



AFL-CIO

AMERICA'S UNIONS



**American Federation
of Labor and
Congress of Industrial
Organizations**

815 Black Lives Matter
Plaza NW
Washington, DC 20006

202-637-5000

aflcio.org

EXECUTIVE COUNCIL

ELIZABETH H. SHULER
PRESIDENT

FREDRICK D. REDMOND
SECRETARY-TREASURER

Cecil Roberts
Matthew Loeb
Randi Weingarten
Baldeemar Velásquez
Lee A. Saunders
James Callahan
Sean McGarvey
D. Taylor
Stuart Appelbaum
Mark Diamondstein
Sara Nelson
Marc Perrone
Eric Dean
Richard Lanigan
Robert Martinez Jr.
Gabrielle Carteris
Mark McManus
Elissa McBride
John Samuelson
Vonda McDaniel
Gwen Mills
Charles Wowkanech
Bonnie Castillo
Ernest A. Logan
James Slevin
John Costa
Tim Driscoll
Everett Kelley
Anthony Shelton
Edward A. Kelly
Evelyn DeJesus
Cheryl Eliano
Matthew S. Biggs
Roxanne Brown
Arthur Maratea
James A. Williams Jr.
Ben Valdepeña
Meghann Burke
Bernie Burnham
Gina Cooper
Frank Christensen
Roland Rexha
Rich Santa
Jason Ambrosi
Kenneth Cooper
Brian Renfro
Shawn Fain
Brent Booker
Michael Coleman
Claude Cummings Jr.
David Heindel
Margaret Mock
David McCall

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:

The American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) and the AFL-CIO Technology Institute (Tech Institute) write to express our support for strengthening and finalizing the “Interagency Guidance Framework for Considering the Exercise of March-In Rights.” The AFL-CIO is a voluntary, democratic federation of 60 affiliated unions representing more than

12.5 million workers in all sectors of our economy. The AFL-CIO is committed to fairness in the workplace and health security for working people and their families; we seek to ensure that hard work is rewarded with family-supporting wages and benefits, and that our workplaces are safe. Our affiliates represent millions of members in manufacturing and advocate for a revitalized manufacturing sector through policies that are good for working people, our communities, and the economy. We also provide an independent voice in politics and legislation for working women and men and make their voices heard in corporate boardrooms and the financial system. The Tech Institute is an independent, non-partisan organization founded by the AFL-CIO in 2021. The Tech Institute seeks to provide workers a co-equal voice in the research and development (R&D) system and to address the technological changes sweeping the workplace and society.

The AFL-CIO and the Tech Institute commend the Administration for clarifying the conditions under which the federal government can utilize its march-in rights to ensure that inventions that are the result of federal investments are available to consumers. Section 202 of the Bayh-Dole Act¹ provides an important tool for preventing the unfair treatment of taxpayers who have already paid for these products once through public research grants and other government funding. In particular, we commend the Administration for recognizing that price is a factor in determining whether a taxpayer-funded invention is accessible to the public. This policy determination will be particularly helpful in addressing the high price of pharmaceuticals developed through federal funding.

Of course, the draft framework applies beyond the question of appropriate pricing of pharmaceuticals developed through federal investments. When finalized, this framework will apply to all products that are the result of federal investments. The decision to seek alternative license holders could be an important instrument in this Administration's efforts to both revive advanced manufacturing and improve the domestic supply chain for critical goods; it is also an important tool for growing an economy that puts workers first and ensuring that federal investments are nurturing high-road employers. The AFL-CIO and the Tech Institute appreciate the admonition for an agency to consider the "totality of the circumstances" when considering whether and how to exercise march-in rights; we believe this should include the track record of alternative licenses.

The draft framework addresses a number of vital issues. We will limit our comments to three specific areas of concern:

- The potential use of march-in rights to address the high price of prescription drugs that rely on inventions funded through federal investments;
- The potential use of march-in rights to improve manufacturing jobs by nurturing and advantaging high-road employers; and
- Using the Bayh-Dole process to aid in revitalizing the manufacturing sector.

Access to Prescription Drugs

We applaud the National Institute of Standards and Technology (NIST) for recognizing the potential role of march-in rights to improve access to medicines. Even for workers with good health insurance, the cost of prescription drugs can be a significant financial burden on working

¹ Patent and Trademark Law Amendments Act (Pub. L. No. 96-517, 94 Stat. 3015 (1980)).

families compared to their peers in other industrialized countries. For more than a decade, the United States has had the highest per capita prescription drug spending, averaging \$1,432 per American in 2021. Prescription drug spending per capita is approximately one-third higher in the U.S. than in Germany, the Organization for Economic Cooperation and Development (OECD) member country with the next-highest spending, and more than double the OECD average. With such high prices, it is not surprising one out of every three adults in the U.S. taking a prescription drug has had to ration their medication due to cost.²

The burden of prescription drug prices is evident in the growing problem of medical debt. According to Census data, approximately 1 out of 6 households owed medical debt in 2019 (defined as owing over \$250 in unpaid medical bills to distinguish this from people who owe relatively small amounts). Approximately 16 million people (6% of adults) in the U.S. owe over \$1,000 in medical debt and 3 million people (1% of adults) owe medical debt of more than \$10,000. By 2021, the high price of prescription drugs was responsible for an estimated 30% of the total \$195 billion in medical debt burdening working families.³

Taxpayers should not have to pay high prices for drugs developed in part through federal funding. In recent years, the federal government has spent billions of dollars on basic research that catalyzes the discovery of drugs or advances their subsequent development.⁴ According to data from the Food and Drug Administration, the public sector funded the necessary basic research for 19 of 26 transformative drugs and drug classes; NIH funding also supported at least one publication related to each of the 210 new medicines approved by the agency between 2010 and 2016.⁵

The AFL-CIO and the Tech Institute commend the Administration for clarifying the conditions under which the federal government can utilize its march-in rights to address the high price of

² Sam Hughes, Nicole Rapfogel, *Following the Money: Untangling U.S. Prescription Drug Financing* (Washington, DC, Center for American Progress, 2023). Available at <https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/>.

³ Matthew Rae, Gary Claxton, Krutika Amin, Emma Wager, Jared Ortaliza, and Cynthia Cox, *The Burden of Medical Debt in the United States* (Washington, DC, Peterson Center on Healthcare and the Kaiser Family Foundation, 2022). Available at [https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/#Share%20of%20adults%20who%20have%20more%20than%20\\$250%20in%20medical%20debt,%20by%20household%20income%20and%20insurance%20status.%202019](https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/#Share%20of%20adults%20who%20have%20more%20than%20$250%20in%20medical%20debt,%20by%20household%20income%20and%20insurance%20status.%202019); Lunna Lopes, Audrey Kearney, Alex Montero, Liz Hamel, and Mollyann Brodie

Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills (Washington, DC, Kaiser Family Foundation, 2022). Available at <https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/>.

⁴ The White House *Fact Sheet: Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition*, December 7, 2023. Available at <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/>

⁵ David Mitchell, "Taxpayers Fund Research and Drug Companies Make a Fortune," *New York Times*, March 24, 2021. Available at <https://www.nytimes.com/2021/03/24/opinion/coronavirus-vaccine-cost-pfizer-moderna.html>; Rena M. Conti, Frank S. David, "Public Research Funding and Pharmaceutical Prices: Do Americans Pay Twice For Drugs?," *F1000 Research*, 9:707 (July 15, 2020). Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642989/>.

prescription drugs. Section 202 of the Bayh-Dole Act provides an important tool for the federal government to assure reasonable access to drugs that taxpayers have already paid for once through federal grants and other funding. While pharmaceutical manufacturers are entitled to a reasonable rate of return, fair pricing must take into account the public investments that made the development and commercialization of drugs possible in the first place.

Broader Consideration of Price

Although the framework carefully lays out the criteria that must be met for an agency to exercise march-in rights, the AFL-CIO and the Tech Institute urge the Administration to take a more expansive view of the role of price.

Under criteria 1, march-in rights may be appropriate when the subject invention is being offered to the public at a price that is not reasonable. In the case of a commercialized product, the draft framework directs the agency to consider “at what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.”⁶

We strongly urge the agency to consider not only the price of the subject invention in the U.S. but in other industrialized countries as well. The healthcare system in the U.S. is a global outlier in the price-setting power of pharmaceutical manufacturers. According to a 2021 study from the RAND Corporation, the price of brand-name prescription drugs in the United States is two and a half times more expensive than in other industrialized nations (Austria, Australia, Belgium, Canada, Germany, Japan, Sweden, Switzerland, and the United Kingdom).⁷ These higher prices are not the result of market forces. Rather, they are a direct result of pricing strategies, patent abuses, and anti-competitive measures that allow the license holder to price these products beyond the reach of many domestic consumers. An analysis of price that is limited to the U.S. market will have a distorted view of reasonableness.

Under criteria 2, the exercise of march-in rights may be appropriate if the contractor sets a price that is “extreme.”⁸ We believe the draft framework sets the bar too high when it comes to meeting the goal of ensuring the development of new products in the U.S. and their availability to consumers here. Limiting the use of march-in rights to cases of “extreme” prices appears to sanction high but not unusual prices for pharmaceuticals that were developed with government funding. Given the admonition for agencies to “prioritize both incentivizing U.S. innovation and promoting access to the fruits of that innovation,”⁹ we believe the standard for medicines should be whether the price is high enough to significantly affect access by patients, including the impact of prices on premiums and cost-sharing. Given that the draft framework directs agencies to consider the unmet health and safety needs of the population, we believe that agencies should consider how payers react to high prices, either through tiering of pharmaceuticals, utilization

⁶ National Institute of Standards and Technologies (NIST), United States Department of Commerce. “Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.” Vol. 88 *Fed. Reg.* No 235, (December 8, 2023): page 85599.

⁷ Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons* (Santa Monica, CA: RAND Corporation, 2021). Available at <https://www.rand.org/news/press/2021/01/28.html>

⁸ NIST RFI, *supra*, note 6.

⁹ *Id.*

management strategies, and decisions not to cover certain drugs or certain type of care that would require the use of high-cost drugs.

Agencies are also directed to consider the scope of the problem. It is our view that the health needs in question should not have to be widespread; there does not need to be a pandemic to trigger march-in rights. The health conditions should not have to be life-threatening; march-in rights should not be limited to federally funded medicines that are used to treat otherwise fatal conditions. There are many health conditions that may not be life-threatening but may have a significant impact on one's quality of life (e.g. rheumatoid arthritis) or may affect a relatively small number of people (sickle cell disease). In fact, an individual needing medicine to address a rare disease will have fewer choices in the marketplace and is more vulnerable to the market power of a license holder.

We agree with the draft framework that the use of march-in rights should not be limited to price increases.¹⁰ We have seen launch prices for pharmaceuticals that would have been considered exorbitant have over the last two decades been normalized.¹¹ The result is that both government programs and commercial insurers have refused or significantly limited access to such drugs.¹² The problem is likely to get worse as additional gene therapies and biologics are commercialized.¹³ Given this trend, it is clear that access to a broad spectrum of drug therapies will depend on the government proactively examining launch prices, rather simply reviewing annual or semi-annual price increases. Any other strategy would leave too many workers without

¹⁰ Price increases are also a major problem in the pharmaceutical sector. The industry has a history of semi-annual price increases that exceed the rate of inflation; these occur long after the drug has been introduced and priced and do not correspond to any change in a drug's clinical value or level of innovation.

¹¹ Between 2008 and 2021, drug launch prices grew 20% annually, starting with an average of \$2,115 to more than \$180,000, researchers said in a new study in the Journal of the American Medical Association. From 2020 to 2021, nearly half — 47% — of new drugs hit the market with prices of more than \$150,000 per year. We are entering an era when it is not uncommon to see biologic drugs with launch prices over a million dollars. Eric Sagonowsky, "Runaway Train: Drug Launch Prices Have Grown 20% Annually For More Than A Decade, and It's Time For Congress to Act, Researchers Say". *Fierce Pharma*, June 9, 2022. Available at <https://www.fiercepharma.com/pharma/runaway-train-drug-launch-prices-have-grown-20-annually-more-decade-and-its-time-congress>

¹² *Options to Reduce State Medicaid Costs: Prescription Drugs*, Center on Budget and Policy Priorities, October 2020. Available at <https://www.cbpp.org/research/health/options-to-reduce-state-medicare-costs-prescription-drugs#:~:text=States%20are%20also%20free%20to,to%20ensure%20their%20efficient%20use>. Hannah Katch, "CMS Opens Door to State Restrictions on Medicaid Beneficiaries' Access to Medications," Center on Budget and Policy Priorities, July 11, 2018. Available at <https://www.cbpp.org/blog/cms-opens-door-to-state-restrictions-on-medicare-beneficiaries-access-to-medications>. Haiden A. Huskamp, "Pharmaceutical Cost Management and Access to Psychotropic Drugs: The U.S. Context." *Int. J. Law Psychiatry*, Sept-Oct; 28(5): 484-495 (2005). Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1378114/>. Stephanie Lomas, *The Debate Over Step Therapy*, Applied Policy, June 2023. Available at <https://www.appliedpolicy.com/step-therapy/#:~:text=Step%20therapy%20has%20been%20identified,adopted%20by%20some%20Medicaid%20programs>. Rachel E. Sachs and Michael Anne Kyle, "Step Therapy's Balancing Act — Protecting Patients While Addressing High Drug Prices," *N Engl J Med* 2022 Mar 10; 386(10): 901-904. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9067323/>

¹³ Fraiser Kansteiner, Zoey Becker, Angus Liu, Eric Sagonowsky, Kevin Dunleavy, "Most Expensive Drugs in the US in 2023," *Fierce Pharma*, May 22, 2023. Available at <https://www.fiercepharma.com/special-reports/priciest-drugs-2023>.

the medical recourse they need; for many, it would effectively shut the door to the medical safety net they have paid for through their tax dollars.

Improve the Administrative Process

We are also concerned about the administrative process described in the draft framework, which lacks timeliness, transparency, or the opportunity for public input. If an agency decides to investigate the appropriateness of march-in rights, the contractor is notified and brought into the process. Consultations occur and the contractor is given the opportunity to submit evidence in opposition to the triggering of march-in rights and, if there is a fact-finding phase, present witnesses and appear with counsel. The contractor is given an opportunity to defend the status quo and suggest alternatives that do not involve the exercise of march-in rights. All of this appears to go on behind closed doors. Stakeholders, whose petition may be the triggering event for the agency's investigation, are not allowed to provide evidence or rebut claims. At the end of the process, a written finding will be sent to the contractor but there is no mention of the agency's decision being made public.

We are not suggesting that the agency investigation resemble a traditional administrative hearing, but all sides should be allowed to submit information and, to the extent feasible given the possible presence of trade secrets and proprietary information, be present during the presentation of information. Petitioners as well as current license holders should be allowed to have counsel present. There should be a decision on the record and, since the license holder's remaining patent life is a mitigating factor, there should be a clear deadline for agency action. We realize these may be seen as significant changes, but they are necessary to instill public confidence in the fairness of the process.

Nurturing High-Road Employers

Our comments so far have focused on the behavior of the current licensee in determining whether any of the statutory criteria for triggering march-in rights have been met. We note the admonition of the draft framework that agencies consider not only the behavior of licensees but whether there is in fact a viable alternative to the current licensee. We urge agencies to employ the same "totality of all circumstances" approach to this equally important question. Specifically, we suggest agencies give substantial consideration to whether the exercising of march-in rights would advance the Administration's broader policy goals of growing the economy "from the middle out and the bottom up." This can be done by ensuring that alternative licensees are "high-road employers." This means looking for alternative licensees that allow employees who want to join a union to do so without objection; it means looking for alternative licensees that pay a living wage with family-sustaining benefits in a safe, healthy, and accessible workplace. We urge agencies to consider whether potential licensees adhere to the Good Jobs Principles developed by the Department of Labor¹⁴. These are criteria that would meaningfully advance the Administration's goal of increasing worker organizing and empowerment.¹⁵ We believe the likely performance of a potential licensee must be carefully considered as part of the exercise of march-in rights.

¹⁴ Department of Commerce and Department of Labor, *Good Jobs Principles*, accessed February 5, 2024, <https://www.dol.gov/sites/dolgov/files/goodjobs/Good-Jobs-Summit-Principles-Factsheet.pdf>

¹⁵ Department of Labor, *White House Task Force on Worker Organizing and Empowerment*, accessed February 5, 2024 <https://www.dol.gov/general/labortaskforce>.

Using Section 204 to Revive and Maintain the Manufacturing Sector

The march-in provisions of the Bayh-Dole Act have the potential not only to improve access to federally funded pharmaceuticals but to help strengthen the manufacturing sector. Federal funding has helped American researchers to discover many of the world's most important technologies. Although Bayh-Dole was intended to accelerate the commercialization of these inventions, it was supposed to do so in a way that retained domestic manufacturing. Unfortunately, it has not worked out that way. Many of these inventions ended up in products that are manufactured overseas.¹⁶ The Economic Policy Institute reports that from 1998 to 2021 more than 5 million manufacturing jobs and 70,000 manufacturing plants have been lost.¹⁷

We applaud NIST for recognizing that compliance with section 204 is a rationale for exercising march-in rights. Such an approach will improve the federal government's ability to make sure that federally funded products invented can be substantially manufactured here. Specifically, we appreciate the recognition in scenario 8 that there needs to be greater accountability for contractors who refuse multiple options for domestic manufacture. This draft framework policy sends a clear message "that the U.S. industry preference provisions of the Bayh-Dole Act will be enforced."

It is worth noting that a more aggressive use of Section 204 also has additional strategic benefits in the longer term. Keeping manufacturing in the U.S. supports technological supply chains and ecosystems that foster innovation critical to local and regional economies.¹⁸ Furthermore, supporting these domestic manufacturing ecosystems promotes a resilient manufacturing base for products that are critical for national security.¹⁹ Multiple products, including pharmaceuticals, semiconductors and advanced packaging, and large-capacity batteries, have been identified by this Administration as critical supply chains where greater domestic manufacturing capacity is sorely needed.²⁰ Using Bayh-Dole to ensure a robust domestic manufacturing base also drives demand for workforce development – producing the kind of skilled workers necessary for

¹⁶ Courtney Flatt and Laura Sullivan, "The U.S. Made a Breakthrough Battery Discovery- Then Gave the Technology to China," *NPR*, August 3, 2022 <https://www.npr.org/2022/08/03/1114964240/new-battery-technology-china-vanadium> ; Sridhar Kota, Justin Zorn, and Tom Mahoney, *How the U.S. Can Build Its Capacity to Innovate* (Harvard Business Review: 2018). <https://hbr.org/2018/10/how-the-u-s-can-rebuild-its-capacity-to-innovate>

¹⁷ Robert E. Scott, Valerie Wilson, Jori Kandra, and Daniel Perez, *Botched Policy Responses to Globalization have Decimated Manufacturing Employment with Often Overlooked Costs for Black, Brown, and Other Workers of Color*, (Washington, DC: Economic Policy Institute, 2022). <https://www.epi.org/publication/botched-policy-responses-to-globalization/>

¹⁸Department of Commerce and Department of Homeland Security, *Assessment of the Critical Supply Chains Supporting the U.S. Information and Communications Technology Industry*, (Washington, DC, Department of Commerce and Department of Homeland Security: 2022).

<https://www.commerce.gov/sites/default/files/2022-02/Assessment-Critical-Supply-Chains-Supporting-US-ICT-Industry.pdf> ; <https://www.eda.gov/news/blog/2023/10/20/tech-hubs-aim-make-united-states-global-leader-technologies-future>

¹⁹Devon Bistarkey, *U.S. Manufacturing Ecosystem Key to Economic Growth, Innovation, Competitiveness*, (Washington, DC, Department of Defense: 2022) <https://www.defense.gov/News/News-Stories/Article/Article/3189049/us-manufacturing-ecosystem-key-to-economic-growth-innovation-competitiveness/>

²⁰White House, *Fact Sheet: Securing America's Critical Supply Chains*, February 24, 2024 <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/fact-sheet-securing-americas-critical-supply-chains/>

products that are part of these supply chains and that help innovation flourish.²¹ The combination of preserving manufacturing jobs, boosting workforce development, increasing economic growth, and protecting national security have powerful, long-term benefits that are mutually reinforcing. Making sure licensees comply with section 204 – rather than ask for a waiver – is an important place to start this virtuous economic cycle.

Section 204 Waiver Process

Although this draft framework is focused on the conditions that would justify an agency exercising its march-in rights, we would be remiss if we did not take this opportunity to urge the Administration to take further action to improve the section 204 waiver process. Specifically, we urge NIST and Department of Commerce officials to consider policies that would introduce greater transparency and accountability into the waiver process. To the extent possible under federal laws governing the confidentiality of sensitive information and company trade secrets, we urge officials to consider additional requirements that introduce more accountability into the process. We believe an agency considering a section 204 waiver should do the following:

- In a timely manner, publish a notice of any application for a waiver;
- Hold one or more public hearings on the waiver application with adequate opportunities for stakeholders to provide input;
- Publish the agency's decision on the waiver application that includes the rationale for the agency's decision; and
- Annually or semi-annually, publish a list of existing waivers with the locations of foreign manufacture and the licensee.

We believe these steps are necessary to ensure that stakeholders with a vested interest in the outcome have an opportunity to participate in the process and for agency officials to understand the broader patterns in U.S. manufacturing.

Conclusion

Thank you for this opportunity to comment on this important policy document, which has the potential to reduce the cost of health care for millions of working families and bolster the manufacturing sector. We look forward to working with you throughout the regulatory process. If you have any questions, please feel free to contact either Lee Goldberg (lgoldberg@aflcio.org), the AFL-CIO's health policy specialist, or Garrett Andrew Schneider (gschneider@aflciotechinstitute.org), the Technology Institute's Research & Policy Director.

Sincerely,

Amanda Ballantyne, Executive Director, AFL-CIO Technology Institute

William Samuel, Director of Advocacy, AFL-CIO

²¹Department of Commerce, *Training a World-Leading and Diverse Manufacturing Workforce*, (Washington, DC: Department of Commerce, 2023) <https://www.commerce.gov/news/blog/2023/10/training-world-leading-and-diverse-manufacturing-workforce>