Congress of the United States

Washington, DC 20515

August 7, 2024

The Honorable Xavier Becerra
Secretary of the Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Gina Raimondo
Secretary of the Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Dear Secretary Becerra and Secretary Raimondo,

We write to urge you to carry out Congress' will as specified in the *Bayh-Dole Act* by strengthening and quickly finalizing the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.[1] Specifically, we urge you to follow the text and the legislative history of the statute, which clearly authorize expert federal agencies to consider price as a factor in determining whether a subject invention is available to the public on reasonable terms. In recent weeks, Republican members of Congress have sought to radically and incorrectly broaden the scope of the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo* to deter you from acting to protect consumers from high drug prices.[2] But *Loper Bright* does not alter the plain terms of the Act, which clearly empower agencies with "march-in" rights under Section 203 of the *Bayh-Dole Act*.[3]

In *Loper Bright*, the Supreme Court held that if a statute is ambiguous, courts should not defer to a federal agency's reading of the law but instead independently determine the meaning of a statute.[4] At the same time, the Court acknowledged that, in some instances, a statute's unambiguous "meaning may well be that the agency is authorized to exercise a degree of discretion."[5] In such instances, "when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation."[6] The Court explained that Congress, through statute, may vest agencies with specific regulatory authority to give meaning to a term or to "fill up the details of a statutory scheme."[7] For example, the Supreme Court identified a clear and lawful delegation of discretionary authority in a statute that directs

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[1] National Institute of Standards and Technology, Department of Commerce, Federal Register Notice, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," December 8, 2023, https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-forinformation-regarding-the-draft-interagency-guidance-framework-for-considering-the.

[2] Letter from Senator Bill Cassidy to The Honorable Xavier Becerra, June 30, 2024, https://www.help.senate.gov/imo/media/doc/loper_bright_letter_hhspdf.pdf.

[3] 35 U.S.C. 203

[4] Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244, 2273 (2024).

[5] *Id.* at 2263.

[6] *Id.* at 2273.

[7] *Id.* at 2263, fn.5, fn.6.

the Environmental Protection Agency to regulate power plants if the agency "finds such regulation is appropriate and necessary."[8]

The *Bayh-Doyle Act*, codified at 35 U.S.C. 200, was enacted, in part, to promote the "public availability of inventions [and to] . . . protect the public against nonuse or unreasonable use of inventions."[9] The statute applies to inventions (including health technologies such as pharmaceuticals, vaccines, medical devices, and other medical products) developed using federal funds and achieves its goal by empowering federal agencies to reclaim and relicense patent rights if they are not being made "available to the public on reasonable terms."[10] Specifically, the relevant portion of the statute provides that:

> With respect to any subject invention . . . the [relevant] Federal agency . . . shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder … to grant [a nonexclusive, partially exclusive, or exclusive license] itself, if the Federal agency determines that such . . . action is necessary because the [patent holder] has not taken . . . effective steps to achieve practical application of the subject invention . . . [or] action is necessary to alleviate health or safety needs which are not reasonably satisfied by the [patent holder].[11]

The law defines "practical application" to mean the product's benefits are being made "available to the public on reasonable terms."[12]

The *Bayh-Dole Act* is replete with clear and lawful delegations of regulatory authority. Specifically, this statute delegates discretionary authority to your agencies to "march in" and reclaim a patent covered by the Act, to set reclamation procedures through regulation, and to determine whether the statutory criteria apply to a specific scenario. If a drug is covered by a patent linked to federal funding and your agencies determine that it is not available to the public on reasonable terms, your agencies continue to have the authority to relicense that patent to another drug company that will produce and sell it on the private market while ensuring that the patent holder is compensated under "terms that are reasonable under the circumstances" through royalties from the licensee.[13] The Supreme Court's decision in *Loper-Bright* does not alter your agencies' authority to take action pursuant to these unambiguous provisions of the Act.

In accordance with the clear provisions of the Act, the National Institute of Science and Technology (NIST) released draft guidance that outlines the recommended prerequisites for exercising march-in rights under this statute.[14] In the guidance, NIST outlines a three-step

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[8] *Id.* at 2263, fn.6, (quoting 42 U.S.C. 7412(n)(1)(A)).
[9] 35 U.S.C. 200.
[10] 35 U.S.C. 203(a); 201(f).
[11] 35 U.S.C. 203(a).
[12] 35 U.S.C. 201(f).
[13] 35 U.S.C. 203(a).
[14] National Institute of Standards and Technology, Department of Commerce, Federal Register Notice, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," December 8, 2023, https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-forinformation-regarding-the-draft-interagency-guidance-framework-for-considering-the.

process to determine whether an enforcement agency should exercise its clearly delegated "march in" authority on a particular patent. In doing so, NIST promulgated the statutorily delegated "procedures" to initiate a "march in" process and through "government regulations," identifies the criteria to determine whether an "invention is being utilized and that its benefits are . . . available to the public on reasonable terms."[15] NIST's guidance falls easily within the explicit authority unambiguously granted to the agency, and the Supreme Court did not disturb this authority in *Loper Bright*.

Moreover, it is well within the text of the statute and congressional intent in enacting the *Bayh-Doyle Act* for the agency to consider the price of prescription drugs in assessing whether to exercise federal "march in" rights.

Consider the text. The statute clearly authorizes a federal agency to promulgate regulations that would allow it to enforce the rights granted under the *Bayh-Dole Act* to determine whether a patent holder has not made the benefits of a product available to the public on reasonable terms and, if not, take over the licensing of that product. Established federal law requires that "ordinary words . . . be interpreted with their ordinary meaning."[16] Further, in the U.S., "the words 'reasonable terms' have uniformly been interpreted to include price.'"[17] As legal scholars have explained, "[p]ractically and legally, making drugs available to the public on reasonable terms clearly means making them available at a reasonable price."[18] The statute's text is the most important source of authority – as reaffirmed by the Supreme Court in *Loper Bright* – and here, it clearly provides that in exercising their "march in" authority, agencies may consider whether a patent holder is making the drug "available to the public on reasonable terms."[19] Price is clearly a consideration in this assessment.

Congressional intent bolsters the statute's plain text. The *Bayh-Dole Act* was drafted, debated, and passed during a time when "burdensome patent policies were [a] barrier to innovation and increased competition."[20] Contemporaneous statements by members of Congress, committee reports, and exchanges during public hearings discussed the "need to maintain competitive market conditions through the exercise of march-in rights,"[21] with one hearing witness noting that patent policy is in the public interest if it "provid[es] the consumer with the goods and

[15] 35 U.S.C. 203(a); 201(f).
[16] Smith v. United States, 508 U.S. 223, 232 (1993) (quoted in Tulane Law Review, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research," Peter S. Arno and Michael H. Davis, 2001, p. 657, https://www.tulanelawreview.org/pub/volume75/issue3/why-dont-we-enforce-existing-drug-price-controls.
[17] Tulane Law Review, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research," Peter S. Arno and Michael H. Davis, 2001, p. 657, https://www.tulanelawreview.org/pub/volume75/issue3/why-dont-we-enforce-existing-drug-price-controls.
[18] Washington Post, "Angry at high drug prices? A letter in The Post is to blame (sort of)," Peter S. Arno and Kathryn Ardizzone, May 30, 2024, https://www.washingtonpost.com/opinions/2024/05/30/post-letter-high-drug-prices/.
[19] 35 U.S.C. 201(f).
[20] Tulane Law Review, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research," Peter S. Arno and Michael H. Davis, 2001, p. 657, https://www.tulanelawreview.org/pub/volume75/issue3/why-dont-we-enforce-existing-drug-price-controls.
[21] *Id.*, p. 662.

services he requires at the lowest possible prices."[22] Industry vehemently opposed the "march-in" provisions in the Act on the grounds that they could be used to impose price controls, indicating that Congress intended and industry expected that your agencies should consider price when deciding whether to "march in."[23]

In fact, as we have previously explained, NIST's draft guidance also takes a needlessly cramped view of agencies' authority to exercise "march-in" rights, and we once again urge you to avoid imposing such "limiting language [that] is not included in the statute [as it] may dissuade agencies from exercising march-in rights outside of extreme conditions."[24] For instance, the NIST draft guidance repeatedly encourages agencies to consider "the totality of the circumstances," including the "potential chilling effect on the agencies' existing relationship with industry."[25] Such considerations appear to disproportionately weigh private interests above public interests and create a much lower standard than the statute's plain text requires. We accordingly urge you to remove this consideration and make additional improvements to strengthen the final guidance.

From 2008 to 2023, the median annual launch price of a new drug in the U.S. increased from $2,115 to $300,000.[26] Even after considering estimated manufacturer discounts, net launch prices increased from $1,376 in 2008 to $159,042 in 2021.[27] These prices mean that that many drugs, including those developed with federal funding, are not available under reasonable terms. The impact of such massive price increases is severe—nearly one in three U.S. adults do not take their medicines as prescribed due to prohibitively high costs.[28] Congress has explicitly and unambiguously delegated authority to your agencies to ensure that federal inventions, including pharmaceuticals and other medical products, developed using federal funds are "available to the public on reasonable terms."[29] We urge you not to be deterred by congressional Republicans who are seeking to hamstring your authority to lower drug costs for Americans and we are reiterating

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[22] *Id.*

[23] *Id.*, pp. 659-667.

[24] Letter from Senator Elizabeth Warren and Members of Congress to Commerce Secretary Gina Raimondo, Health and Human Services Secretary Xavier Becerra, and Commerce Under Secretary Laurie E. Locascio, February 6, 2024, https://www.warren.senate.gov/imo/media/doc/Bayh-Dole%20Interagency%20Guidance%20Comment%20Letter%20FINAL%202.6.24.pdf.

[25] National Institute of Standards and Technology, Department of Commerce, Federal Register Notice, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," December 8, 2023, https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-forinformation-regarding-the-draft-interagency-guidance-framework-for-considering-the.

[26] Journal of the American Medical Association, "Trends in Prescription Drug Launch Prices, 2008-2021," Benjamin Rome, Alexander Egilman, Aaron Kesselheim, June 7, 2022, pp. 2145-2147, https://jamanetwork.com/journals/jama/article-abstract/2792986#248455023; Reuters, "Prices for new US drugs rose 35% in 2023, more than the previous year," Deena Beasley, February 23, 2024, https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/.

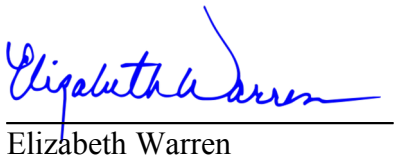
[27] Journal of the American Medical Association, "Trends in Prescription Drug Launch Prices, 2008-2021," Benjamin Rome, Alexander Egilman, Aaron Kesselheim, June 7, 2022, p. 2145, https://jamanetwork.com/journals/jama/article-abstract/2792986#248455023.

[28] KFF, "Public Opinion on Prescription Drugs and Their Prices," Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, and Liz Hamel, August 21, 2023, https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

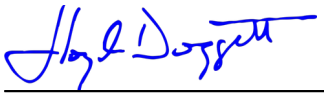
[29] 35 U.S.C. 201(f).

the need for your agencies to immediately strengthen and finalize the proposed guidance issued under this statute so that Americans may receive the benefits that Congress intended.

Sincerely,



Elizabeth Warren
United States Senator



Lloyd Doggett
Member of Congress

Angus S. King, Jr.
United States Senator