Congress of the United States

Washington, DC 20515

May 29, 2024

The Honorable Gina Raimondo Secretary Department of Commerce 1401 Constitution Ave. NW Washington, DC 20230 Laurie E. Locascio Under Secretary of Commerce for Standards and Technology Department of Commerce 100 Bureau Drive Gaithersburg, MD 20899

Dear Secretary Raimondo and Under Secretary Locascio:

We write in support of strengthening and finalizing the "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" which would help boost competition and reduce prices for American families by allowing the federal government to act when private actors, including drug manufacturers, charge exorbitant prices for products that taxpayers helped to develop.

Our review of the comments indicates that the exercise of march-in rights has received broad support from seniors, from dozens of health care providers, and from the broader public.¹ More than 85 percent of comments were in favor of the proposal, and these comments reveal that this is a popular framework that will help reduce exorbitant drug costs.

The comment period for this new guidance closed on February 6, 2024, and staff reviewed all public comments as of May 2024.² The comments revealed that Americans are paying more for drugs their tax dollars paid to develop than what residents in other high-income countries are paying for those same drugs. The comments further reflect concerns from health care providers, who are calling for change on behalf of their patients and Americans all across the country, especially seniors, who are struggling to afford their medication and view march-in rights as a way to reduce drug prices.

To ensure full due process for all parties, this framework should require transparent proceedings with equal opportunity for consumers to present evidence and witnesses, and a right to an independent appeals process and timeliness standards. Further, the framework should require balanced evaluation of march-in rights that does not offer inappropriate and biased consideration of "the potential chilling effect on the agencies' existing relationships with

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, <u>https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the.</u>

² Regulations.gov, "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," <u>https://www.regulations.gov/docket/NIST-2023-0008/document</u>. industry."³ Support for federal-private partnerships should never interfere with agencies' responsibility to enforce federal law and protect taxpayers and consumers.

As you work to finalize the guidance, we urge you to consider the overwhelming support for the framework, including the thousands of comments calling for the "use of march-in authority to lower prescription drug prices."⁴

Widespread Public Support for the Proposed Framework

The National Institute of Standards and Technology's draft guidance received over 50,000 public comments, and more than 85%, or 43,000, supported the inclusion of price as a consideration for agencies in deciding whether to use its march-in authority.⁵ Commenters from all 50 states expressed their support for the proposed framework.

One commenter from Arkansas shared:

"I support this wholeheartedly...If they're taxpayer funded, then they should be available to the taxpayers without having to fight for-profit insurance companies or being forced to make the choice between food and shelter or medicine."⁶

A commenter from Alaska noted:

"I support the use of march-in authority to lower prescription drug prices. While working at Aviano [Air Force Base] in Italy from 2018 to 2022, I filled my prescriptions at Italian *farmacia* instead of the base pharmacy because prices were up to 90% lower for the same drug in Italy. This is unconscionable, since so many of these drugs were developed in the US with American tax dollars."⁷

A commenter from Montana noted:

"I think it is absolutely horrible that we, the people, pay the highest prices in the world for medicines that were developed with our tax dollars."⁸

³ 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, <u>https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the</u>.

⁴ Regulations.gov, "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," <u>https://www.regulations.gov/docket/NIST-2023-0008/comments?filter=%22use%20of%20march-in%20authority</u> <u>%20to%20lower%20prescription%20drug%20prices%22</u>.

⁵ Regulations.gov, "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," <u>https://www.regulations.gov/docket/NIST-2023-0008/comments</u>.

⁶ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-0176</u>.

⁷ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-45318</u>.

Many other commenters echoed similar themes. NIST should finalize this framework to ensure that taxpayer-funded inventions are accessible and affordable to the public. Doing so would send a clear message that government is on the side of the American people, who underwrite these important discoveries—not Big Pharma.

Health Care Providers Support the Proposal

In comments supporting the proposal, health care providers discussed the impact of high drug costs on patients.

One doctor from California shared:

"I strongly support the use of march-in authority to lower prescription drug prices.

As a physician I have seen the horrific effect of high drug prices and the terrible decisions that forces patients to make between paying for housing, food OR their necessary medicines. This is unconscionable! & we, as citizens, need to ensure that everyone can easily afford and access their required prescription medications - to pursue life & liberty WITH dignity!

Americans shouldn't pay the highest prices in the world for medicines that were developed with our tax dollars."⁹

Another doctor from Georgia commented:

"As a physician and the widow of a man with a serious chronic illness, I support the use of march-in authority to lower prescription drug prices."¹⁰

A retired Nurse Practitioner from Hawaii commented:

"[It] was always heart [] breaking to attempt to take care of patients who could not afford the medication they needed for their disease...You must stop the price gouging."¹¹

A doctor from North Carolina noted:

"I support the use of march-in authority to lower prescription drug prices. Americans shouldn't pay the highest prices in the world for medicines that

⁸ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-0872</u>.

[°] Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-46447</u>.

¹⁰ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-45663</u>.

¹¹ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-9474</u>.

were developed with our tax dollars... We need these guidelines to be iron-clad and bring down the exorbitant prices of prescription drugs! As a physician, I find it infuriating that my patients [cannot] even afford their medications in this country while the pharmaceutical industry makes obscene profits at the expense of all of us. Please exercise your march-in rights in the interest of the U.S."¹²

In addition to the comments highlighted above, dozens of health professionals from across the country indicated in their comments that they supported the proposed framework.

Seniors Support the Framework

In their comments, older adults repeatedly raised that they are struggling to afford their medications, often having to make difficult decisions about where their limited funding can go and underscoring the importance of march-in rights.

Finalizing this framework would make a real difference to a commenter from Illinois who "support[s] the use of march-in authority to lower prescription drug prices," and noted that, "as a senior, one of my greatest fears is having to choose between paying for my medication and keeping my house heated."¹³

Another commenter from Pennsylvania noted:

"As a 72 year old retired person on a fix[ed] income and on Social Security and Medicare with some very high priced medications being prescribed for me[,] I support the use of march-in authority to lower prescription drug prices."¹⁴

A commenter from Colorado shared:

"As a senior constituent from Colorado Springs, CO (80904) outraged by exorbitant prices charged by pharmaceutical companies for prescription drugs developed with taxpayer funds, I strongly support the use of marchin authority to lower prices for these drugs. Americans already pay the highest prices in the world for prescription drug[s]. We certainly should not be paying such prices for medicines that were developed with our tax dollars."¹⁵

One retired registered nurse shared:

¹² Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-8413</u>.

¹³ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-49036</u>.

¹⁴ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-8167</u>.

¹⁵ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-9385</u>.

"I support the use of march-in authority to lower prescription drug prices. Americans shouldn't pay the highest prices in the world for medicines that were developed with our tax dollars...As a retired registered nurse, living on my social security and a meager pension, I have difficulty paying for the medications that my training has taught me are so important to my health."¹⁶

Conclusion

Thousands of Americans, from all 50 states, have stated loudly and clearly that they support the administration's proposed framework, and NIST should listen to their voices as it moves to finalize this guidance. Although big pharmaceutical companies are fighting this common-sense framework, there is a consensus among seniors, health care providers, and the general public: price must be a factor in agencies' considerations for the use of march-in rights. We urge you to strengthen and finalize the guidance without delay to ensure that American taxpayers and consumers are able to access taxpayer-funded inventions at affordable prices.

Sincerely,

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Elizabeth Warren United States Senator

Lloyd Doggett Member of Congress

¹⁶ Regulations.gov, "Comment on FR Doc # 2023-26930," <u>https://www.regulations.gov/comment/NIST-2023-0008-45816</u>.