



January 23, 2024

National Institute of Standards and Technology
101 Bureau Drive
Gaithersburg, MD 20899

RE: AUTM’s comments in response to NIST’s *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Federal Register/Vol. 88, No. 235/Dec. 8, 2023) (“Draft Guidance”)

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development of academic research that drives innovation and changes the world. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses, and government organizations around the globe. AUTM’s members are primarily from academic settings (67%).

AUTM members in academic settings are focused on advancing early-stage inventions and other technologies to the marketplace, primarily through licensing and further development with partners (i.e., implementers). Between 2013 and 2022 (the most recent decade for which we have data), our skilled professionals filed over 160,000 patents for academic inventors and almost 17,000 in 2022 alone. Between 2013 and 2022, our U.S. members negotiated over 70,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions, and in 2022 alone over 8,000 such license agreements. It is estimated that the American economy has received nearly \$2 trillion in benefits from the technology transfer carried out by AUTM members over the past 30+ years.

As such, AUTM members are at the very crossroads of innovation, taking ideas from the laboratory and helping move those ideas into commercialization so that all Americans can benefit from these discoveries. This is why understanding AUTM’s views on this issue is critical to retaining American leadership in innovation and technology.

Summary of AUTM's Comments

AUTM strongly believes in promoting public access to inventions and technologies created by universities, including drugs and other medical innovations for which the federal government funded some of the basic research. Many AUTM members work at or are affiliated with hospitals and clinics that treat patients, and as such, are empathetic to concerns about high drug prices. However, as explained in detail below, the use of march-in rights to lower drug prices is improper under the Bayh-Dole Act, would not in fact achieve lower drug prices, and would wreak havoc on innovation in medicine and countless other disciplines.

First, Senators Birch Bayh (D-IN) and Bob Dole (R-KS) themselves were crystal clear that the Bayh-Dole Act intentionally omitted drug pricing as a consideration for use of march-in rights:

“Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional....”

Senators Bayh and Dole's joint statements in a Washington Post article, 2002, available at https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=lk_inline_manual_11 (emphasis added).

And this omission was for good reason. When the NIH attempted to include pricing terms when it licensed federally funded inventions to industry partners (a necessary step for further testing and development of such inventions), the NIH quickly recognized its mistake and backtracked. This is because the result was fewer federally funded inventions being developed and made available to the public, which the NIH noted directly contradicts the purpose of the Bayh-Dole Act. In addition to Senators Bayh and Dole and the NIH, both Democratic and Republican Administrations, other federal agencies, former judges, former government officials, and scholars have concluded that the Bayh-Dole Act does not allow the use of march-in based on drug pricing. Any such use of march-in rights would have to be authorized by Congress via separate legislation or amendments to the Bayh-Dole Act. For this reason, AUTM's comments do not address the specific questions posed by NIST in the Request for Information since the questions are based on a false pretense.

Second, U.S. taxpayers and the U.S. economy have greatly benefited from the public-private partnerships enabled by the Bayh-Dole Act. Before Bayh-Dole, 33,000 patents that were developed at least in part based on federal funding sat on the shelf without any investors, startups, or companies taking an interest in developing them into products and services that could benefit Americans. 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 backwards. By making it less likely that industry will license and devote time, effort, and resources to developing federally funded innovation, the Draft Guidelines will result in fewer products and less market competition—which equates to higher (not lower) prices. Moreover, most drug innovations rely on patents that were not federally funded or require access to other types of intellectual property rights (e.g., know-how); therefore, march-in would not be an available option even if the Draft Guidelines were implemented as is.

Finally, even if march-in rights could be used for pricing purposes under the Bayh-Dole Act (they cannot), and even if march-in could lower drug prices (it will not), the adverse effects on innovation and access to drugs and other technologies will be devastating. Before Bayh-Dole and during the NIH's ill-fated experiment with pricing requirements, even a small amount of federal funding "contaminated" academic innovations such that investors and industry partners avoided even attempting to commercialize such federally funded inventions. Under the Draft Guidelines, even promising medical innovations will wither in academic research laboratories because investors and shareholders will be unwilling to expend millions of dollars and years of effort for the testing and approvals that are necessary to bridge the gap between the research laboratory and the marketplace because of the expanded risk that the federal government will march in under undefined pricing models and render all of that investment valueless. Fewer medical innovations will be advanced through public private partnerships and, as a result fewer, potentially lifesaving solutions, will be available on the market, and Americans will suffer as a result. Furthermore, these Draft Guidelines will affect not just federally-funded **medical innovations** but innovations from **every discipline**, drastically inhibiting the entire American innovation ecosystem.

Let us turn now to those three essential points with additional information.

I. The Draft Guidelines do not align with the letter and intent of the Bayh-Dole Act.

A. The Draft Guidelines act to amend and distort the Bayh-Dole Act.

The Draft Guidelines are fundamentally flawed as the framework presupposes that the pricing of a product is relevant to the analysis as to whether a federal agency can and should exercise the Bayh-Dole Act's march-in provision. This inappropriate presumption acts to amend the Bayh-Dole Act and directly conflicts with the U.S. government's very own interpretation and application of the march-in provision over the last 43 years. Thus, before any guidelines are provided as to *when and how* product pricing may be considered, NIST must first establish its statutory basis for newly empowering government agencies to use the march-in provision of the Bayh-Dole Act to dictate a product's price in the marketplace.

NIST's Draft Guidelines attempt to broaden the circumstances under which the following two criteria under 35 U.S.C. § 203 may be used to exercise the march-in provision of the Bayh-Dole Act:

- **Criterion 1:** *"action is necessary because the contractor or assignee* has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use"*
- **Criterion 2:** *"action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees"*

Despite the fact that neither of these criteria refer to a product's marketplace pricing or terms as a basis for an agency to exercise its march-in rights, the Draft Guidelines state in relation to Criterion 1: *"Whether action may be needed ... may include consideration of ... the reasonableness of the price and other terms at which the product is made available to end-users"*, and in relation to Criterion 2: *"... the agency is not limited to reviewing price increases; the initial price may also*

be considered". These statements contradict the plain language of the Bayh-Dole Act, which is clear that the analysis is to be focused on the product's *availability* in the marketplace.

B. The Draft Guidelines directly conflict with the intent – and 43+ years of the U.S. government's interpretation – of the Bayh-Dole Act.

Pricing has never been used as a basis for an agency exercising the march-in provision. In fact, Senators Bayh and Dole and every agency presented with this question have expressly and specifically refuted that the march-in provision may be used to dictate a product's price in the marketplace. Also, the interpretation and application of 35 U.S.C. § 203 have consistently concluded that the march-in provision was never intended to be used as a tool for controlling drug prices. For example, see the following consistent, historical statements made by Senators Birch Bayh and Bob Dole, the founding fathers of the Bayh-Dole Act:

- *"Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research. . . . The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."* See Senators Bayh and Dole's joint statements in a Washington Post article, 2002, available at https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=ik_inline_manual_11 (emphasis added).
- *"NIH itself has found that price controls are not contemplated by Bayh-Dole. Under pressure in 1989, NIH placed a provision in its intramural collaborations with industry that resulting inventions must demonstrate 'a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.' When industry collaborations began evaporating, and NIH explored the reasons and found: Both NIH and its industry counterparts came to the realization that this policy [to include a "reasonable pricing" provision in NIH licenses and CRADAs] had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act."*
- See Senator Bayh's Statements to the NIH in response to the NIH's invitation to comment on Congress' intent when it enacted the Bayh-Dole Act, 2004, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf> (emphasis added).

Similarly, the NIH, Department of Health and Human Services (HHS), and the Department of the Army have made repeatedly and consistently clear that product pricing is not a consideration under the march-in provision of the Bayh-Dole Act:

- *“Viability and success in the private sector is appropriately governed by the marketplace.... It would be inappropriate for the NIH, a public health agency, to exercise its authorities under the Bayh-Dole Act to procure for CellPro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to CellPro's management and the marketplace.”* See NIH’s Determination In the Case of Petition of CellPro, Inc., 1997, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf> (emphasis added).
- *“Drug Pricing: ... NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.”* See NIH’s Determination In the Case of Petition of Norvir, 2004, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf> (emphasis added).
- *“[T]he NIH believes that the extraordinary remedy of march-in is not an appropriate means for controlling prices. . . .”* See NIH’s Determination In the Case of Petition of Xalatan, 2004, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf> (emphasis added).
- *“As stated in previous march-in considerations, the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities.”* See NIH’s Determination In the Case of Petition of Norvir, 2013, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf> (emphasis added).
- *“NIH is sensitive to the impact of pricing on access to Xtandi® by patients and continues to believe the broader issue of drug pricing would be most appropriately addressed through legislative channels to develop remedies that have implications for the cost of healthcare overall.”* See NIH’s letter in response to Knowledge Ecology International’s appeal to NIH, HHS, and Department of the Army regarding the pricing of Xtandi, 2017, available at <https://bayhdolecoalition.org/wp-content/uploads/2023/05/Francis-Collins-response-Xtandi-Appeal-7June2017.pdf> (emphasis added).
- *“NIH’s analyses in response to the petition request have found Xtandi to be widely available to the public on the market. ... [P]ractical application is evidenced by the ‘manufacture, practice, and operation’ of the invention and the invention’s ‘availability to and use by the public. . . . Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs.”* See NIH’s letter in response to Knowledge Ecology International’s appeal to NIH and HHS regarding the pricing of Xtandi, 2023, available at <https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf> (emphasis added).

In fact, in September 2023, twenty-five highly esteemed former judges, former government officials, and scholars who are experts in patent law and/or healthcare policy recently sent a letter to members of Congress expressing their concerns about lobbying efforts being made for the government to leverage laws, including the Bayh-Dole Act, to impose price controls on patented drugs. They too agree that the march-in provision of the Bayh-Dole Act does not authorize the federal government to impose price controls on drugs:

- *“Neither the Bayh-Dole Act nor § 1498 are price-control statutes, and thus they do not authorize the federal government to impose price controls on patents. This is clear by their plain legal text, as well as by their consistent interpretation by courts and agencies.”*
- *“The statutory text does not support this argument for imposing an unprecedented policy of price controls on patented drugs produced by private companies and sold to private patients in the healthcare market.”*
- *“First, the Bayh-Dole Act expressly identifies several general policies and objectives. It does not state that patented innovations should be available at reasonable prices. Second, the specific march-in provision in the Bayh-Dole Act does not state that ‘prices’ or ‘reasonable prices’ are a condition triggering the march-in power. This provision specifies four conditions for when an agency is authorized to invoke the march-in power. All four represent different situations by which a product or service is unavailable in the marketplace.”*

See September 28, 2023 letter to Chairman Sanders, Ranking Member Cassidy, Chairman Smith, and Ranking Member Neal (available at <https://sciencecenter.org/uploads/documents/Letter-to-Congress-Bayh-Dole-and-1498-Not-Basis-for-Price-Controls-on-Drugs94.pdf>). See also Hon. Paul R. Michel’s (Chief Judge (ret.), U.S. Court of Appeals for the Federal Circuit) OpEd: “The Law is Clear: There’s No Legal Authority to Control Prices Via Bayh-Dole” (available at: <https://www.realclearpolicy.com/articles/2022/08/02/the-law-is-clear-theres-no-legal-authority-to-control-prices-via-bayh-dole-845601.html>) (“The government has no authority to set prescription drug prices under existing law. The claim that it does is facially absurd.”).

For at least the above reasons, AUTM respectfully requests that NIST revise the Draft Guidelines to make expressly clear that a product’s pricing and terms in the marketplace *is not* a viable basis for pursuing and/or granting a march-in petition.

II. Implementation of the Draft Guidelines will do little to nothing to reduce drug costs; in fact, it will likely have the opposite effect.

A. U.S. taxpayers greatly benefit from having strong, robust public-private partnerships.

Strong, robust partnerships between academic research institutions and industry are essential for ensuring U.S. taxpayers benefit from federal support of scientific research. These partnerships (often in the form of collaborations or license agreements of federally funded inventions) translate nascent innovations from an academic lab to industry for further development so that new products and services can reach the marketplace for public benefit. Thanks to tech transfer, this ever-

evolving group of new products and services promotes competition, lowers prices, and helps the U.S. remain competitive in the global economy. We count on these products to help us take better care of ourselves and our planet.

Prior to the Bayh-Dole Act, 33,000 patents (!) were just sitting on the shelf and not being licensed or developed. As a result, many useful innovations remained undeveloped and unrealized – the U.S. taxpayers lost the opportunity to benefit from therapies and technologies and the U.S. economy missed out on a lot of potential economic growth. Since then, all major universities have built expert patenting, licensing and technology transfer teams that facilitate the transfer of federally supported inventions from their academic labs to industry.

The genius of Bayh-Dole is that it provides a legal infrastructure for organizations with complementary skills and cultures to work together. Academic investigators often try ideas that do not work. In contrast, industry must focus on manufacturing and distribution of quality-controlled products at scale. This crucial handshake and handoff benefit not only the individuals involved and their respective organizations, but also U.S. taxpayers for at least the following reasons:

- Public-private partnerships increase options for patients. Taxpayers and their healthcare providers often try *a variety of products* to find the best option with the desired therapeutic result and a manageable side effect profile. Robust public-private partnerships are crucial for ensuring patients continue to have increased options.
- Public-private partnerships increase the U.S.'s global competitiveness. Industries maintain their position by adding new products and by replacing their older products with newer ones. The U.S. cannot compete globally in healthcare, *or in any other industry*, without a pipeline of new products and services.
- Public-private partnerships incentivize industry to cost share and shoulder product liability burdens. Industry shoulders the lion's share of the burden of funding and performing the applied research and experimental development needed to bring the products to market. Industry must make, sell, and in some cases, monitor, maintain and service safe products for the benefit of all. If industry steps away, taxpayers end up paying for more of the translational work and will need to engage with industry later anyway for manufacturing, distribution and if needed, servicing.

B. The Draft Guidelines will dismantle and create barriers for public-private partnerships, and the U.S.'s economy, taxpayers and patients will suffer as a result.

Transferring federally funded inventions from academic labs to industry is already a complex and challenging process for all, especially the implementers. Adding encumbrances to this process will tip the risk of failure/reward of success analysis for entrepreneurs and investors away from federally funded inventions. Thus, less human and financial capital will be invested in startups and other companies developing federally funded inventions, and this impact will be experienced across all technology sectors (e.g., cleantech, medical devices, manufacturing, etc.).

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 when it is time to market a product. Universities rarely have more than one entity interested in taking a license. And that one entity (~70% of the time) is typically a small agile company or a startup formed by an entrepreneur who sees a diamond in the rough and is willing (even eager) to take on the risk of failure, and put in the significant uncompensated time and effort necessary to attract sufficient investment, to develop the technology so that it can ultimately find its way to the commercial market.

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 – and more importantly the overall intent of the Bayh-Dole Act which states in 35 U.S.C. 200:

“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts...”

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.

Companies may, as an afterthought, add a nonexclusive license to federally funded technology to their intellectual property portfolio. These licenses typically have little development obligations in them, as their implementer partners will rely on other technologies and other competitive wedges to help bring products to market. Note that 35 U.S.C. 203 itself allows the marching-in Federal agency to grant *exclusive licenses*, showing a tacit understanding of the importance of such licenses.

SBIR funds will be similarly tarred. Currently, tech transfer offices encourage their entrepreneurially inclined inventors to sign up for the NSF I-Corps program and to apply for SBIR funds for their startups. Mentors will now have to warn company founders of the potential hazard of taking government money.

C. The Draft Guidelines are akin to proactively running a bulldozer over a fruitful garden out of fear of weeds, when there are few (if any) weeds to pull.

The march-in provision does not reach non-federally supported proprietary know-how, manufacturing expertise, or the commercialized product itself. The march-in provision provides the government the right to march-in solely with respect to patents filed on subject inventions. The commercializing entity will have no obligation to grant any right or license to other IP and/or know-how in its portfolio that may be needed to successfully commercialize a drug. As is the case for iPhones and cars, there are typically many kinds and pieces of IP associated with pharmaceutical products.

For example, Pharma’s incredible success in responding to the COVID pandemic is largely credited to pharma companies providing access to the *manufacturing know-how* needed to bring the COVID vaccines and drugs to market. See <https://www.ifpma.org/areas-of-work/fostering-innovation/technology-transfer/>, which describes transferring manufacturing expertise:

- *“In the first year of COVID-19 vaccines, there were over 380 manufacturing and production deals [emphasis added] worldwide. Around 75% of these involved some sort of technology transfer.”*
- *“For example, Pfizer and BioNTech successfully developed a promising mRNA vaccine for use against COVID-19 in March 2020, taking less than a year. Moderna and Lonza joined forces to support drug substance manufacturing [emphasis added] for the global supply chain of their COVID-19 vaccine.”*
- *“With COVID-19 treatments, biopharmaceutical companies have entered 138 voluntary manufacturing arrangements [emphasis added] with partners across the world. Over 92% collaborations involved technology transfer, and 43 of these came within the first year of the pandemic.”*

Indeed, NIH has repeatedly acknowledged that the march-in provision does not apply to non-federally supported tangible materials, unpatented technical know-how, or the product itself. For example, see:

- *“The march-in provision is, however, only directed to Bayh-Dole Act subject inventions and not to tangible materials or unpatented technical know-how. NIH’s determination decision is directed solely to use of its march-in authority to the subject invention.” NIH rejection of petition to march in on Fabrazyme 12/1/2010, available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf>.*
- *“Pfizer holds at least three other U.S. patents that cover certain aspects of the marketed compounds and methods and are not subject inventions within the meaning of the term as defined in 35 U.S.C. 201(e). These inventions would not be subject to the Government march-in authority.” See NIH’s rejection of petition to march in on Xalatan 9/17/2004, available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf>.*
- *“By law, the funding agency retains residual interest in grant- and contract-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes. This right does not extend to a licensee’s final commercial product, nor does it extend to proprietary information or trade secrets that belong to another party and may be incorporated in the final product.” See NIH’s Response to the Conference Report Request for A Plan to Ensure Taxpayers’ Interests are Protected, July 2001, available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf>.*

The Bayh-Dole Act’s march-in provision would apply only to a small fraction of commercialized drugs. In addition to the inability of the government to reach proprietary know-how, manufacturing expertise, and tangible materials, even if the government wanted to march-in, there would be very few drugs with respect to which it could. A 2023 study found:

- *“The overwhelming majority of drugs in our cohort have no associated patents with a GIS [Government Interest Statement]. Only 5 of the 361 novel therapies in the cohort include a GIS in all MoA [Mechanism of Action] and CoM [Composition of Matter] patents covering the inventions in the medicine. Because march-in rights apply to patents, not products, exercising march-in would serve no purpose unless every invention and every patent covering a drug is subject to Bayh Dole. Such drugs are exceedingly rare.”*
- *“99% of the therapies in our cohort cannot be marched-in upon, as the key patents studied do not cover the entire asset’s intellectual property.”*
- *“Exercising march-in rights as a cost control would risk chilling the entire innovation ecosystem for little to no gain”*

See “March-in rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents,” available at https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

D. What constitutes a “reasonable price” is difficult to define, is subjective, and will send investors and industry running away.

There is no statutory definition for what constitutes (or how to determine) a “reasonable price.” Senator Bayh said Congress would have defined it if it thought that it was supposed to be part of the statute. “Reasonable” is a very subjective term, especially when a patent alone virtually never covers, in its entirety, the product sold in commerce. Determining “reasonable” will require fact intensive processes and will be expensive; agencies themselves are not equipped to make this determination. Who decides what expenses are considered? Will each party have to retain an expert? If so, who should pay for this?

This is anything but a short cut to getting the drug distributed to a broader population. Unpredictable and plausible side effects can include pharmaceutical companies increasing prices to make up for additional risk in their ecosystem and adding a discussion of march-in to their SEC filings as a risk factor. Destabilizing this long established, successful, fruitful bipartisan law will result in fewer federally funded inventions reaching the marketplace, reduce the impact that federally funded research has on the U.S. economy, cost taxpayers time and money, reduce consumer choices, demoralize a generation of entrepreneurs, and have an overall detrimental effect on U.S. competitiveness. Run, don’t walk, from march-in.

III. These Draft Guidelines will chill investment in federally funded technologies and drive industry to sever its academic collaborations out of fear of being “contaminated by federal funding.”

While the march-in provision when given a cursory glance may seem like an attractive solution for fixing a specific price for a single drug, if exercised the negative ramifications will quickly and broadly spread like poison to the rest of the innovation ecosystem causing investment in federally funded technologies and broad fruitful academic-industry collaborations to quickly dry up. The intent of the Bayh-Dole Act is to increase the U.S.’s global competitiveness through encouraging investment in small businesses and startups developing federally funded technologies and fostering collaborations between academia and industry, not to control U.S. drug prices. The Bayh-Dole Act

has proven to have enormously positive impacts on the U.S. economy and patients' lives, and the Draft Guidelines will bring this incredible success to an abrupt halt.

A. The Draft Guidelines will severely chill private investment in federally funded technologies across industry sectors.

Private investments in small businesses and startups developing federally funded technologies are crucial to maintaining the health and robustness of the U.S. economy. Opening the door for a startup's competitors to leverage the Bayh-Dole Act's march-in provision as a sword to keep a federally funded invention out of the marketplace will chill investment in federally funded technologies. *Investors have options* – the fear of government intervention in its ability to recoup its investment will grossly outweigh *any* possible upside.

The National Academies of Sciences, Engineering, and Medicine recently warned of the long-term disastrous effects that marching in would have on the U.S.'s innovation ecosystem:

- *“Marching in, if implemented, would chill for many years, perhaps for decades, the inclination to invest in research and development and to create new biotechnology companies.”* See the National Academies' 2018 Study Report titled “Making Medicines Affordable, A National Imperative”, available at: <https://nap.nationalacademies.org/catalog/24946/making-medicines-affordable-a-national-imperative> (emphasis added).

The NIH itself has defined the march-in provision as an “extraordinary remedy” and appreciated the devastating repercussions that would be generated in the marketplace across technology sectors if the NIH used the Bay-Dole Act to control prices:

- *“In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.”* See NIH's rejection of petition to Norvir, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf>.

B. The Draft Guidelines will drive industry to sever its collaborations with academic researchers, inflicting substantial damage on the U.S. economy and patients.

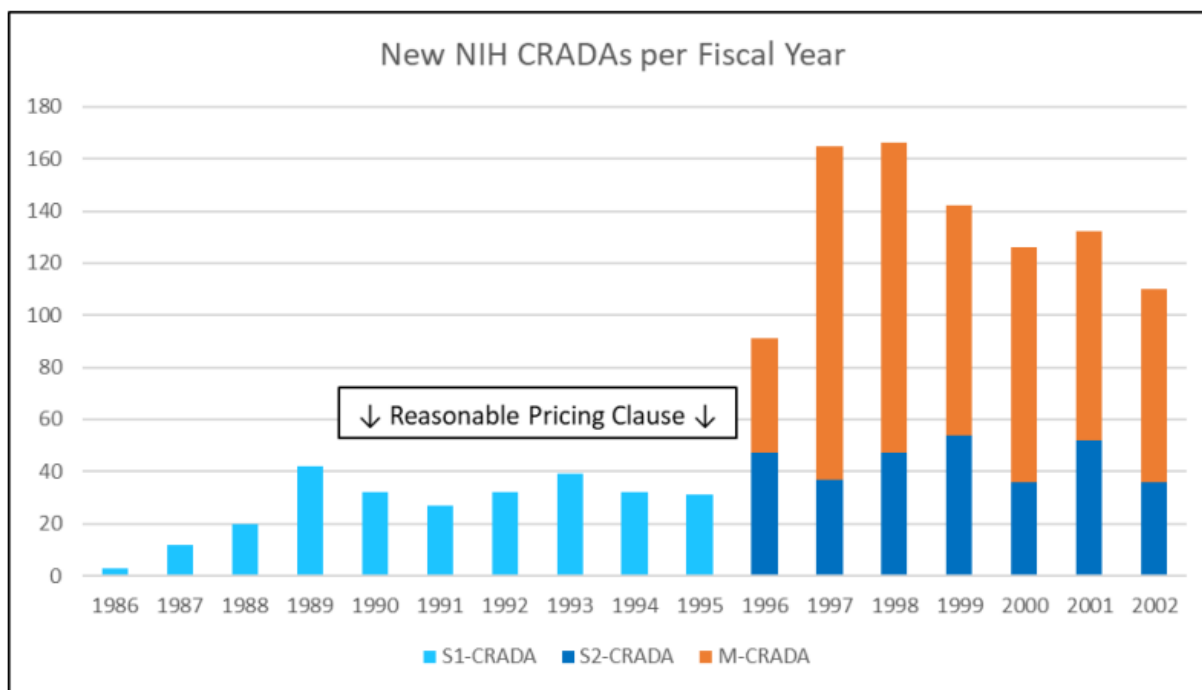
It is very well established that the Bayh-Dole Act has been instrumental in building robust bridges between academic research institutions and industry and, as a result, the public and patients have greatly benefited:

- *“The [Bayh-Dole] act motivated collaboration between academia and industry, that in turn has helped enhance the transition of products from the laboratory to the public and resulted in better treatment options for patients.”* See the National Academies' 2018 Study Report titled “Making Medicines Affordable, A National Imperative,” available at:

<https://nap.nationalacademies.org/catalog/24946/making-medicines-affordable-a-national-imperative> (emphasis added).

The NIH has also painfully learned firsthand through (very expensive and disastrous) trial and error that “reasonable pricing” clauses will drive industry to close its doors to federally funded collaborations. In 1989, in reaction to pressure from Congress about drug prices, the NIH adopted a policy that required NIH’s patent licenses and Cooperative R&D Agreements (CRADAs) to include a “reasonable pricing” clause. However, just a few years later, NIH’s Director Harold Varmus, M.D. publicly retracted this policy on the basis that it was driving industry away, which in effect was hurting patients:

- “An extensive review of this matter over the past year indicated that the *pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public*,” said Dr. Varmus. “*Eliminating the clause will promote research that can enhance the health of the American people*,” he said. See NIH News, April 11, 1995, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf> (emphasis added).
- Below is graph included in “The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995” based on an analysis of NIH CRADAs by Mark L Rohrbaugh, PhD, JD, and Jennifer Wong, PhD, Office of Science Policy, National Institutes of Health, published November 15, 2021, available at <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%2021%20FINAL.pdf>.



In 2001, the NIH recounted how it has learned from this negative experience in its response to a request from Congress for “A Plan to Ensure Taxpayers’ Interests are Protected”:

- *“Shortly after the policy of ‘reasonable pricing’ was introduced, industry objected to it, considering it a form of price control. Many companies withdrew from any further interaction with NIH because of this stipulation. Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.”*
- *“The consequences of NIH’s ‘reasonable pricing clause’ policy can be seen in the relatively flat growth rate of CRADAs that occurred between 1990 and 1994, and the subsequent rebound in CRADAs following revocation of the policy (see Appendix 4).”*

See “A Plan to Ensure Taxpayers’ Interests are Protected”, 2001, available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf> (emphasis added).

There is no need to repeat history merely to learn the same lesson -- the fear of government intervention in pricing strategies will discourage the willingness of companies to engage in partnerships with academic institutions and to participate in other public-private partnerships. Such hesitancy will impede the translation of groundbreaking research into tangible products and services, ultimately dismantling the Bayh-Dole Act’s established success in fostering innovation through effective collaboration between academia and industry. The private sector will no longer view its robust partnerships with universities as mutually beneficial, but rather as a poison pill that could endanger their broader product lines and IP portfolios.

C. The Draft Guidelines will compel industry to shun federally funded technologies and they will wither on the vine, just like they did in the pre-Bayh-Dole days.

The investment risk/reward analysis of the nascent inventions coming out of academic labs is already too delicate. Academic technology transfer offices work incredibly hard to find qualified suitors for these technologies. The corporate sector simply will not develop federally funded technologies if it means that there is a risk that the government could step in and remove its ability to recoup its investment. In fact, company leaders may believe they have a *fiduciary duty to their shareholders* to shun federally funded inventions.

Unfortunately, the impact of these Draft Guidelines will be that federally funded inventions will languish on the shelf and bring the ecosystem back to the pre-Bayh-Dole Act days. There is no doubt – as history has taught us – there will be fewer drugs available to patients, less competition in the marketplace to serve as checks and balances on drug prices, and no longer any new federally supported drugs available for the government to march-in on. Preserving the enormous benefits that the Bayh-Dole Act has had on public welfare and the U.S. economy is crucial to the U.S. maintaining its lead among academic research institutions and industry and the Draft Guidelines threaten that continued success.

Conclusion

In its Request For Information, NIST asks five questions to help it shape future usage of march-in rights. AUTM has determined that, given the underlying premise in all of NIST’s questions is incorrect (i.e., that the Draft Guideline’s expansion of march-in rights is legal and will lower drug prices without harming American innovation), AUTM will not attempt to improve the fatally-

flawed process proposed by NIST.

Before upending 40+ years of legislation, we encourage NIST/the Administration to fully engage stakeholders (beyond the limited 60-day comment period provided) and commission a study on the impact of these Draft Guidelines on U.S. innovation, the U.S. economy, and the public good.

Congress has acted directly to control drug pricing twice in the past several years. It has capped prices for some drugs and will allow Medicare to negotiate pricing with manufacturers. While we take no position on those actions, they demonstrate that government action on drug pricing can take place without rewriting forty-plus years of one of the most successful pieces of legislation in history – the Bayh-Dole Act.

We urge that NIST and the Department of Commerce to study the potential devastating impact these changes could have on the U.S. innovation ecosystem, economy, and public before even considering rewriting this landmark law.

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