February 6, 2024

Laurie Locascio
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Attention: Docket 230831-0207

Dear Director Locascio,

We Work For Health welcomes the opportunity to comment on the National Institute of Standards and Technology (NIST) Request for Information (RFI) entitled "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," published in the *Federal Register* on December 8, 2023.

Since the passage of the Bayh-Dole Act in 1980, the law's provisions have helped deliver more than 200 new medicines to patients. We Work For Health urges you to explore all that this policy has allowed over the past 40 years and its original intent. We recommend this proposed framework is withdrawn as written so that future patients do not lose out on the important medicines that can result from the successful public-private partnerships that the Bayh-Dole Act allows and embraces.

Founded in 2007, We Work For Health (WWFH) brings together national and local business leaders, along with labor, biopharmaceutical, patient advocacy, and other healthcare-related stakeholders to support policies and initiatives that foster innovation and facilitate the delivery of lifesaving and life-enhancing medicines. As the bedrock of innovative jobs in the U.S. today, the life sciences sector supports more than 4.4 million American employees and directly provides over 900,000 jobs.[1] Together, these jobs provide 22% of all high-quality research and development jobs, the largest of any U.S. industry.[2] Advancing and protecting these jobs is critical for those employees, the economies they support, and the patients they serve.

The Bayh-Dole Act enabled research institutions to patent and offer exclusive license rights for discoveries made while receiving federal funds.[3] Creating a path for further development and incentives enabled the private sector to advance these subject inventions and ensure

[1] We Work For Health. 2021. Available at: https://www.weworkforhealth.org/in-the-states.
[2] Ibid.
[3] The University and Small Business Patent Procedures Act of 1980, Public Law 96-517. December 12, 1980.

discoveries did not remain stuck in research laboratories or academic papers. The Bayh-Dole Act codified four limited circumstances enabling "march-in" rights and requiring licensure to another entity to ensure further actions were taken to develop and achieve practical applications of these patents.

Over the years, petitions have requested the four criteria to consider for march-in rights to be expanded and include price. In 2021, A Notice of Proposed Rulemaking included provisions prohibiting the exercise of march-in rights based exclusively on price. [4] However, these provisions were halted and NIST was directed to solicit stakeholder feedback on a comprehensive framework.[5] The resulting "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" now considers price a factor. The proposed framework seeks to 1) guide federal funding agencies regarding facts and factors to consider when determining whether to exercise march-in rights, 2) safeguard the policy and objectives of the Bayh-Dole Act, 3) ensure consistent and predictable application of march-in authorities across agencies, and 4) balance incentives for industry investment with public use of the inventions discovered while under federal funding.

Our comments focus on biopharmaceuticals and medical innovation but are applicable across technology sectors and industries. We remain concerned that this proposed framework is antithetical to the original intent and will depress the robust research and development ecosystem within the U.S., and we recommend withdrawing this proposed framework. Our concerns focus on three provisions:

- Inclusion of Price in March-In Criteria Threatens the Success of the Bayh-Dole Act and Its Policy and Objectives
- Inclusion of Price Would Chill Technology Transfer and the Development and Commercialization of Federally Supported Innovations
- Flaws Hinder Rather Than Help with the Interpretation of the Framework

Inclusion of Price in March-In Criteria Threatens the Success of the Bayh-Dole Act and Its Policy and Objectives

Before the Bayh-Dole Act, government-funded research was out of reach for the American public. Medical discoveries remained inaccessible to patients given the complex, costly, and challenging process of developing, seeking regulatory approval, and commercializing new treatments. Across all technologies, over 28,000 patented inventions existed, but fewer than 1,000 were developed for public use.[6] Despite significant investment in scientific and medical

[4] Notice of Proposed Rulemaking. Rights to Federally Funded Inventions and Licensing of Government Owned Inventions. Federal Register. vol 86, no 35, 35-44. January 4, 2021.
[5] Final Rule. Rights to Federally Funded Inventions and Licensing of Government Owned Inventions. Federal Register vol 88, no 57, 17730-40, March 24, 2023.
[6] U.S. General Accounting Office, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities, GAO/RCED-98-126, 3. May 1998. Available at: https://www.gao.gov/assets/rced-98-126.pdf.

research, Congressional testimony noted, "not a single drug has been developed when patents were taken from universities by the federal government."[7]

The proposed framework outlines that "encouraging development and commercialization is a central objective of the Bayh-Doyle Act." In the 25 years between 1996 and 2020, these transfers contributed to over 6,800 startups and between $333 billion and $1 trillion to the U.S. gross domestic product (GDP).[8] In 2022 alone, more than 850 commercial products were developed, and 998 startups were formed.[9] From airport scanners, honey crisp apples, Google search algorithms, cloud computing, firefighting drones, and touchscreen technology, these inventions impact the economic engine of the United States and our daily lives.[10]

Since 1980, more than 200 new medications approved by the Food and Drug Administration (FDA) for public use have been associated with federal funding. Though roughly 9-10 percent of new drugs have at least one government-interest patent disclosure, very few of these include "mechanism of action" or 'composition of matter" patents. [11,12,13] Most federal health research funds do not extend beyond basic science. Translating this research into evidence, knowledge, and practical application is associated with high failure rates, numerous collaborations, and lengthy testing – all of which are undertaken by the private sector. Consider, for example, the revolutionary gene-editing therapies based on CRISPR technologies. It took more than two decades for researchers worldwide to adapt this technology to human cells. However, licenses and another decade of testing were needed to transform this technology into treatment for sickle cell disease.

Significant private sector investment is critical to transforming the discovery of a target, chemical, or pathway forward for further development, testing in clinical trials, FDA approval, and delivery to patients. Among products approved with some federal funding in the last 20 years, the private sector invested $67 for every $1 provided by the federal government. This substantial ratio of private to public sector funding holds across neurology ($80 to $1),

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[7] Statement of Elmer B. Staats, Comptroller General of the United States, Before the Committee on the Judiciary United States Senate, "S. 414-The University and Small Business Patent Procedures Act," May 16, 1979. Available at: https://www.gao.gov/assets/100/99067.pdf.
[8] Pressman L, Planting M, Moylan C, Bond J. Economic Contributions of University/Nonprofit Inventions in the United States. 1996-2020. Available at: https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf.
[9] AUTM 2022 Licensing Activity Survey. A Survey of Technology Licensing Related Activity for the US? Academic and Nonprofit Research Institutions. Available at: https://autm.net/surveys-and-tools/surveys/licensing-survey/2022-licensing-survey.
[10] Success Stories. Bayh-Dole Coalition. Available at: https://bayhdolecoalition.org/about/#stories.
[11] Long G. Federal Government-interest Patent Disclosures for Recent Top-Selling Drugs. J Med Econ. 2019;22(12):1261-7.
[12] Stevens AJ, Jensen JJ, Wyller K, Kilgore PC, Chatterjee S, Rohrbaugh ML. The role of public-sector research in the discovery of drugs and vaccines. N Engl J Med. 2011;364:535–41.
[13] O'Loughlin G, Schultess, D, March-in Rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents. 2023. Available at: https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

radiology ($196 to $1), rheumatology ($411 to $1), and oncology ($431 to $1) – some of the most complex and challenging conditions to treat.[14,15]

In totality, the Bayh-Dole Act has encouraged further development of inventions supported by federal funds, fostering private and non-profit collaborations. The resulting innovations for public use have been heralded as widely successful by leaders from both sides of the political spectrum.

As outlined by both the legislators and former staff, only four specific criteria were legislated to ensure the intended policy and objectives of Bayh-Dole. The price of the resulting product was not included in those criteria.[16,17] Indeed, the bill authors noted in the Washington Post more than 20 years ago:

> "*Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price dictated by government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research*."[18]

Recommendation:

The innovation ecosystem – which for decades has shepherded incredible advances in research and medicine – relies on the private and public sectors to collaborate and for the private sector to further develop new technologies. Broadening the limited circumstances in which public use and accessibility are considered based on price puts Bayh-Dole's long-standing successes at risk. Thes oversteps on march-in rights is antithetical to the law's policy and objectives and should be rescinded to avoid a setback to the U.S.'s leadership in life sciences, medical innovation, and, even more critically, to the potential health discoveries and benefits for the American public.

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[14] Schulthess D, Bowen HP, Popovian R, Gassull D, Zhang A, Hammang J. The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals. Therapeutic Innovation & Regulatory Science. 2023; 57:160-9.
[15] Vital Transformations. March-in Rights Under the Bayh-Dole Act & NIH Contributions to Pharmaceutical Patent. November 30, 2023. Available at: https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.
[16] NIH Public Meeting on Norvir/Ritonavir March-in Request (May 25, 2004). Available at:https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf.
[17] Joseph P. Allen. Public Comment. NIST-2021-001-0015. Available at: https://www.regulations.gov/comment/NIST-2021-0001-0015.
[18] Birch Bayh and Robert Dole. Our Law Helps Patients Get New Drugs Sooner. Washington Post, April 11, 2002, at A28. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

Inclusion of Price Would Chill Technology Transfer and the Development and Commercialization of Federally Supported Innovations

Drug development is one of the riskiest industries for developing new and successful products. Unlike other technologies, medical innovation includes high upfront research and development costs, lengthy development timelines, a strict regulatory framework, and significant market access and reimbursement challenges.[19] Only one of every ten drugs that make it into clinical trials is approved by the FDA.[20] And the investment required to develop a new medication is estimated to be between $2-3 billion.[21]

It is widely accepted that investment decisions – including pharmaceutical research and development – are based on money (expected revenues vs. expected costs), time, and level of uncertainty or risk. [22] Including price as a factor for exercising march-in rights would have material effects on each.

First, this proposal would impact potential revenues and reduce investments in research and development. Multiple simulation models exist – including those by the Congressional Budget Office, academics, researchers, and investors– that demonstrate higher investment rates are based on lower development costs and higher expected future profits.[23] Policies that increase the market size or potential expected future profits (e.g., the passage of Medicare Part D benefits or expanded health care coverage after exchange plan adoption) have been associated with increased investments in research. [24,25] Therefore, it holds that policies with the potential to limit future profits through march-in rights would be associated with diminished investment in projects with subject inventions and the potential to put future profits at risk.[26]

Second, higher levels of uncertainty increase risk for investors. Policies, such as the Orphan Drug Act, that increase intellectual property and decrease uncertainty have been associated with increased private investments in related research. In contrast, policies that have the

[19] FTI Consulting. The Role of Intellectual Property in the Biopharmaceutical Sector. September 2022. Available at: https://www.ifpma.org/wp-content/uploads/2023/01/i2023_2022_The-role-of-IP-in-the-biopharmaceutical-sector.pdf.
[20] BIO. Clinical Development Success Rates and Contributing Factors 2011-2020. Available at: https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020.
[21] DiMasi J, Grabowski H, Hansen R. Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. 2016;47:20-33.
[22] U.S. Congress, Office of Technology Assessment. Pharmaceutical R&D: Costs, Risks, and Rewards. OT-H-522. (Washington DC; U.S. Government Printing Office, February 1993). Available at: https://ota.fas.org/reports/9336.pdf.
[23] Congressional Budget Office. CBO's Simulation Model of New Drug Development. August 2021. Available at: https://www.cbo.gov/system/files/2021-08/57010-New-Drug-Development.pdf.
[24] Blume-Kohout ME, Sood N. Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development. Journal of Public Economics. 2013;97:327–336. Available at: https://doi.org/10.1016/j.jpubeco.2012.10.003.
[25] Dranove D, Garthwaite C, Hermosilla MI. Expected Profits and the Scientific Novelty of Innovation. Working Paper 20-16.2020. Available at: https://www.nber.org/system/files/working_papers/w27093/w27093.pdf.
[26] Smith WS, Popovian R. The Importance of Intellectual Property Protections for Patients. White Paper 264. October 2023. Available at: https://pioneerinstitute.org/wp-content/uploads/PNR-536-IP-WP-v04.2.pdf.

potential to rescind exclusive licenses and overturn intellectual property protections increase uncertainty and risk, resulting in diminished investment. It stands to reason that the private sector will seek fewer licenses from academic universities, and the ability to attract and retain talent in these academic centers will be challenged. Even the Congressional Research Service notes:

> "*One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property*."[27]

Third, as the private sector investment lessens, federal funding and expertise will be needed. This will require both additional resources and personnel with expertise in commercializing products in an environment with concerns about federal spending. Both the increased investment and time required to build may stall these inventions' application and the ultimate FDA approval required to make these applications available to the public.

The chilling effect of limiting the potential return on investment and private-sector funding are not theoretical. In the early 1990s, the National Institutes of Health (NIH) included a "reasonable pricing clause" in cooperative research and development agreements (CRADA) between government researchers, academia, and industry.[28] Collaboration agreements stalled. As noted by the NIH*:*

> *"An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public."*

Subsequently, the ill-informed policy was rescinded, and cooperative agreements increased four-fold.[29]

Beyond the reduced research investment, these policies would have a material impact on the U.S. economic engine. Models estimate that every 10% reduction in intellectual property rights for medicines is associated with 0.2% reduction in U.S. GDP, $6.43 trillion less consumer social surplus, and 445,000 fewer jobs over the next 30 years.[30] Considering the additional technology sectors and industries impacted beyond healthcare, these numbers are conservative.

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[27] Schacht W. The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service Report 7-5700. December 3, 2012). Available at: https://sgp.fas.org/crs/misc/RL32076.pdf.
[28] NIH News. NIH Notice Rescinding Reasonable Pricing Clause. April 11, 1995. Available at: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.
[29] The NIH Experience with Reasonable Pricing Clause in CRADAs FY1990-1995. November 15, 2021. https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.
[30] FTI Consulting. The Role of Intellectual Property in the Biopharmaceutical Sector 2022. September 21, 2022. Available at: https://www.ifpma.org/wp-content/uploads/2023/01/i2023_2022_The-role-of-IP-in-the-biopharmaceutical-sector.pdf.

Recommendation:

We Work For Health is concerned this proposed framework will have broader implications on the research ecosystem and conflict with the Bayh-Dole objectives. Including price as a factor for march-in rights, limits the expected return on investment while also raising risk due to weakened intellectual property protections. This policy will discourage investment in "subject inventions," which have a material impact on the U.S. economy and impair our ability to bring life-saving treatments to patients. We Work For Health recommends withdrawing this proposed framework.

Flaws Hinder Rather Than Help with the Interpretation of the Framework

Product Price Does Not Relate to Unsatisfied Health and Safety Needs

Petitions to exercise march-in rights have been made that assert the public has diminished access based on comparative prices to other nations. However, these petitions ignore access to these medicines. For example, the average delay from approval to availability of new medications is 1-3 months in the U.S. compared to 10-18 months for other high-income countries – often with restricted patient access criteria.[31,32] Americans get access to life-changing new medicines years earlier than patients in other countries.

Some petitioners have noted that the price is akin to "shelving" a subject invention and limiting patient use. As outlined in the proposed framework and described in Scenario 2 of the Framework,

> "*The mere fact that a potential competitor might be able to bring a subject invention to market more quickly than the contractor does not mean the contractor is impermissibly shelving a subject invention.*"

If one were to replace the words "more quickly" with "lower priced," the implications are the same. The contractor is not shelving a subject invention and limiting patient use.

Finally, health plan benefits, formularies, and coverage policies determine patient affordability and access to individual medical technologies or pharmaceuticals. Health plans and pharmacy plan managers determine patient deductibles, copays, and coinsurance levels. Similar to the example outlined in Scenario 5, patient access and affordability are outside of the licensee's control and would not warrant march-in rights.

Alternative Solutions Exist to Improve the Health and Safety of the U.S. Public

Multiple market-based solutions already exist. First, competition within the market lowers costs. Take as an example the Hepatitis C products that launched with a price tag of $1,000 a

[31] PhRMA. The United States vs. Other Countries: Availability of New Medicines Varies. November 25, 202. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Comparison-of-Availability---All-New-Meds---112520.pdf.

[32] PhRMA. Global Access to New Medicines Report. April 11, 2023. Available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

day for a 12-week course that spurred public outrage. A congressional investigation showed higher prices could have been justified if pricing was based on commonly accepted thresholds for value due to improved health and cost offsets. Further, as additional competition entered the market, the cost of these products dropped by nearly 70%. Second, the social contract underlying the patent system is rooted in a balance between incentivizing pharmaceutical innovation through exclusive rights and widespread access to generic and biosimilar medicines after a period of time. The availability of generics and the newly expanding biosimilar portfolio offer substantial savings. Finally, market-based solutions such as outcomes-based contracts, warranties, or subscriptions allow guarantees of product effectiveness and work to address pricing and financial or clinical uncertainty of products. Market-based approaches that promote competition rather than commoditization are needed.

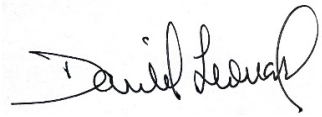
Recommendation:
We Work For Health seeks to highlight the challenges of including price in the proposed framework and strongly encourage the agency to remove price as a consideration for march-in. Given the complex payment and delivery of healthcare we encourage the administration and policymakers to look beyond the Bayh-Dole Act to policy solutions that can improve accessibility to medicines in the United States without hurting innovation. We believe alternative solutions exist and should be employed to improve health and safety that does not have a chilling effect on needed collaborations to innovate and improve the health of the American people.

Conclusion

We Work For Health is deeply concerned that diminishing the robust research and development ecosystem will reduce high-quality jobs and economic growth and weaken America's position as a leader in healthcare and medical innovation. Most importantly, American patients could have access to fewer life-improving and life-saving new drugs.

We Work For Health underscores our concerns and recommends that NIST and the Interagency Working Group for Bayh-Dole withdraw this proposed framework. We Work For Health values the public-private partnerships essential to delivering new medicines to patients.

Sincerely,



Dan Leonard
Executive Director
We Work for Health