

The Honorable Gina Raimondo
Secretary of Commerce
Washington, DC 20230

The Honorable Laurie E. Locascio
Under Secretary of Commerce for Standards and Technology
Washington, DC 20230

February 6, 2024

Civil Society Comments¹ Re: Docket No.: 230831-0207, “Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights”

Dear Secretary Raimondo and Undersecretary Locascio,

Our groups, representing patients, consumers, health care providers, people of faith, workers and public health experts are committed to ensuring access to affordable medicines, including fair pricing of medicines invented with public funds. We write you today to express our support for strengthening and finalizing the Interagency Guidance Framework for Considering the Exercise of March-In Rights.

Despite the indispensable role the United States government and our public institutions play in biomedical research and development,² too often medicines are priced out of reach for patients. In the United States, prescription drug corporations routinely charge prices three times as high as those they charge in other wealthy countries.³ Three-in-ten Americans report not taking their medicine as prescribed due to costs.⁴ High prices of medicines and hormones like insulin that millions of people throughout the country need to stay alive have led to rationing, and ultimately death.⁵ Black, Hispanic, and lower-income patients bear a disproportionate share of the burden of difficulty affording prescription drugs.⁶

Exorbitant drug prices also put an enormous strain on the coffers of public health programs, and consequently public tax dollars. Of the more than \$400 billion spent on retail prescription drugs in 2022,

¹ Some of our organizations have also submitted individual comments in response to the RFI with additional recommendations.

² Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 *BMJ* I5766 (2019).
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812612/>

³ Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*. (February 2024),
<https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf>

⁴ Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

⁵ Bram Sable-Smith, *Insulin’s High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018),
<https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>

⁶ Lunna Lopes, Marley Presiado, and Liz Hamel, *Americans’ Challenges with Health Care Costs*, KFF (Dec. 21, 2023),
<https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/>

nearly \$135 billion came from Medicare and \$45 billion from Medicaid.⁷ Additionally, more than \$150 billion more are estimated to be spent on nonretail drugs each year.⁸

The Administration is making significant progress in tackling our nation's drug pricing crisis through implementation of Medicare drug price negotiation, inflationary rebates, and other provisions of the Inflation Reduction Act, but far more is needed to provide relief to all patients facing unbearably high prescription drug prices, including people with private insurance and those without insurance.

Instances of patients and public health programs facing drug corporation price gouging on medicines that were invented wholly or in part with the support of taxpayer dollars are particularly egregious. Thankfully, the U.S. government holds an array of tools to help protect the public interest and ensure people get access to the medicines they need, and that the federal government and taxpayers are not ripped off, particularly with regard to these sorts of medicines.⁹

The Bayh-Dole Act is a key area of U.S. law “to promote utilization of inventions arising from federally supported research and development,” including prescription drugs and other medical inventions.¹⁰ One of its core policies is to provide ownership of federally-supported inventions to grant recipients and contractors while preserving rights for federal funding agencies to protect and advance the public interest, including by “ensur[ing] that the Government obtains sufficient rights in federally supported inventions **to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions**” (emphasis added).¹¹

Through \$50 billion in annual investments, the U.S. government and taxpayers undergird the biomedical R&D upon which new drugs rely.¹² Experts in pharmaceuticals and intellectual property law have identified that around 11% of newly approved drugs rely on at least one patent that discloses government rights, including the right to march-in, stemming from an inventor making an invention in the performance of work under a federal funding agreement.¹³ Additionally, researchers have shown that medicines invented with public sector financial support are more likely to receive approval through expedited development or review pathways, and to be first in class, indicating they are potentially of greater therapeutic

⁷ Centers for Medicare and Medicaid Services, National Health Expenditure Tables, <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet> (last visited Feb. 5, 2024).

⁸ IQVIA, *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*, (May 2, 2023), <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023>

⁹ Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf> (last accessed Feb. 6, 2024).

¹⁰ 35 U.S. Code § 200, Bayh-Dole Act Policy and Objective.

¹¹ *Id.*

¹² United States Senate, Health, Education, Labor, and Pensions Committee Majority Staff, *Public Investment, Private Greed*, (June 12, 2023), <https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf>

¹³ Ledley FD, Cleary EG (2023) NIH funding for patents that contribute to market exclusivity of drugs approved 2010–2019 and the public interest protections of Bayh-Dole. *PLoS ONE* 18(7): e0288447. <https://doi.org/10.1371/journal.pone.0288447>

importance than drugs that were not invented with public funds.¹⁴ Thus, the application of march-in rights and other public interest protections under the Bayh-Dole Act have profound implications for access to medicines and drug pricing for patients and consumers.

Unfortunately, despite numerous petitions presented over the 40-plus year history of the Bayh-Dole Act, not once has a federal agency exercised its right to march-in and license competition to remedy price gouging (which constitutes a failure of the owner of a subject invention to make that invention available to the public on reasonable terms), or otherwise.

We applaud the administration for articulating through this guidance that price, indeed, is a factor in exercising march-in rights, which more accurately reflects a plain reading of the statute and the intent of legislators who passed the Bayh-Dole Act into law. While recognition of price as a factor represents a paradigm shift from positions held by previous administrations, still, the guidance is inappropriately restrictive and narrowly construes conditions under which agencies might initiate march-in proceedings.

Below, we outline several recommendations to provide clarity and more closely align the proposed guidance with statute while advancing the public interest objectives of the Act.

1) Include international pricing disparities as a major consideration for exercising march-in rights.

The first statutory criterion for using the march-in authority allows the government to march-in when the patent holder has not achieved “practical application,” which means to manufacture the invention and “establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations **available to the public on reasonable terms**” (emphasis added).¹⁵ Price gouging U.S. patients and consumers for an invention made with public, taxpayer dollars is a clear failure to make such an invention available on reasonable terms, and it would defy the plain reading of the statute to suggest otherwise.

Dozens of academic experts in pharmaceutical and intellectual property law agree that “pricing alone should provide sufficient grounds for exercising march-in rights.”¹⁶ In a 2022 letter, they confronted the most common arguments against the Act’s application to price; the following quotes the letter at length:¹⁷

Based on the plain text of the statute, excessive pricing alone should provide sufficient grounds for exercising march-in rights. Section 203(a)(1) permits march-in licenses if the patent holder has not effectively achieved “practical application” of the drug, which § 201(f) defines as, *inter alia*, making the drug “available to the public on reasonable terms.” Years after the Bayh-Dole Act’s enactment, former Senators Birch Bayh and Bob Dole (who were then working for

¹⁴ Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 *BMJ* I5766 (2019).

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812612/>

¹⁵ 35 U.S. Code § 203; 35 U.S. Code § 201(f).

¹⁶ Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf> (last accessed Feb. 6, 2024).

¹⁷ *Id.*

Washington firms that lobbied for pharmaceutical manufacturers) argued that Congress did not intend “reasonable terms” to cover excessive pricing. But the text of the statute contradicts this interpretation. The statute’s plain text matters more than a single newspaper op-ed expressing subjective intent of individual lawmakers, particularly when that intent is expressed years *after* the law has already been passed. Moreover, there were numerous, *contemporaneous* examples from debates around the passage of the Act that clearly link the Act’s march-in provisions with the need to control prices and promote accessibility to the public.

Price is a crucially important element of the terms of a transaction, and providing goods or services only at excessive prices is offering only unreasonable terms. This interpretation is supported by federal court cases interpreting other statutes discussing the meaning of “reasonable terms.” Reviewing the reasonableness of prices is well within the competence of both courts and agencies, as illustrated by other aspects of patent law, contract law, utilities regulation, and more. Finally, other industry representatives have argued that the government’s failure to *exercise* march-in rights means that those rights do not exist. Yet, as the Supreme Court has long held, “[t]he fact that powers long have been unexercised well may call for close scrutiny as to whether they exist; but if granted, they are not lost by being allowed to lie dormant.”

We applaud the Biden administration for recognizing this key reality in the proposed framework, particularly as the previous administration actively sought to deny the application of march-in rights to pricing.¹⁸ However, we are concerned that the current framework does not adequately encompass clear instances of unreasonable pricing and could leave U.S. patients and taxpayers at continued risk of pricing abuses.

Currently and mistakenly, the practical application section of the framework seems to only mention instances in which unreasonable pricing for end users is also unreasonably limiting the availability of the invention. But the Bayh-Dole Act states clearly that the *reasonableness of the terms* of availability is at issue; not whether the resulting availability to end users of the invention is reasonable. Focusing only on how available a taxpayer funded invention is, without any consideration of whether the invention is available on reasonable terms to the public, impermissibly eliminates language in the statute and narrows the scope of the public interest protections. Take, for example, a taxpayer funded drug priced hundreds or even thousands of dollars more per month in the US compared to other countries, incurring significant financial burdens to Americans in terms of out-of-pocket costs and insurance premiums. Because insurance coverage helps make the drug available, an agency may refrain from marching-in, even though the terms on which the drug is available to the public is patently unreasonable given the public’s funding of the drug.

President Biden and White House officials have made statements that express intention for a broader application of march-in right to pricing abuses:¹⁹

¹⁸ Docket No.: 230315-0076, *Rights to Federally Funded Inventions and Licensing of Government Owned Inventions*, <https://www.federalregister.gov/documents/2023/03/24/2023-06033/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions>

¹⁹ Also noted in the December 19, 2023 letter to Secretary Becerra from Robert Sachs, Clare Love, and Eric Sawyer renewing appeal of the NIH rejection of the Xtandi march-in petition. <https://www.keionline.org/wp-content/uploads/sachs-becerra-121923.pdf>

“Today, we’re taking a very important step toward ending price gouging so you don’t have to pay more for the medicine you need.”

– President Biden²⁰

“When drug companies won’t sell taxpayer funded drugs at reasonable prices, we will be prepared to let other companies provide those drugs for less. [...] If American taxpayers paid to help invent a prescription drug, the drug companies should sell it to the American public for a reasonable price.”

– Lael Brainard, National Economic Advisor, White House²¹

We recommend adding language clarifying that “reasonable terms” explicitly includes consideration for the price and other terms at which a subject invention is sold in the United States, reflecting total costs incurred by public agencies, including by Medicare, Medicaid, and by other public and private payers, including private insurance providers, and end users.

Further, we recommend the framework express that pricing disparities between the United States and other high-income countries (HICs) for subject inventions should be a major consideration taken by agencies in their assessments of whether to exercise march-in rights. Additionally, the guidance can set forth a clear pricing standard, which would both help ensure that agencies do not fail to exercise march-in rights when doing so is necessary to protect the public interest, and provide clarity to patent holders on what is likely to constitute price gouging grounds for an agency to march-in.

The NIH and other agencies have been petitioned repeatedly²² to exercise march-in rights on the basis that the owner of a taxpayer-funded invention (or inventions) is charging patients and consumers in the United States prices in gross excess of those charged in other high-income countries.

For example, in 2004, the NIH was petitioned to exercise march-in rights to license generic competition for ritonavir, an important HIV treatment, when Abbott Laboratories increased the U.S. commercial price by 400%, resulting in employers, insurers and patients paying five to ten times more than their counterparts in other high-income countries.²³ More recently, prostate cancer patients petitioned the NIH to march-in on patents for enzalutamide (brand-name Xtandi) due to Astellas and Pfizer setting a price in the United States 3-5 times those charged in other wealthy countries.²⁴

A policy recently formalized and announced by the Administration for Strategic Preparedness and Response (ASPR) at the Department of Health and Human Services offers a conservative standard that could also constitute an obvious violation of the practical application requirement, serving as a clear

²⁰ The White House, *President Biden is Taking Important Steps to Combat Price Gouging*, (Dec. 7, 2023), <https://www.youtube.com/shorts/ENDURMtyKeo>

²¹ Robert J Sachs, Clare M Love, Eric Sawyer, *Letter to Sec. Becerra Re. Appeal of NIH decision rejecting petition for HHS to exercise Federal rights in patents on Xtandi in order to address price discrimination against US cancer patients*, (Dec. 19, 2023), <https://www.keionline.org/wp-content/uploads/sachs-becerra-121923.pdf>

²² Timeline regard[ing] Bayh-Dole march-in rights requests. Knowledge Ecology International. <https://www.keionline.org/march-in-rights-timeline>

²³ Statement of James Love, President, Essential Inventions, Inc. at the NIH Meeting on Norvir/Ritonavir March-In Request, May 25, 2004. <https://www.essentialinventions.org/legal/norvir/may25nihjamie.pdf>

²⁴ Clare Love and Robert Sachs letter to Secretary Becerra. November 18, 2021. <https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf>

indication of when an agency should consider licensing competition to remedy unreasonable pricing.²⁵ Specifically, ASPR is standardizing the practice of including a fair pricing requirement in its contracts supporting clinical development by including a most favored nation clause, which states that a commercialized product must have a list price equal to or less than its price in comparable global markets.²⁶

In reference to this ASPR most favored nation pricing policy, President Biden stated:²⁷

“It’s a simple principle. You shouldn’t pay the highest price in the world for drugs that your tax dollars have already helped create.”

We believe the principle articulated by President Biden is just as applicable to medicines and other federally-funded inventions as it is to medicines with clinical trials supported by ASPR. Thus, it would be appropriate to articulate a pricing benchmark in the march-in framework that aligns with the fair pricing policy championed by President Biden and ASPR.

Not only should United States patients and taxpayers not be subjected to the highest prices in the world for drugs our tax dollars have helped create, but U.S. patients and taxpayers should get *by far* the best deal for medicines we pay to invent. It should be indisputable that charging us more than people in other high-income countries constitutes failing to make a product relying on a taxpayer-funded invention available to the public on reasonable terms.

Specifically, we recommend including language on page 11 of the framework, in the section addressing the practical application criterion, which states:

“Agencies may also give strong consideration to whether action may be needed to meet the needs of the Government or protect the public against unreasonable use of the subject invention in the form of excessive pricing.”

To provide additional clarity, in section IV of the practical application criterion section of the framework, it should set forth this corresponding standard:

“Is the product utilizing the subject invention being sold or offered for sale in the United States at a price that is greater than the lowest price available in other high-income countries?”

While we strongly believe the most-favored nation standard is most appropriate for inclusion in this guidance, we do not believe or intend to suggest through these comments that international pricing disparities are the only ways in which a product should be considered excessively priced and not available on reasonable terms. In some instances, particularly in cases where the patent holder has already made enormous revenues far greater than any private investment it has made in the medicines, including with consideration for risk entailed in development, a reasonable price may be substantially lower than what a

²⁵ The White House, *Fact Sheet: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation*, Triggering Medicare Rebates, (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/>

²⁶ *Id.*

²⁷ The White House, *Remarks by President Biden on Progress to Lower Prescription Drug Costs*, (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/12/14/remarks-by-president-biden-on-progress-to-lower-prescription-drug-costs/>

most favored nation requirement would allow. In other words, this and other examples presented in the framework *should not* be considered exhaustive.

That said, as a less preferred alternative to the above suggestion, the framework could also provide additional clarity on price through setting forth the following standard, a form of which was unanimously supported by members of the Senate Armed Services Committee in 2018,²⁸ and which is yet more conservative than the most favored nation standard:

“Is the product utilizing the subject invention being sold or offered for sale in the United States at a price that is greater than the median of the lowest prices available in other high-income countries?”

Clarifying a greater scope of the practical application criterion for price through adding suggested language on international pricing disparities is essential to maximizing the value of the framework in protecting consumers and taxpayers against price gouging for government-funded medicines and other inventions.

2) Consider more broadly the impact of excessive prices on whether health and safety needs are not reasonably satisfied.

The second criterion of the march-in statute authorizes agencies to march-in when “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees[.]”²⁹ Excessive pricing of medicines can prevent public health and safety needs from being satisfied, and numerous march-in petitions have been presented to the federal government on this basis.

For example, march-in petitioners alleged government action was necessary because Abbott’s pricing of ritonavir threatened the health and safety of people living with HIV/AIDS.³⁰ The latanoprost petition asked the government to march-in, in part based on the health and safety needs criterion, because poor and elderly Americans could not afford Pfizer’s discriminatory pricing.³¹ At the time of the petition, latanoprost was the most commonly used medicine for treating glaucoma; consumers who could not afford it risked going blind without access.³²

²⁸ Knowledge Ecology International, *Senate Armed Services Committee directive on use of Bayh-Dole rights for DoD funded drugs*, (July 17, 2017), <https://www.keionline.org/23404>

Specifically, the Senate Armed Service Committee directive stated: *The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.*

²⁹ 35 U.S. Code § 203(a)(2)

³⁰ Essential Inventions, *Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220*, (Jan. 29, 2004), <https://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf>

³¹ Letter from James Love, President, Essential Inventions, & Sean Flynn, Counsel, Essential Inventions, to Tommy Thompson, Secretary, Department of Health & Human Services (Jan. 29, 2004), <https://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf>

³² *Id.*

While the draft framework correctly acknowledges that price is implicated by the health and safety needs criterion, its consideration of price seems narrower than what plain reading of the statute would permit. Specifically, in the context of second march-in criterion, the framework asks agencies to consider, “Is the contractor or licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?” The guidance presents a corresponding example in scenario 6, under which a company takes advantage of increased demand for a mask during a respiratory virus pandemic to sharply increase price and potentially does not have adequate supply to meet demand.

The “extreme and unjustified” language and the scenario provided suggest a considerably higher threshold for action than demanded by statute, which asks the simple question of whether health and safety needs are not reasonably satisfied. High price could very well pose a barrier to health and safety needs even if they are not “extreme and unjustified” in the broader context of excessive pharmaceutical prices in the United States that have become commonplace. The drug industry’s standard practice of charging U.S. consumers exorbitant sums contributes to three in ten Americans rationing medicine due to cost.³³ In the context where treatment rationing driven by high prices is the norm, it is not clear what would be required to meet the “extreme and unjustified” standard proposed in the framework. Furthermore, widespread drug rationing demonstrates that price can prevent health and safety needs from being met, even as manufacturing supply of a product is not in shortage.

To ensure that the framework allows sufficient space to allow agencies to respond to the failures of patent holders to meet health and safety needs through excessive pricing, we recommend inclusion of the following language in the section on criterion 2:

“Is the contractor or licensee setting a product price that unreasonably contributes to members of the public not accessing a subject invention that could alleviate health and safety needs?”

It should be noted that in reviewing this question, the agency may consider whether an intermediary purchaser has put forth access restrictions in response to the product price. For example, if in response to a high product price set by a contractor or licensee, a private provider of health insurance coverage puts a drug on a formulary tier with high cost-sharing, or puts in place step-therapy or other prior authorization requirements that are not based on medical necessity, the agency may consider the resulting access restriction as directly following from the pricing of the contractor or licensee.”

“Is the ability of any public program to fulfill its mission to serve health and safety needs unreasonably impeded by the product price set by the contractor or licensee?”

³³ Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

3) Consider the Bayh-Dole Act domestic manufacturing preference when evaluating potential licensees for the exercise of march-in rights.

The draft framework guides agencies to ask questions about alternative licensees and their capacity. We support that inquiry but suggest there are additional factors beyond the timing of production, marketing capacity, and price.

When considering alternative licensees for sale of the subject invention in the United States, agencies should evaluate whether such licensees would be able to comply with the requirement of section 204 that the invention be substantially manufactured domestically. While the section 204 requirement only expressly applies to *the exclusive right to sell in the United States*, agencies should retain this preference while considering march-in licensees, when possible.³⁴

Additionally, agencies should also consider other factors, including but not limited to whether a potential licensee currently allows employees a collective voice at work or do they waste resources combatting efforts to unionize?, Do they pay a living wage? Do they have a record of bringing historically underrepresented groups into the manufacturing sector? Such criteria are in line with the Biden Administration's whole-of-government approach to using its leverage to support workers who are organizing and pro-union employers; such criteria are also in line with this administration's promise of "invent it here, make it here."

Thank you for the opportunity to provide feedback on the administration's vital work to protect the public interest in publicly-funded inventions.

Sincerely,

ACA Consumer Advocacy
American Federation of State, County & Municipal Employees (AFSCME)
AIDS Healthcare Foundation
Alliance for Retired Americans
American Family Voices
Beta Cell Action
California Alliance for Retired Americans (CARA)
Center for Popular Democracy
Congregation of Our Lady of Charity of the Good Shepherd, U.S. Provinces
Consumer Action
Health Care Voices
Health Global Access Project
Labor Campaign for Single Payer
Medicare Rights Center
MomsRising
National Advocacy Center of the Sisters of the Good Shepherd
National Committee to Preserve Social Security and Medicare (NCPSSM)
National Nurses United

³⁴ Inability to identify a domestic manufacturer licensee after reasonable efforts should not prevent licensing to another responsible applicant or applicants.

NETWORK Lobby for Catholic Social Justice
People's Action
Public Citizen
Public Interest Patent Law Institute
Revolving Door Project
Rise Up WV
Salud y Farmacos
Service Employees International Union (SEIU)
Social Security Works
T1International
United Food and Commercial Workers International Union (UFCW)
Universities Allied for Essential Medicines
WV Citizen Action

Cc: The Honorable Xavier Becerra, Secretary of Health and Human Services
Dr. Monica M. Bertagnolli, Director, National Institutes of Health
Neera Tanden, Director, Domestic Policy Council, White House