FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

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

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

Honorable Laurie Locascio
Under Secretary of Commerce for Standards and Technologies
Department of Commerce
100 Bureau Dr,
Gaithersburg, MD 20899

Submitted electronically via regulations.gov

Re: 88 FR 85593 - Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Dear Secretary Raimando, Secretary Beccera, and Director Locascio,

Families USA thanks the National Institute of Standards and Technology (NIST), Department of Commerce, and Department of Health and Human Services (HHS) for the opportunity to respond to the *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, and is appreciative of the work of the Interagency Working Group for Bayh-Dole in reviewing this matter. Families USA is a leading national, non-partisan voice for health care consumers which, for over 40 years, has been dedicated to achieving high-quality, affordable health care and improved health for all. Central to realizing that vision is reducing the burden of prescription drug costs on America's families.

The high and rising cost of prescription drugs in the United States is a profound health problem and a significant economic burden on our nation's families. Large drug companies, in their efforts to extract exorbitant profits, too often raise the prices of both existing and new prescription drugs to obscene, price-gouging levels. As a result, U.S. drug prices are nearly twice as high as prices in other comparable countries, even after rebates.[i] The impact of these high prescription drug costs on individuals and families who rely on these medications is clear: because of cost, almost 30% of adults did not take their medications as prescribed in the past year — rationing, skipping doses, or not filling their prescriptions at all.[ii] Being forced to make those decisions directly results in poorer health outcomes. Rationing and skipping needed medication causes an estimated 125,000 deaths per year.[iii]

Families USA appreciates the administration's work to rein in out-of-control drug costs and hold drug companies accountable for pricing abuses. Specifically, we believe implementation of the *Inflation Reduction Act* (IRA), particularly through the Medicare drug price negotiation program, will provide critical relief for the millions of older adults and people with disabilities who rely on Medicare for their medications. The reforms put into effect in the past year—including capping out-of-pocket costs for

insulin at $35, ensuring drug corporations are held accountable when they raise costs higher than the rate of inflation, and making additional adult vaccines free of cost—will save families millions of dollars.[iv]

In addition to these reforms, march-in authority is an important tool available for federal agencies to promote access to prescription drugs. March-in rights allow the federal government to change the patent or licensing rights for a subject invention—a product or invention whose development was federally funded—for a different party's use. This process is available in instances when the federal government must act to achieve practical application, alleviate a health or safety need, meet the requirements for public use, or address a failure in manufacturing for U.S. commerce.[v] Families USA applauds the administration's efforts to strengthen and promote access to products developed with funding from the federal government, and by extension the taxpayers, through the use of march-in rights. The efforts are especially critical for prescription drug research and development, and affordability. Clarifying the march-in guidance will help protect consumers and taxpayers by ensuring federal investments in life saving and sustaining prescription drugs yield affordable and accessible products for those who rely on them.

To assist in the administration's review, this comment letter will focus on two specific questions included in the RFI:

- Question 1. After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?
- Question 4. Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?

Question 1. After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?

Families USA strongly supports the Department of Commerce's guidance that explicitly includes price as a factor in determining whether to initiate march-in proceedings and recommends clarifying what constitutes "unreasonable" and "extreme, unjustified, or exploitative" prices.

Because of market dominance, many drug companies can price gouge freely, raising prices year after year at shocking rates – often on medications that they have long since released. These price increases are wholly unrelated to the effectiveness of a drug over time. One study of high-spend drugs showed that seven of the 10 drugs reviewed provided no additional clinical benefit relative to other available drugs to justify their high list price or price hikes.[vi] By establishing price as a factor for march-in, the proposed guidance makes a critical recognition that abusive pricing practices of drug companies and their overinflation of existing drug prices are key drivers of health and health care affordability. Families USA supports the proposed march-in guidance as it will help HHS address unfounded and out-of-control prescription drug prices and provide an opportunity to critically evaluate the pricing and patenting practices of big drug companies.

Specifically, price is identified as a factor that must be considered in two important places within the proposed guidance:

- In criterion 1, the proposed guidance describes the "reasonableness of price" as a factor in determining practical application and access to the product.[vii]
- In criterion 2, the proposed guidance describes weighing whether the "contractor or the licensee [is] exploiting a health or safety need in order to set a product price that is extreme and unjustified" as well as whether "the price is extreme, unjustified, and exploitative" as factors in determining whether health and safety needs are satisfied. [viii]

Families USA recommends that, in addition to establishing price as a factor, the guidance provide more clarity on what specifically constitutes an "unreasonable" or "extreme, unjustified, or exploitative" price.[ix] Providing more clarity around these terms is necessary to protect consumers. Additional clarity will allow researchers, policymakers, consumer advocates, and drug companies to better monitor prices and take appropriate action to prevent or address out-of-control prices. Greater clarity will also offer better protection to consumers by leaving less room for subjective interpretations of the guidance. To accomplish this, the final guidance should offer additional steps, considerations, and methods for evaluating a prescription drug's price.

We acknowledge that constructing this guidance will require some degree of flexibility in order to account for unique or unforeseen circumstances, and that "one size fits all" thresholds are not desirable. But there are successful programs already implemented by the federal government that evaluate fair drug prices and unreasonable price increases, guided by examples of certain kinds of evidence. For example, the IRA inflation rebate program identifies unreasonable price increases that require government intervention by tracking increases beyond the rate of inflation. Moreover, the Medicare drug price negotiation program has established a process to evaluate and reach fair prescription drug prices in Medicare that includes (but is not limited to) consideration of comparative effectiveness, unit costs of production and distribution, therapeutic value in comparison to alternatives, and addressing unmet medical need.[x] **Families USA recommends that the Department of Commerce and HHS look to examples from these successful programs to determine their own metrics for evaluating price as a factor in march-in proceedings and in this proposed guidance.** Clear and strong guidelines for assessing prices are critical to the agency's ability to improve access to these products in a market where pricing distortions are already present and prominent.

Question 4. Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?

Families USA recommends that the administration explicitly consider the frequency and implication of abuse in the pharmaceutical patent system when addressing public utilization, utilization of inventions, and the central objectives of the *Bayh-Dole Act*. The proposed guidance highlights how the practice of march-in proceedings should support the goals of the *Bayh-Dole Act* in promoting U.S. innovation and the "public availability" of those products whose development was funded by the federal government and taxpayers.[xi] However, practices like pay-for-delay (paying potential competitors to not produce a generic drug) and patent thickets (blanketing one drug with multiple overlapping patents) are

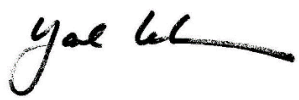
commonplace in the prescription drug market and result in elongated exclusivity for certain drugs, and restriction on additional innovation and marketing of competition. These practices ultimately allow drug companies to raise prices on their products year after year,[xii] stifle innovation, and put lifesaving and sustaining medications out of reach for U.S. consumers. The administration should also consider these practices during march-in right proceedings for prescription drugs as they are critical to the accessibility of medications and whether a march-in order would serve the *Bayh-Dole Act's* goal of promoting invention and commercialization of products.

Families USA is concerned about guidance language that makes special considerations for industry, even when many industry actors are currently abusing their privileged market position to make outrageous profits, as many drug companies do. Specifically, when considering whether to initiate march-in proceedings, agencies should not be weighing the "potential chilling effect on the agencies' existing relationships with industry and ability to address Administration priorities" as currently written in the proposed guidance at 88 FR 85593, 85601. A more appropriate standard focused on the ability to address administration priorities would relate to ensuring market access to subject inventions for all consumers.[xiii] Many drug companies already demonstrate a propensity toward abusing patent law, limiting competition, and price gouging rather than engaging in fair market practices that will help people live longer, healthier lives.[xiv] They do not need another policy lever in their arsenal.

In short, Families USA recommends that the guidance consider the effects of pharmaceutical patent law, and drug company patent abuse practices, when assessing public utilization of subject inventions, and remove language from the guidance that puts the importance of industry relationships over impact on consumers.

Families USA thanks the NIST, Department of Commerce, and HHS for the opportunity to weigh in on this important issue and provide information on proposed guidance for the use of march-in rights. Ensuring that life saving and sustaining medications are accessible and affordable for all those who need them is critically important for the health and financial wellbeing of people across America, and Families USA commends the administration for their continued investment in this mission. For further information or questions, please contact Hazel Law at hlaw@familiesusa.org.

Sincerely,



Yael Lehmann
Interim Executive Director
Families USA

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[ii] "Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, Including Larger Shares Among Those With Health Issues, With Low Incomes and Nearing Medicare Age," KFF, n.d., https://www.kff.org/ health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicinesincluding-larger-shares-with-low-incomes/.;
Ashley Kirzinger et al., "Public Opinion on Prescription Drugs and Their Prices," KFF, August 21, 2023, https://www.kff. org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

[iii] Hayden Bosworth et al., "Medication Adherence: A Call for Action," American Heart Journal 162, no. 3 (September 2011): 412–424, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/.;
Fred Kleinsinger, "The Unmet Challenge of Medication Nonadherence," Permanente Journal 22 (2018): 18–33, https:// www.ncbi.nlm.nih.gov/pmc/articles/PMC6045499/.

[iv] https://www.aspe.hhs.gov/index.php/reports/inflation-reduction-act-2022-one-year-anniversary-highlights-aspe-drug-pricing-reports

[v] 35 US Code 203, https://www.law.cornell.edu/uscode/text/35/203

[vi] Eliot Fishman, Our Broken Drug Pricing and Patent System Diverts Resources Away From Innovation and Into Mergers, Patent Gaming and Price Gouging (Washington, DC: Families USA, August 2021), https://familiesusa.org/wp-content/ uploads/2021/08/RX-2021-209_Innovation-Drug-Pricing-Issue-Brief.pdf.

[vii] 88 FR 85593 pg. 18, 21. 2023-26930.pdf (federalregister.gov)

[viii] 88 FR 85593 pg. 18, 21. 2023-26930.pdf (federalregister.gov)

[ix] 88 FR 85593 pg. 27. 2023-26930.pdf (federalregister.gov)

[x] "Inflation Reduction Act and Medicare," CMS, last updated September 12, 2023, https://www.cms.gov/inflation-reduction-act-and-medicare#:~:text=The%20new%20law%20requires%20drug,price%20increases%20by%20drug%20companies.;
Medicare Drug Price Negotiation Program, "Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program," CMS, September 2023, https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf

[xi] 88 FR 85593 pg. 25, 2023-26930.pdf (federalregister.gov)

[xii] Law, Hazel, and Sophia Tripoli, "Paying the Price: How Drug Manufacturers' Greed Is Making Health Care Less Affordable for All of Us," Families USA, November 2023, https://familiesusa.org/wp-content/uploads/2023/11/Rx-Premium-paper_-for-publishing.pdf;
Kelmar, Patricia, and Abe Scarr, "The Cost of Prescription Drug Patent Abuse," U.S. PIRG Education Fund, April 2023, https://pirg.org/edfund/resources/the-cost-of-prescription-drug-patent-abuse/

[xiii] 88 FR 85593 pg. 28. 2023-26930.pdf (federalregister.gov),
"Would exercise of march-in impact utilization of subject inventions more broadly?... Agencies should consider the potential chilling effect on the agencies' existing relationships with industry and ability to address Administration priorities."

[xiv] Eliot Fishman, Our Broken Drug Pricing and Patent System Diverts Resources Away From Innovation and Into Mergers, Patent Gaming and Price Gouging (Washington, DC: Families USA, August 2021), https://familiesusa.org/wp-content/ uploads/2021/08/RX-2021-209_Innovation-Drug-Pricing-Issue-Brief.pdf.