with hundreds of other cutting-edge treatments — might never have reached the market to benefit patients...As the NIH looks to the future, it is crucial to acknowledge the importance of protecting intellectual property rights, fostering public-private partnerships, and driving the development of medical breakthroughs.”



Walter G. Copan

Vice President for Research and Technology Transfer, Colorado School of Mines

Senior Adviser, Renewing American Innovation Project, CSIS

Under Secretary of Commerce for Standards and Technology, 2017-2021

“The delicate balance between the early-stage federally funded research conducted by universities and research institutions and conditions for high risk late-stage development undertaken by the private sector relies heavily on the predictability of rules for IP rights provided in exclusive licensing. Without this essential component, the entire technology transfer framework unravels to the detriment of the American public.”



Stephen Ezell

Vice President, Global Innovation Policy, Information Technology and Innovation Foundation (ITIF)

“The technology transfer regime the United States has implemented over the past four decades, largely as enabled through the Bayh-Dole Act, has been tremendously effective in stimulating innovation, especially in the life-sciences. While all such processes should be continuously streamlined or tweaked where improvement is possible, the current system is not nearly broadly in need of serious modification or reform, which would likely be counterproductive to a largely well-functioning technology transfer dynamic that effectively transmits technologies to private-sector companies...”



John Stanford

Executive Director, Incubate

“Rather than modifying agency policies in ways that could stifle innovation, we should harness the NIH’s capabilities to foster innovation and bolster competition. The value of strong public-private partnerships becomes evident here, as they serve as a bridge between research and real-world applications. By fast-tracking groundbreaking innovations from the lab to the market, the NIH — with the support of these public-private partnerships — fosters a dynamic environment brimming with various therapeutic choices.”



Robert Taylor

General Counsel, Alliance of US Startups and Inventors for Jobs

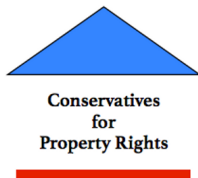
“Most everyone understands that startups, small companies, entrepreneurs and their investors make a major contribution to our nation’s development of new products based on research funded by NIH...What are not as widely understood are the motivating factors that incentivize and disincentivize these entities to start down the lengthy and risky path that leads to the new products. I encourage NIH to examine these factors...”



Andrew Schlafly

Counsel, Eagle Forum Education and Legal Defense Fund

“Since the Bayh-Dole Act became law in 1980, the NIH has generally played an important part in technology transfer, primarily as a funder of research at universities and other nongovernmental research institutions. Those entities own the discoveries, determine the appropriate IP protection, decide the best terms and partners for specific technology transfer efforts, and transfer technology as they deem appropriate, without interference from Washington. This model has worked extraordinarily well and successfully. Thus, the goal of NIH’s present initiative should be ‘First, do no harm.’”



James Edwards

Executive Director, Conservatives for Property Rights

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



Erik Iverson & Michael Falk

Erik Iverson, Chief Executive Officer, Wisconsin Alumni Research Foundation (WARF)
Michael Falk, Chief IP and Licensing Officer, Wisconsin Alumni Research Foundation (WARF)

“For more than 40 years, WARF has been a champion of the Bayh-Dole framework because we have seen it serve the national interest while also empowering offices like ours to fulfill our charitable mission. We have been gratified to see NIH demonstrate a steadfast commitment to upholding and defending Bayh-Dole. Today, we encourage the agency, and all federal agencies, to extend and reinforce that commitment.”



Katharine Ku

Chief Licensing Advisor, Wilson Sonsini Goodrich & Rosati
Executive Director, Office of Technology Licensing, Stanford University (1991-2018)

“The NIH serves an indispensable role in fostering basic research. But the agency is ill-equipped for the risky, expensive work of transforming that research into safe, effective products and should never be imposing arbitrary and nebulous price restrictions on a product so long before it ever becomes a reality.”



Adam Mossoff

Professor of Law, Antonin Scalia Law School, George Mason University

“Proposals for the NIH to use the Bayh-Dole Act or 28 U.S.C. § 1498 to impose price controls on patented therapeutics and diagnostics contradict the plain text and function of these two federal statutes.”



University of
Massachusetts
Amherst

Fred Reinhart

Senior Advisor for Technology Transfer, UMass Amherst

“With respect to inventions derived from research in academia and teaching hospitals, over 300 important vaccines and therapeutics have reached the public as a result of academic licenses to industry. It would be foolish and counterproductive to undermine such an effective model yet several groups (specifically KEI and UAEM) are trying to do just that.”



John Fraser

President, Burnside Development and Associates

**Assistant Vice President, Office of Commercialization, Florida State University
(1996-2014)**

“Research at a National laboratory and an academic center [led] to the new, now widely known drug (Ozempic and Wegovy). This occurred in the environment supportive of innovation provided by both the Stevenson-Wydler Technology Innovation Act of 1980 and the Bayh-Dole Act of the same year.”