

**Congress of the United States**  
Washington, DC 20515

February 6, 2024

Gina Raimondo  
Secretary  
Department of Commerce  
1401 Constitution Ave. NW  
Washington, DC 20230

Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

Laurie E. Locascio  
Under Secretary of Commerce for Standards and Technologies  
Department of Commerce  
100 Bureau Drive  
Gaithersburg, MD 20899

**RE: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, National Institute of Standards and Technologies (NIST), United States Department of Commerce. 88 FR 85593, Agency/Docket Number: Docket No.: 230831-0207**

Dear Secretary Raimondo, Secretary Becerra, and Under Secretary Locascio:

We write to express our support for strengthening and finalizing the “Interagency Guidance Framework for Considering the Exercise of March-In Rights” to protect the public’s health and safety by ensuring reasonable prices on taxpayer-funded inventions.

We appreciate that the Administration has, for the first time, specified that price is a factor in determining whether a taxpayer-funded invention is accessible to the public. Reining in out-of-control prescription drug prices is one of the most pressing challenges facing the United States, and taxpayers are investing more than ever in biomedical research, sometimes funding 80 to 100 percent of the cost of developing a new medical product. As the angel investors underwriting the risk of development, taxpayers deserve access to these products on reasonable terms, including fair pricing that accounts for the investment made.

While we recognize the important role of the private sector in research and development and support the ability to make a reasonable profit, industry interests should not outweigh meeting health and safety needs for all consumers and providing accountability to taxpayers. To ensure

the Interagency Guidance appropriately balances these interests and offers robust due process protections, we offer the following comments to strengthen the final framework.

### **1. Considerations for exercising march-in rights**

The draft framework offers a lengthy list of considerations for agencies to weigh before exercising march-in rights. We strongly support and welcome the Administration's acknowledgement that price is an important consideration for the use of march-in. Price gouging is never justified, and it is agencies' responsibility to protect consumers from monopoly abuse. An unaffordable product is the equivalent of an unavailable product.

There is considerable debate concerning what is an appropriate price. We encourage you to include additional considerations to assist agencies in determining when a product's price is unjustified. Such considerations may include the impact of price on an individual's ability to afford a product as well as the cost to develop, produce, and deliver the product. Further considerations may include a comparison of prices charged to federal purchasers versus commercial purchasers, a comparison of prices charged in other comparable countries, a comparison of prices between similar products, and a comparison of prices for alternative methods to meet the same health or safety need. For example, a product's price could be unjustified if the price in the U.S. exceeded the median price charged in comparable wealthy countries. These considerations must be accompanied by a clear directive that price gouging on a taxpayer-funded product is never justified, and the availability of alternatives should not be a factor in declining to exercise march-in rights.

Many taxpayer-funded products are developed for the purpose of alleviating a health or safety need. We appreciate the framework's commitment to assisting agencies in weighing whether such a need is being met, but we are concerned that it inappropriately imposes some new conditions beyond statutory requirements that will deter agencies from exercising march-in rights. For example, the framework encourages agencies to consider the scope of the health or safety need, thereby implying that a need impacting a smaller population is less important. Such a condition is not included in the statutory requirements for exercising march-in rights and the inclusion of this new condition would likely deter agency action on critical products that may be life-changing or lifesaving. Similarly, the framework refers to "an emergency or urgent public health or safety issue." Such limiting language is not included in the statute and may dissuade agencies from exercising march-in rights outside of extreme conditions such as when there is an existing public health emergency declaration. Any unmet health or safety need is a reason to use march-in rights and the framework should not impose additional conditions on this criterion.

The draft framework frequently encourages agencies to examine the "totality of circumstances." A robust fact-finding is necessary, but the framework must strike the correct balance between industry interests and the obligation of agencies to protect taxpayer interests and consumers' health and safety. We are concerned by the draft framework's imbalance in weighing these interests, most notably apparent in encouraging agencies to consider "the potential chilling effect on the agencies' existing relationships with industry." While we support federal-private partnerships to advance shared priorities, this should never interfere with agencies' responsibility to enforce federal law and protect consumers and taxpayers. Just as the Department of Health and Human Services (HHS) would hopefully not consider "the potential chilling effect on...

relationships with industry” in negotiating fair Medicare drug prices under the Inflation Reduction Act, HHS should not be considering how unhappy it makes the pharmaceutical industry to comply with federal law in its enforcement of march-in rights. We strongly encourage you to remove this consideration and ensure the final framework strikes an appropriate balance and does not overly emphasize one party’s concerns.

## **2. Procedures for exercising march-in rights**

The draft framework details robust procedural steps before exercising march-in rights. To ensure full due process for all parties involved, we strongly urge you to ensure transparent proceedings, provide equal opportunity for petitioners to present evidence and witnesses, and provide an independent appeals process and timeliness standards.

Inexplicably, the framework states “all portions of the march-in proceeding are closed to the public and are held confidential.” March-in proceedings should be open to the public, who have the most at stake as the financiers of the subject invention. Only very narrow exceptions to transparent proceedings should be permitted when commercially confidential information or other statutorily protected information is disclosed. Private investors receive transparency and regular reports on the status of their investments. When the taxpayer is the investor, the same transparency is owed, especially when potential misuse or abuse is being discussed.

Notably, the secret proceedings outlined in the draft framework offer contractors the right to counsel and ability to present evidence and witnesses during a march-in proceeding, yet petitioners are not mentioned once in the “Regulatory Procedures for March-In” section. Petitioners should be afforded equal opportunity to be represented by counsel and fully participate in a march-in proceeding. Taxpayers and affected consumers have a right to be heard by agencies to ensure their interests are fairly represented and considered.

To ensure due process, march-in proceedings must also include a right to appeal by petitioners and all appeals should be considered by someone not involved in the initial decision. In a recent appeal to a denied march-in petition, petitioners wrote that review by the same office “would be tantamount to no review at all.” We agree with this assertion and urge you to specify that all appeals should receive independent and fair review by a new, impartial party.

Finally, march-in petitions and proceedings should be subject to timeliness requirements. Prior march-in petitions have gone unanswered for several months, and sometimes years. These delays resulted in continued price gouging on Xtandi, a prostate cancer drug, which in a single year cost taxpayers over \$2 billion to provide to Medicare beneficiaries. A primary reason that the National Institutes of Health (NIH) gave for its recent rejection of a march-in petition on Xtandi was “the remaining patent life and the lengthy administrative process involved for a march-in proceeding.” Such concerns may not have been present if NIH had responded to the initial petition in a timely manner, when it was first filed in 2021.

The draft guidance encourages agencies to consider patent life and market circumstances when determining whether the time involved in a march-in proceeding is worth undertaking. While we are concerned that the guidance may permit the continued price gouging of taxpayer-funded inventions, at a minimum, the final framework must include guidance on the timely

consideration of a petition to ensure bureaucratic red tape does not interfere with the final outcome.

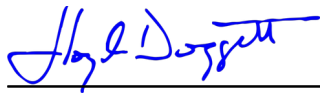
### 3. Implementation of march-in rights


While we welcome the Administration’s acknowledgment of one of its most important authorities to prevent price gouging and provide taxpayer accountability, this framework is only as meaningful as the resulting action you take. The fact that agencies have failed to use march-in rights is not due to issues with implementation of the authority, but rather an indication of how industry narratives have negatively impacted agency behavior. We are concerned by accompanying statements with the release of this draft guidance that asserted the Administration “is not expected to [exercise march-in rights] against any individual medicines.”

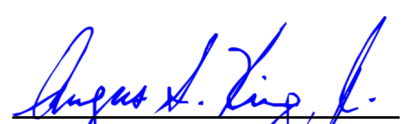
Taxpayers invest approximately \$115 billion annually in research and development, over \$54 billion of which is spent on biomedical research, yet they are too often denied access to the resulting inventions because of astronomical monopoly prices. It is imperative that the Administration protect these investments and access to critical innovations by exercising its clear statutory authority, which also includes licensing authority on all patents using Section 1498 and the use of royalty-free rights. Not only does the framework fail to mention separate authorities, it dismisses their use by encouraging agencies not to exercise march-in rights “if only one of several patents necessary to produce a product is subject to march-in.” We are deeply concerned this framework may only reaffirm past inaction. When issuing the final framework, we strongly urge you to include a directive to agencies to review all federally funded inventions under their purview within six months and determine whether to use march-in rights, either solely or in conjunction with Section 1498 and/or royalty-free rights.

We appreciate your timely attention to these comments and urge you to strengthen and finalize the draft framework without delay. We look forward to working with you and all agency partners in implementing a strengthened final framework to deliver long overdue relief to American taxpayers and consumers.

Sincerely,

  
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Lloyd Doggett  
Member of Congress

  
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Elizabeth Warren  
United States Senator

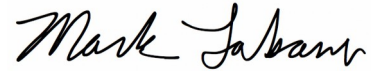
  
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Angus S. King, Jr.  
United States Senator



Dwight Evans  
Member of Congress



Sara Jacobs  
Member of Congress



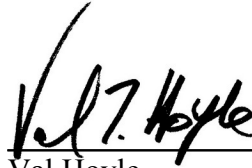
Mark Takano  
Member of Congress



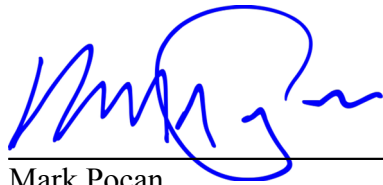
Katie Porter  
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Ro Khanna  
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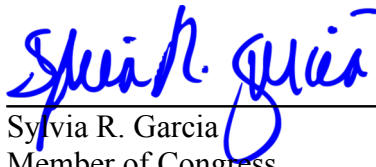
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Africans -  
Sacrificed to Make America  
Great



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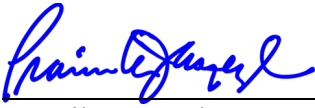
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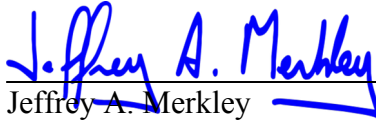
Barbara Lee  
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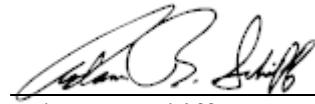
Judy Chu  
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United States Senator



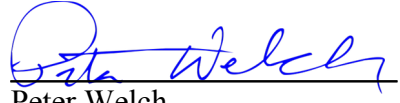
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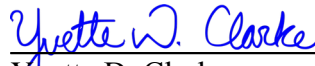
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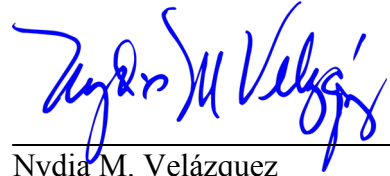
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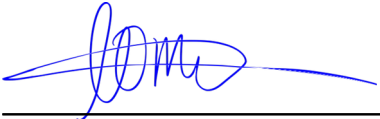
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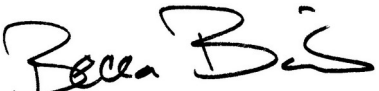
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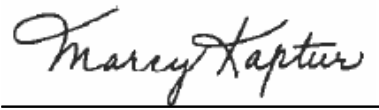
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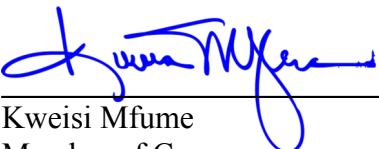
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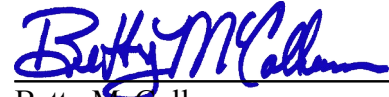
Sheila Jackson Lee  
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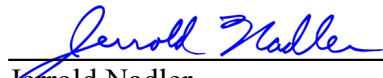
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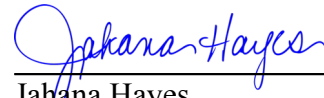
Troy Carter  
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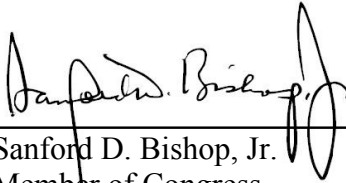
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Dina Titus  
Member of Congress



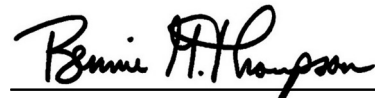
Jahana Hayes  
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Sanford D. Bishop, Jr.  
Member of Congress



Alexandria Ocasio-Cortez  
Member of Congress



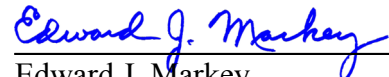
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Brad Sherman  
Member of Congress

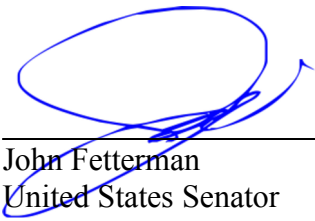


Andy Kim  
Member of Congress



Edward J. Markey  
United States Senator





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John Fetterman  
United States Senator



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Richard Blumenthal  
United States Senator



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Emanuel Cleaver, II  
Member of Congress



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Frederica S. Wilson  
Member of Congress



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Teresa Leger Fernández  
Member of Congress



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Summer Lee  
Member of Congress