January 17, 2024

Via Electronic Submission
Laurie E. Locascio
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Director Locascio,

On behalf of the Bayh-Dole Coalition -- a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act -- I urge you to withdraw the recently published Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. The proposed framework violates both the letter and spirit of the Bayh-Dole Act and would cause untold harm to American companies, workers, and consumers if implemented.

I've spent the majority of my professional life helping to enact, implement, and defend the Bayh-Dole Act. As the former Senate Judiciary Committee staffer to Senator Birch Bayh (D-IN), I was present at the inception of the law, put together its hearings, wrote the report of the Senate Judiciary Committee, staffed its passage through Congress, and worked with Senator Bob Dole (R-KS) to move the oversight authority to the Department of Commerce.

After doing so, I served as the Director of the Office of Technology Commercialization at the Department of Commerce and worked with Secretary Malcolm Baldrige to form the Interagency Committee on Technology Transfer, which I ran for many years. I now serve as the executive director of the Bayh-Dole Coalition, which aims to inform policymakers and the American public of the law's many benefits.

Simply put, the framework would irreparably undermine one of the most successful laws in American history. It attempts to inject a concept into the law that was expressly rejected by its authors and voted down repeatedly in Congress, including by then-Senator Joe Biden.[1]

The draft framework is being justified as a weapon to lower drug costs. It is no such thing. It Is unlikely to have much, if any, impact on drug costs. What it will do is turn the Bayh-Dole Act and the innovation that it spurs across every other industry on its head.

As the bill's official name -- the University and Small Business Patent Procedures Act -- implies, one main objective was to encourage entrepreneurial small companies to accept government research contracts and to license federally-funded inventions. That effort was remarkably successful. Bayh-Dole is the foundation of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs touted by the Small Business Administration as "America's Seed Fund."[2][3] Small companies license more than 70% of academic patents.[4] The proposed framework puts all that in jeopardy.

The guidelines return us to the pre-Bayh-Dole days when federal funding was toxic. Under the guidelines, anyone founding a start-up company or licensing a federally-funded invention has a target on their back as competitors, the unscrupulous, and even foreign adversaries can file march-in petitions objecting to the price of a successfully developed product based on a government-supported invention. The issuance of the guidelines is already casting a cloud over public/private sector partnerships at a time when we need them to promote public welfare by solving pressing problems, growing our economy, and meeting the threat posed by rivals such as China to eclipse our lead in the technologies that will determine who leads the 21st century.

The guidelines should immediately be withdrawn.

Just a cursory glance at the proposal reveals its serious flaws. The document begins by asking whether "its application will both fulfill the purpose of march-in rights and uphold the policy and objectives of the Bayh-Dole Act." It would do neither.

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[1] https://www.govtrack.us/congress/votes/96-1980/s592
https://www.senate.gov/legislative/LIS/roll_call_votes/vote1062/vote_106_2_00168.htm

[2] https://www.sbir.gov/about

[3] https://seedfund.nsf.gov/

[4] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf

Twenty years after its enactment, opponents of the law claimed they had discovered a hidden meaning in the march-in rights clause. They alleged that it gave the government the authority to march in if a successfully-developed product wasn't reasonably priced.[5] That claim was immediately rejected by Senators Bayh and Dole, who wrote to The Washington Post:

> "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."[6]

When the critics of Bayh-Dole began filing march-in petitions based on the flawed theory, the National Institutes of Health (NIH) held its only public meeting on the issue. Senator Bayh was the first speaker. He demonstrated how the petitioners were deliberately distorting the Senate Judiciary Committee report on Bayh-Dole, which I wrote. Petitioners claimed the report endorsed the concept of using march-in rights to control prices. But in reality, they were quoting and combining two unrelated portions of the report -- portions that had nothing to do with march-in rights -- out of context to create a misleading picture of what the law permits.

Senator Bayh concluded by saying:

> "If Congress does decide to amend Bayh-Dole someone must clearly define what is a 'reasonable price.' Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that 'bet the farm' on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover.
>
> "What will happen to the start-up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What

[5] http://www.cptech.org/ip/health/bd/arnodavis012001.pdf

[6] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

> evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH."[7]

Because the law does not mention pricing as a march-in trigger, NIST lacks the authority to direct federal agencies "to further assess whether march-in is warranted" when "the contractor or licensee has commercialized the product, **but the price** or other terms **at which the product is offered to the public are not reasonable."**

The framework also misinterprets other sections of the law. For instance, in the "Definitions" section of the framework, NIST fails to note that "practical application" in the march-in section **only applies to the contractor** (normally the academic institution making the invention), **not the licensee** (which sets the price).[8]

Similarly, the statutory definition of practical application -- that the benefits of the product are "available to the public on reasonable terms" -- **clearly refers to the terms of the license, not to the price of a product**. If Congress had intended this clause to apply to the price of a product, it would have included the licensee in this trigger, as in the other three triggers.

The framework contradicts more than 40 years of precedent set by both Democratic and Republican administrations. Every administration that has considered a march-in petition on the basis of price since Bayh-Dole's enactment has rightfully rejected it, including the Biden administration just last spring.

Here's what NIH said in March 2023 while rejecting the sixth march-in petition for the prostate cancer drug, Xtandi (which was denied three times by the Obama-Biden administration):

> "NIH's analyses in response to the petition request have found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH has determined that initiation of a march-in proceeding is not warranted in this case. This decision is consistent

[7] https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf, page 5

[8] https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the

> with NIH's determination in 2016, in which KEI and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense march-in based on the price of Xtandi, but each declined. In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013), and Xalatan (2004), practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public…." Astellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021. **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. NIH has reviewed the information submitted by the current petitioners, which is substantially the same as that submitted in 2016, and reached the conclusion that Xtandi is still widely available as a prescription drug.[9]"

Note that NIH said that the University of California, not the licensee Astellas, had met its obligation under the statute.

Notably, in the "Definitions" section, the framework does not list "reasonable pricing" as a term defined in the law -- for good reason.[10] As Senators Bayh and Dole noted, this term has no standing under their statute. But under the pending guidelines, that concept becomes the pivot point of the law. This is already causing venture capitalists and potential licensees to again be wary of commercializing federally-funded inventions, as they were before Bayh-Dole.[11]

In one stroke, the framework would turn the law on its head.

The request for information asks whether use of the new standards will "have wider implications," "unintended consequences," cause prospective licensees to "avoid future collaborations with federally-funded research institutions, organizations, small businesses,

[9] https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-21march2023.pdf

[10] https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the

[11] https://www.biospace.com/article/jpm-2024-on-the-ground-in-san-francisco/

and other investigators," or "send a clear signal to industry so other contractors and licensees can rely on that agency's prior decisions to avoid similar issues in the future."[12]

History proves that it would.

Once before, in 1989, an administration bowed to political pressure to include "reasonable pricing" in its technology transfer programs. NIH adopted that term in its exclusive licenses and cooperative R&D agreements (CRADAs) until the mid-1990s. The result wasn't a golden age of cheaper drugs. Instead, industry walked away from such partnerships.

Here's what then-NIH Director Harold Varmus said as he ended this disastrous experiment in 1995:

> "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.
>
> "Over the past year, NIH analyzed its CRADA activities including the scope of scientific research under CRADAs, the resources brought to the collaborations by NIH scientist and industry, intellectual property arising from the CRADAs, and the effect of the "reasonable pricing" clause on products developed under CRADAs. NIH also sought advice from scientists, patient advocacy groups, and representatives of academic institutions and industry on how the clause has affected research and development collaborations and the advancement of scientific discoveries."[13]

In its statement announcing the removal of this "reasonable pricing" clause from its exclusive licenses and CRADAs, NIH included this astute observation: "**No law or regulation requires or expressly authorizes the inclusion of the 'reasonable pricing' clause.**"[14]

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[12] https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the

[13] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[14] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

That was true then, and it's true now. There is no statutory authority for this misguided effort. When attempts were made to reinstate the failed "reasonable pricing" experiment by statute, they were uniformly rejected by Congress. One of those wisely opposing this misguided effort was then-Senator Joe Biden.[15]

Ironically, even the draft framework implicitly acknowledges that misusing the march-in provision for price controls will have little, if any, impact on lowering drug costs -- the purported reason for this exercise. For example, the guidelines ask agencies to consider: "What intellectual property, in total, is needed to make the product in question? Does making the product or performing the service also require use of intellectual property that was not government funded and is not subject to Bayh-Dole?"

When it comes to pharmaceuticals, that question is easy to answer. A new study looked at 361 novel, non-generic, small and large molecule drugs listed in the FDA's Orange and Purple Books between 2011 and 2020, and found that:

> "92% of the therapies in our cohort have no mechanism of action or composition of matter patents with a government interest statement or federally funded co-development program in connection to them.
>
> "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. There are only 5 out of 361 pharmaceutical products in which all available MoA (mechanism of action) and CoM (composition of matter) patents include a government interest statement and could be subject to march-in rights."[16]

The draft framework will do effectively nothing to lower drug costs, but it will lower American innovation. Bayh-Dole inventions are essential in meeting our energy, environmental, food production, and other needs, as it is a uniform policy for all federal agencies, not just NIH. Because it applies to all government-funded R&D, the draft framework opens a Pandora's box, providing a mechanism for competitors, the unscrupulous, or even our foreign adversaries to harass the innovative small companies that drive our technological progress.

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[15] https://www.senate.gov/legislative/LIS/roll_call_votes/vote1062/vote_106_2_00168.htm

[16] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, slide 19

As there is no definition of what constitutes a "reasonable price," prospective licensees or those founding start-up companies around Bayh-Dole inventions have no idea what standards they will be judged by if they commercialize a product under these guidelines. What they do know is that they can be challenged by those claiming they could make their product cheaper. Even if these march-in petitions are ultimately unsuccessful, the broad notification that they have been filed could cause potential funders or partners to stay away.

The draft framework would return us back to the bad old days before Bayh-Dole, when government-funded inventions were considered toxic.

The Bayh-Dole Act also sought to end government micromanagement of federally-funded inventions and the documented inefficiencies of a "Washington knows best" approach to patent licensing that left tens of thousands of federally-funded inventions gathering dust rather than being turned into useful products. Bayh-Dole has succeeded beyond our wildest expectations. A key reason why the government has never needed to invoke march-in rights is that universities are successfully monitoring their licenses.

Even Bayh-Dole proponents were not sure that would be the case when the law was written, as most schools did not have technology transfer offices for a good reason -- the government took their patents away from them. As a safeguard, Congress created the first march-in trigger to ensure that the terms of academic licenses were 1) reasonable and 2) included monitoring mechanisms that licensees were making good faith efforts to bring federally-funded inventions to the marketplace where they benefit the public. It was not by happenstance that this trigger only applies to the patent owner (i.e. the university) and not the licensee which sets the price.

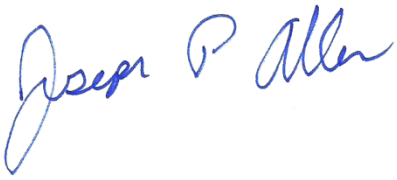
There is no reason for the government to now re-insert itself in micro-managing academic patent licensing. The framework does not cite a single real-world case in over 40 years where march-in rights should have been used. Instead, the framework relies only on hypotheticals.

The Bayh-Dole system is a keystone of American innovation. *The Economist Technology Quarterly* aptly described it as: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything,

this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[17]

It would be enormously counterproductive to undermine the law that has served American innovators, workers, and consumers so well. The Bayh-Dole Coalition urges you to withdraw the framework and would be happy to discuss these concerns at your convenience.

Sincerely,



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[17] https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose