

On December 7, 2023, the Biden administration proposed a new “framework” for exercising march-in rights under the Bayh-Dole Act. If enacted, the proposal will encourage the use of march-in rights on the basis of price, decimating confidence in the reliability of universities and federal laboratories as R&D partners, undermining private sector investment incentives, and severely handicapping American innovation.

In response, many universities, university tech transfer offices, and former university officials submitted comments to the National Institute of Standards and Technology (NIST) warning against this dangerous misuse of march-in rights. Below are some excerpts from their submissions:

Yale

Yale University

“The discretion allowed under the Bayh-Dole Act and related regulations has enabled Yale to encourage startups based on Yale inventions to locate in New Haven, thereby contributing to the economic renaissance of our host city...The shift of final control of licensing away from universities would have significant adverse effects on universities’ efforts in knowledge transfer.”



University of Pennsylvania

“The mere issuance of the guidelines is already casting a cloud over public/private sector partnerships. Here at the University of Pennsylvania we are receiving a greater level of pushback from potential licensees and companies that sponsor research at the university who are worried that the proposed expansion of march-in rights will be enacted.”



BROWN

Brown University

“As drafted, the framework has the potential to exacerbate [the difficulty of technology commercialization], and inhibit early-stage funding for startups. This would have a detrimental effect on Brown’s efforts to grow university research, create a vibrant faculty and student culture around innovation, and rejuvenate regional economic development around the life sciences in Providence and Rhode Island.”



Cornell University

Cornell University

“The risk of price-based march-in rights will discourage potential licensees, disincentivize the commercialization of federally funded inventions, and decrease the likelihood of university technology adoption...This would have a negative impact on Cornell’s technology transfer enterprise, making it much harder to find willing commercial partners.”

Stanford University

Stanford University

“Our technology transfer activities have enabled over 2,500 Stanford inventions to become commercially sold products and services...Concerns about the potential loss of critical patent rights... could stifle the thriving economy that has developed out of the close interactions between universities like Stanford and industry partners.”



Duke University

“Our partners depend on the revenues of the few successful discoveries to subsidize countless misfires...Enabling a lower barrier for invoking march-in rights results in investors losing the opportunity to recoup their investments, and the next generation of researchers and investors learning that remuneration is far from guaranteed.”



California Institute of Technology

“Three-quarters of the startup companies based on Caltech technology have an exclusive license to at least one federally funded patent. The threat of march-in would jeopardize the survival of these companies and greatly reduce the number of companies formed in future.”



Johns Hopkins University

“Thanks to our country’s intellectual property system and the Bayh-Dole Act of 1980, Johns Hopkins has hundreds of impactful technologies at various stages of commercialization...The proposed framework – and specifically its endorsement of price as a basis for the exercise of march-in rights – would repel the private investment community on which we rely to bring to market these types of inventions.”



University of California System

“UC is a leader in technology transfer and was granted more U.S. utility patents last year than any other university in the world...Any perceived possibility for misuse or added uncertainty on the interpretation of this [march-in] provision will have significant harmful effects on the universities’ ability to collaborate with or license federally funded inventions to industry partners.”



Rice University

“By every measure, the Bayh-Dole Act was a resounding success because it encouraged academic research institutions to work with industry to explore if and how federally funded innovations could reach and benefit the public. The Draft Guidelines take a huge step backward from this success.”



Vanderbilt University

“Vanderbilt University believes that, though well intended, the use of march-in rights in an attempt to control drug pricing will be ineffective, and the collateral damage caused by doing so will be catastrophic for university-industry collaborations, academic technology licensing efforts, and investments in startups developing products based on federally funded research.”



University of Notre Dame

“Considering the potential impacts on university research and innovation, there is concern that the proposed framework would stifle Notre Dame’s ability to deliver cutting-edge, globally significant research that is a force for good in the world.”



Michigan's University Research Corridor (URC)

"The URC's industry, entrepreneur and economic development partners depend on reliable, predictable pathways to partner with our universities for commercializing technologies. Proposed changes to the federal government's ability to exercise march-in rights on innovations based on an indefinable view of market value would erode their faith in these pathways and hamstring the ability of the URC to realize the greatest good from translational research."



University of North Carolina at Chapel Hill

"[L]ooking at our own university, more than 900 total UNC-affiliated startups—including nearly 160 of which are based in UNC-owned intellectual property—have been launched by a combination of Carolina faculty, students, alumni and other founders...The startup-to-small business pipeline is something the U.S. must continue to cultivate, not stymie with the potential threat of federal march-ins."



Emory University

"Emory is committed to collaborating with researchers and industry to build and nurture partnerships that will move ideas from the lab to the marketplace in a fair and equitable manner. NIST's proposed framework would have a negative impact on our future ability to find partners for promising new innovations arising from our research community."



University of Virginia Licensing & Ventures Group

"As someone who worked in companies that licensed technology from universities and as a professional who currently licenses university technology to companies, no companies will license government-funded university research if the government reserves the right to step in [and] take control of the product."



Washington University in St. Louis

"A change to March-In rights provisions under Bayh Dole would not only handicap companies...from bringing economic value and jobs to regions like St. Louis but would also inhibit companies...from spinning out of a university and edifying academic founders around startups and startup success. Rather, changes to March-In Rights would hamstring company formation."



University of Texas System

"Over the past 15 years alone, the UT System has been issued more than 2,900 patents and seen more than 3,100 licenses and options executed, and consistently ranks in the top five on the National Academy of Inventors' worldwide rankings of most patents granted...The uncertainty created by the expanded availability of march-in will make licensing federally funded technologies substantially more difficult for universities."

**NYU**

New York University

“Bayh-Dole is a rare instance of a law where we can measure its success, and the US economy has benefitted greatly from its implementation. Adding additional risk into the already complex ecosystem of technology commercialization will only hinder the creation of new solutions to benefit society.”

**ILLINOIS**

University of Illinois Urbana-Champaign

“Few entrepreneurs in any industry would risk building an entire company around an exclusive patent license from UIUC or another university if that exclusivity could be abruptly cancelled by the exercise of march-in rights. Breakthrough advances funded by the federal government...would stagnate.”



Wisconsin Alumni Research Foundation (WARF)

“We wish to state, in no uncertain terms, that the draft guidance, if implemented as written, will be detrimental to WARF’s philanthropic mission and have disastrous results for our colleagues and partners across the technology transfer industry.”



Rutgers University

“The success of the Bayh-Dole Act is attributed to academic research institutions working with industry to find ways for federally funded innovations to reach and benefit the public. This Draft Guidance will achieve just the opposite, causing industry to be unwilling to invest time, money, effort, and resources in developing federally funded innovations.”



Ohio State Innovation Foundation

“Following decades of ineffective transformation by the federal government of university research into goods and services, the [Bayh-Dole] Act empowered universities to take ownership of federally-funded inventions...Now, the Framework threatens to upend that unquestioned success – to the detriment of American taxpayers and the US economy, while also benefiting ill-intentioned parties, including our foreign adversaries.”



Purdue University

“Having been involved from its infancy and understanding its legislative history, Purdue knows that Bayh-Dole was not designed to provide the federal government a mechanism to set prices on successfully commercialized products.”



University of Maryland

“The draft guidelines, if enacted according to the Framework, would compromise our ability to continue to deliver such outstanding performance and achieve our objective of transforming UMD research discoveries into products, services, and new small businesses that deliver economic and societal benefit to the citizens of Maryland, the United States, and the world.”



Virginia Tech Innovation and Partnerships

“The Draft Guidelines risk undermining the foundational principles that have made the Bayh-Dole Act a cornerstone of American innovation. By introducing the possibility of government intervention in pricing strategies, the guidelines could create a chilling effect on investment in federally funded technologies.”



Northeastern University Center for Research Innovation

“[V]enture capital groups will not invest in startup companies that have licensed technologies from the university if the framework allows for the expanded march-in rights...Given that 80% of Northeastern’s early-stage technologies are licensed to startup companies for de-risking before being acquired by larger corporations, the Draft Guidelines are particularly troubling to our research technology transfer enterprise.”



University of Minnesota

“University of Minnesota performs more than \$1B in research annually, in a broad range of fields spanning pharmaceutical compounds and other medical technologies to clean energy to food and agriculture, just to name a few...The draft interagency guidelines have a strong potential to chill investment in federally funded technologies across industry sectors.”



State University of New York System

“[T]he March-In Rights contained in the Draft Guidance...[r]un counter to the core intent of Bayh-Dole and would [inhibit] the advancement of life-changing innovation and technology commercialization supported by federal funding...[They will] dismantle and create barriers for public-private partnerships thereby negatively impacting the US, taxpayers and beneficiaries of ground-breaking research and discovery.”



Michigan State University

“Enactment of these guidelines will raise the level of uncertainty to such an extent to put a chill (and possibly a freeze) on investment in federally funded technologies, creating immediate job losses and negative economic impact in the state of Michigan and around the country, as well as limiting our citizens’ access to lifesaving drugs and transformative technologies.”



George Washington University

“The Draft Guidance could slow technological progress and economic growth by disincentivizing companies from licensing technologies from government-funded research. GW is proud that our university can play an active role in technological advancement and economic growth in partnership with government, other universities, our community, and industry.”



Colorado School of Mines

"Bayh-Dole revitalized the American R&D ecosystem by creating a cornucopia of new technologies, new products, and widely distributed wealth...Colleagues across academia, research organizations, the venture capital and corporate investment communities, and regional economic development organization concur that this innovation boon will come to an abrupt halt if march-in rights expand as contemplated in the Framework."



University of Illinois Chicago

"UIC believes the addition of pricing consideration is directly counter to Bayh-Dole's express intent of promoting innovation by fostering collaboration between the public and private sectors...The proposed guidance has significant potential to reduce licensing revenue that universities rely upon to foster the mission of promoting innovation for the public benefit."



Arizona State University Knowledge Enterprise

"The intent of Bayh-Dole and the conscious exclusion of price considerations as part of march-in decisioning are well documented...By introducing business uncertainty in pricing strategies, the Draft Guidelines threaten to destabilize the public-private partnerships required for successful commercialization of federally-funded research."



University of Colorado Boulder

"[F]rom 2018-2022, [CU Boulder's] commercialization of federally funded research discoveries contributed \$8 billion to the U.S. economy...We are concerned that the pricing elements of the Draft Framework would erode or eliminate similar future impact from CU Boulder and research institutions across our nation."



Tech Launch Arizona

"[T]he proposed guidelines put a cloud of uncertainty over all government-funded IP, which will turn away venture investors. What investor would want to risk millions or billions of dollars with the knowledge that someday down the road, the government might decide the market price for that technology is 'unreasonable'?"



Colorado State University STRATA

"[T]he Draft Guidelines will significantly reduce the chances federally funded inventions will be licensed...As technology transfer offices are keenly aware, fewer licenses translates to fewer new products and a less competitive marketplace and, as a result, higher, not lower, prices – if there are new products to price in the first place."



University of Kentucky Innovate

"Predictability in the rights to research results, including IP, is a cornerstone for incentivizing high-risk private sector investments in continued research and development work. Private sector investments are not only necessary to move federally funded research discoveries to market, they significantly outweigh the federal investment in the early research discoveries."

University of Louisville

“Under the new framework, large corporations could submit march-in petitions under the auspices of price...The result would be a chilling effect on the start-ups and small businesses collaborating with universities on basic and applied research, such as through the [SBIR/STTR] programs.”



University of Wisconsin-Milwaukee Research Foundation

“We want to emphasize that during licensing negotiations, patent holders – including UWMRF and our university inventors – have no control over the consumer price of our licensed products. We will therefore face the threat of our licenses being invalidated for reasons that are fully out of our hands.”



Dakota State University

“DSU is genuinely concerned that these Draft Guidelines would take a step backwards and significantly impair our ability to form partnerships with private industry for research which benefits our university, faculty, students, partners, the public, and the greater good.”



Association of American Universities (AAU)

“The use, or even the threat of using, march-in rights as an approach to regulate pricing of inventions emerging from university collaborations would create substantial uncertainty for private sector technology development partners and have a dramatically negative impact on the U.S. innovation ecosystem.”



Association of Public & Land-Grant Universities

“The consideration of price within march-in petitions will decrease industry’s willingness to partner with universities, especially small businesses...This comes at a time when universities are looking to increase collaboration with industry and to build the research and development talent pipeline of the future.”



Association of University Research Parks (AURP)

“We believe the framework violates the letter and spirit of the Bayh-Dole Act...Having federal funding agencies micromanage patent licensing from federally supported research will create substantial harm to the nation’s technology competitiveness.”



AUTM

“The Draft Guidelines will place U.S. academic and research institutions in the impossible position of requiring that their licensees agree to be in a continual state of uncertainty about whether the government will march-in based on alleged unreasonable pricing...Thus, the Draft Guidelines will significantly reduce the chances federally funded inventions will be licensed. This runs counter to the mission of university technology transfer.”



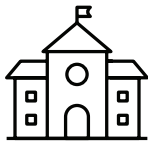
Council on Governmental Relations (COGR)

“We believe that the proposed Framework will cause irrevocable damage to the 40+ year success story of the Bayh-Dole Act, and our nation’s successfully tried and true technology transfer practices will be undermined. The Framework will harm the ability of research institutions to license patents vital to new products, processes, and technologies that start-up companies and others rely on to commercialize products and services that benefit our nation’s health, security, and economy.”



Association of American Medical Colleges

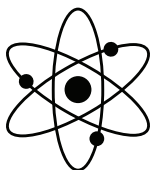
“The AAMC’s member institutions conduct a substantial amount of research that is directly subject to the Bayh-Dole Act, including more than 60 percent of the extramural research funded by the National Institutes of Health (NIH)...Implementation of the framework would make it less likely that private investors or industry would seek to license inventions by [these] U.S. academic medical centers and universities.”



American University Associations

“American innovation, economic competitiveness, and national economic security are best served by protecting and enhancing the robustness of the American academic research and technology transfer ecosystem in the U.S. Unnecessary, vague, and unwarranted changes to the Bayh-Dole Act and its implementation cannot be allowed to harm one of the greatest public policy achievements in U.S. history.”





Intellectual Property Academics

“Senators Bayh and Dole [made] clear that the inclusion of “reasonable price” as a criterion authorizing the march-in power is unconnected to the text or purpose of their statute. The proposed Guidance Framework...is an unprecedented assertion of agency power to control prices in private market transactions without a legal basis in the Bayh-Dole Act.”

Alden F. Abbott

Senior Research Fellow, Mercatus Center,
George Mason University

Jonathan M. Barnett

Torrey H. Webb Professor of Law, Gould
School of Law, University of Southern
California

The Honorable Susan G. Braden

Chief Judge, U.S. Court of Federal Claims
(2017-2018); Jurist in Residence, Center for
Intellectual Property x Innovation Policy,
Antonin Scalia Law School, George Mason
University

Daniel R. Cahoy

Robert G. and Caroline Schwartz Professor
of Business Law, Smeal College of Business,
Pennsylvania State University

The Honorable Ronald A. Cass

Vice-Chairman and Commissioner,
United States International Trade
Commission (1988-1990); Dean Emeritus,
Boston University School of Law

Richard A. Epstein

Laurence A. Tisch Professor of Law, New
York University School of Law; Peter and
Kirsten Bedford Senior Fellow, Hoover
Institution, Stanford University; James
Parker Hall Distinguished Service Professor
of Law Emeritus, University of Chicago Law
School

Chris Holman

Professor of Law, UMKC School of Law

Justin “Gus” Hurtwitz

Senior Fellow and Academic Director,
Center for Technology, Innovation &
Competition, University of Pennsylvania
Carey Law School

Keith N. Hylton

William Fairfield Warren Distinguished
Professor, Boston University School of Law

The Honorable Andrei Iancu

Under Secretary of Commerce for
Intellectual Property and Director of the
USPTO (2018-2021)

Layne Keele

Associate Professor of Law, Cumberland
School of Law, Samford University

Geoffrey A. Manne

President and Founder, International
Center for Law & Economics

Damon C. Matteo

Chairperson, Patent Public Advisory
Committee, United States Patent &
Trademark Office (2008-2013)

The Honorable Paul R. Michel

Chief Judge, United States Court of Appeals
for the Federal Circuit (2004-2010)

Emily Michiko Morris

David L. Brennan Endowed Chair and
Associate Professor of Law, University of
Akron School of Law

Adam Mossoff

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

The Honorable Kathleen M. O’Malley

Circuit Judge, United States Court of
Appeals for the Federal Circuit (2010-2022)

Kristen Osenga

Austin E. Owen Research Scholar and
Professor of Law, University of Richmond
School of Law

Peter Pitts

President and Co-Founder, Center for
Medicine in the Public Interest; Visiting
Professor, University of Paris School of
Medicine

Aurelien Portuese

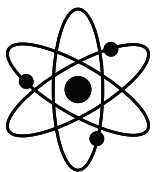
Research Professor and Founding Director
of the GW Competition & Innovation Lab,
The George Washington University

The Honorable Randall R. Rader

Chief Judge, United States Court of Appeals
for the Federal Circuit (2010-2014)

Ted Sichelman

Judith Keep Professor of Law and Herzog
Endowed Scholar, University of San Diego
School of Law



Scholars affiliated with C-IP²

“[T]here is little evidence or reason to believe that exercising march-in rights on patents to government-funded inventions alone would yield any influence over biopharmaceutical prices...the one result that does seem fairly predictable is that the using march-in rights to control drug prices would deter private industry from using publicly funded patents as foundations for new and socially beneficial biopharmaceuticals.”

Emily Michiko Morris

David L. Brennan Endowed Chair, The University of Akron School of Law; Senior Fellow in Life Sciences, Center for Intellectual Property x Innovation Policy (C-IP2), George Mason University Antonin Scalia Law School; Co-Director, Global Innovation Policy Institute

David Grossman

Senior Director, Technology Transfer & Industry Collaboration, George Mason University

Joshua Kresh

Interim Executive Director, Center for Intellectual Property x Innovation Policy (C-IP2), George Mason University Antonin Scalia Law School

Seán M. O'Connor

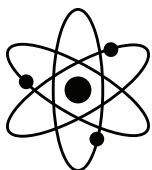
Professor of Law and Faculty Advisor, Center for Intellectual Property x Innovation Policy (C-IP2), George Mason University Antonin Scalia Law School

Kristen Jakobsen Osenga

Associate Dean for Academic Affairs and Austin E. Owen Research Scholar & Professor of Law, University of Richmond School of Law

Mark F. Schultz

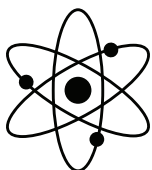
Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law and Director of the Intellectual Property & Technology Law Center, The University of Akron School of Law; Senior Scholar, Center for Intellectual Property x Innovation Policy (C-IP2), George Mason University Antonin Scalia Law School; Co-Director, Global Innovation Policy Institute, UAIP



Lou Berneman

Founding Partner Emeritus, Osage University Partners (OUP); Managing Director, University of Pennsylvania Center for Technology Transfer (1995-2005); President, AUTM (1999)

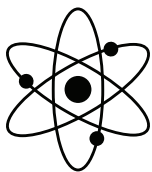
“The impact [of the framework] would reverberate through clinics, labs, lecture halls, and production lines nationwide. Venture financing that keeps promising startups alive would dry up. Public research spending would necessarily shift overseas.”



Wesley D. Blakeslee

Principal and Founder, Blakeslee LLC; Executive Director, Johns Hopkins Technology Transfer (2006-2014)

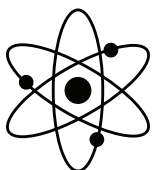
“Overall only about 25% of university inventions are ever licensed, and most universities spend more on their effort to license technologies than they receive in income from licenses...The Draft Guidelines would further reduce the number of inventions licensed from universities, and could well destroy the university technology transfer industry that has been a significant economic benefit to our country.”



Almesha Campbell

Assistant Vice President for Research and Economic Development, Jackson State University; Chair, AUTM

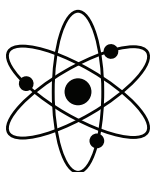
"I am deeply concerned about how this proposal could disrupt the carefully cultivated innovation ecosystem built over many years -- and ultimately undermine our endeavors to empower innovators from diverse backgrounds...[T]here is a real risk of impeding the progress of entrepreneurs, especially those from historically marginalized communities or with ties to HBCUs."



John Fraser

President, Burnside Development and Associates; Assistant Vice President, Florida State University Office of Commercialization (1996-2014); President, AUTM (2006)

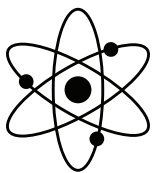
"The Bayh-Dole Act made the United States a leader in technology innovation, contributing billions of dollars to our economy and supporting millions of jobs... Adopting the proposal would amount to shooting ourselves in the foot while China's leaders watch and laugh."



Katharine Ku

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

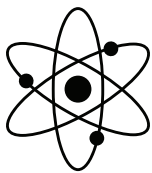
"While I was at Stanford, we licensed hundreds of new technologies that eventually brought life-changing technologies to the marketplace...It is extremely troubling to consider the chilling effect that the newly proposed framework would have on technology licensing nationwide."



Carol Mimura

Assistant Vice Chancellor for Intellectual Property & Industry Research Alliances (IPIRA), University of California, Berkeley

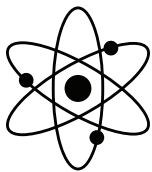
"As written, the new framework threatens the very essence of Bayh-Dole and the vital public-private partnerships it has nurtured -- which are foundational to America's success."



Lori Pressman

Consultant and Advisor, MIT Deshpande Center

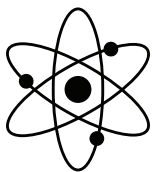
"Using price as a pretext to empower federal agencies to effectively terminate contracts negotiated in good faith by and between university licensors and their industry licensees will destabilize the public-private partnerships which drive our U.S. innovation ecosystem and strengthen U.S. global competitiveness."



Fred Reinhart

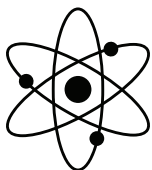
Senior Advisor for Technology Transfer, UMass Amherst (2014-2024); President, AUTM (2015)

"[T]his misguided framework...would gravely endanger our world-class system of public-private partnerships -- and the revolutionary inventions, products and public benefits arising from such collaboration."

**Kim Rosenfield**

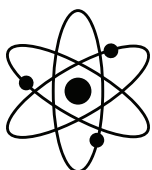
Director of Technology Transfer, Dartmouth College

"I have led technology transfer offices, started spin-off companies, and worked in industry and law firms. Based on my experience, I am certain the processes in the draft framework will suppress translational research and harm non-profits and small businesses."

**Jon Soderstrom**

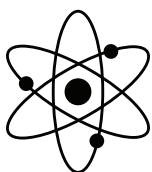
Managing Director, Yale University Office of Cooperative Research (1996-2021); President, AUTM (2008)

"The Bayh-Dole Act enables universities to earn substantial revenue for reinvestment into future research. Unfortunately, the framework proposed in December threatens this critical cashflow and will have a profound effect on the academia-to-private-sector pipeline that has benefited Americans over the past four decades."

**Chris Stoner**

Director of Intellectual Property & Commercial Agreements, Oregon State University

"Taken together, the Draft Guidance threatens through uncertainty and miscalculation to undermine the trust that industry partners have with their government and academic collaborators. If implemented, we risk returning to the days when Federal funding was to be avoided, and inventions arising from it withered on the vine, never to be commercialized for the benefit of the country."

**David Winwood**

Interim Associate Vice President, Wake Forest Innovations

"[Bayh-Dole] empowers our office, and tech transfer offices across the nation, to patent university scientists' federally funded inventions and license them to private companies for commercialization...The new march-in framework has injected grave uncertainty into this system."