February 6, 2024

VIA ELECTRONIC SUBMISSION

Alicia Chambers
Executive Secretariat
National Institute of Standards and Technology
Attention: Mojdeh Bahar, Associate Director for Innovation and Industry Services
100 Bureau Drive
Gaithersburg, MD 20899

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No. 230831-0207, NIST-2023-0008

Dear Ms. Chambers:

The Alliance of U.S. Startups and Inventors for Jobs ("USIJ") responds herein to the Request for Information ("RFI") published in the Federal Register on December 8, 2023, by the National Institute of Science & Technology ("NIST") , describing a so-called "Framework" to guide all departments and administrative agencies of the U.S. government that provide research grants to universities, private research labs and private companies (collectively referred to as "contractors") as to when and how to exercise "march-in rights" under the Bayh-Dole Act, 35 U.S.C. §203. USIJ comprises inventors, startup companies and the investors that support them, all of whom depend on reliable and enforceable patents to justify the risk of investing time and capital in developing new and unproven technologies. USIJ was founded nearly a decade ago, in the face of declining governmental support for strong patent rights, to help inform government officials, members of Congress, and the Federal Judiciary regarding the role that patents play in promoting investment, R&D and the transfer of technology that is essential to bring new advancements to U.S. consumers and to advance our global competitive advantage and national security.

I. Introduction and Summary of Comments.

USIJ shares the views expressed by the Bayh-Dole Coalition ("BDC")[1], the entire U.S. higher education system[2], the National Venture Capital Association ("NVCA")[3] and dozens of other experts, business leaders and former government officials[4] in urging the immediate withdrawal of this ill-conceived effort to reinterpret Section 203. The Framework erroneously purports to be carrying out the intent of the Bayh-Dole Act, but it clearly departs from the fundamental purpose and statutory language of the Act in ways likely to diminish the role of the federal government in funding future public/private partnerships. Nothing in the Bayh-Dole Act supports the use of march-in rights based on prices charged by a contractor or its licensee, a power erroneously assumed by the authors of the Framework.

The continued discussion of promulgating a Rule based on the Framework – even though merely a proposal at present – is already having a chilling effect on investors and entrepreneurs who are considering the possibility of commercializing government funded technology. Some venture capital firms have begun to ask startups seeking investment capital whether any of the company's patents are subject to march-in rights, and when the answer is yes, that normally terminates further discussions. This number will increase rapidly as the entire investment community becomes more aware of the issue, and as lawyers and financial analysts perform formal due diligence work for investors.

The actual conversion of the Framework into a Rule will, for many companies and investors, terminate further dealings with federal government contractors to license patents based on government funded research. In addition, adoption surely will trigger multiple lawsuits against NIST, NIH and other agencies by companies and investors that already have invested time and resources in developing new commercial enterprises on the assumption that they have exclusive licenses. Such lawsuits will take months or years to resolve, during which time development work on existing projects will either slow down or cease altogether and commitments to future projects will be postponed or rejected.

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[1] Letter to Hon, Laurie E. Locascio, Director of NIST, dated January 17, 2024, from Joseph P. Allen, Executive Director of the Bayh-Dole Coalition, providing comments to the RFI. https://bayhdolecoalition.org/wp-content/uploads/2024/01/Bayh-Dole-Coalition-Comments-on-NIST-Draft-March-in-Framework-2.pdf#new_tab

[2] https://autm.net/AUTM/media/About-Tech-Transfer/Documents/Higher-Ed-Coalition-Letter-on-the-NIST-Bayh-Dole-Framework.pdf

[3] Letter to Hon. Joseph R. Biden, President, dated January 23, 2024, from Bobby Franklin, President and CEO of NVCA addressing the NIST RFI (https://nvca.org/wp-content/uploads/2024/01/NVCA_WH-Letter-on-March-In.pdf).

[4] https://c4ip.org/wp-content/uploads/2024/02/Fmr-Commerce-Dept-Officials-Letter-to-President-Biden-re-Draft-Interagency-Guidance-Framework-for-Considering-the-Exercise-of-March-In-Rights.pdf

II. The Framework Reflects an Elaborate Effort to Conceal Its Primary Objective – Federally Mandated Price Controls in Critical Industry Sectors.

The Framework is a thinly-veiled effort to import price controls into the analysis of march-in rights under Section 203, an effort that has failed multiple times. The timing of the RFI, the short time period for response, the 33 references to pricing in the document, and recent public statements about the Administration's efforts to lower drug prices – all show that the objective of this complex and confusing set of theoretical scenarios is to mask yet another effort to use the mechanism of march-in rights to bring about a government scheme to control prices and access to new innovation. The Framework applies its extra-statutory expansion of march-in to cover all Federal agencies and all technologies, not just NIH which is responsible for the vast majority of federally funded drug research. By positing ambiguous "scenarios" that address a number of technologies other than health care, and by seeking to conflate the limited uses of march-in contemplated by Congress with a reasonable pricing requirement not found in Section 203, the Framework would put nearly any company that has a university research relationship and/or has participated in a government-supported research program at risk of facing, potentially multiple, march-in petitions.

There are numerous defects in this, or any government price control scheme, most importantly that the venture capital community and the hundreds of companies that currently contract with federal agencies to carry out research are likely to walk away, which will return our country to the pre-Bayh-Dole days, when massive amounts of federally funded technology collected dust in file drawers rather than being converted to consumer products for the benefit of all Americans.

For reasons set forth in the NVCA letter to President Biden noted in Part I, it is likely to be a disaster for our nation if NIST moves forward with adoption of the Framework. To buttress the NVCA point, USIJ asked a large venture capital firm with several hundred nationwide investments to conduct a straw poll of its portfolio companies to determine how many startups are parties to university licenses and how many are licenses of patents that carry a federal funding notice. The firm invests in both health care and technology startups, with a total portfolio of more than 350 companies. The survey showed, for a representative sample of 90 companies that responded, that 56% of the firm's health care investments involve university licenses and 39% have licenses that carry Bayh-Dole notices. The first group has an aggregate valuation of nearly $3B and the second of nearly $2B. For nonhealthcare companies, the numbers are smaller but still significant; 17% have university licenses and 7% are licensees on patents subject to march in. This is just one of several hundred VC firms and illustrates the magnitude of what is likely to disappear if this proposal is not withdrawn.

The irony is that the scheme will not have much impact, if any, on drug prices, which is clearly the rhetorical and political objective of this exercise. For reasons discussed at page 6 and fn.16 of the letter from the Bayh-Dole Coalition to Director Locascio also noted in Part I it is clear that the vast majority of relevant therapies sold today were either developed without any federal funding at all, or are protected by additional patents owned by the licensee-developers that did not involve federally funded research. No follow-on licensee, assuming one steps forward, will be able to make the drug without assistance from the original developer, which is not likely to be forthcoming. The impact of the scheme on decisions made by venture investors and startups contemplating university research collaboration and/or seeking federal funding, however, will be devastating.

III. The Framework Ignores the Risk Assessments that Are Central to Every Decision to Invest in Developing New Technology.

The Framework appears to have been created in a vacuum, without any consideration of the many factors that must be evaluated by investors, entrepreneurs or any private sector entity before entering into patent license agreements for the development of new technologies. These entities enter into collaboration agreements in hopes of seeing a financial return at some point in the (often distant) future. The overhang of a federal agency retaining the power to decide – years later and on the whim of some bureaucrat or politician – that the company's prices are "not reasonable" will be the kiss of death for many if not most such arrangements.[5] No rational business wants to enter into a collaboration agreement that will not produce income for years, and under circumstances where, even if successful, its ability to enjoy a risk-adjusted profit looms as a giant question mark that will last until expiration of the patents.

This is particularly the case with small companies that lack multiple diversified streams of income to offset losses, and it is especially true in the development of new pharmaceuticals and other health care therapies, which, per multiple statements by the Administration[6], are the primary (but not only) target of the Framework's plan to achieve "reasonable pricing" using march-in rights. More than 50% of all new therapies developed in the U.S. are created by

[5] This is demonstrably true based on the earlier effort by NIH, during the period 1989 to 1995, to include a "reasonable pricing clause" in CRADAs and other collaboration agreements, as described at page 6 of the BDC response to the RFI, quoting Harold Varmus, a former Director of NIH: "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public." Notably, this earlier effort was not based on march-in rights applied retrospectively, as contemplated by the Framework, but rather a prospective provision included contractually at the outset of negotiations. The economic impact of the Framework is far more consequential, in that it undermines settled investments and expectations, and most importantly trust in the integrity of intellectual property rights.

[6] 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/

startups in collaboration with universities.[7] This innovation ecosystem has developed, uniquely in the U.S., based on the reliable legal standards for technology transfer instituted by Bayh-Dole over the past 40 years, the incredible passion and commitment of entrepreneurs and startups and the world's most extensive and sophisticated venture capital system. The authors of the Framework apparently assume that if the Framework is adopted as a Rule, development activity by these startups and their venture capital investors will continue as if nothing has happened. This assumption is stunningly naïve.

An overarching consideration in the mind of any startup entrepreneur or venture investor is the high probability at the outset that the enterprise will fail, often ending in the complete loss of invested time and money by the founders.[8] There are many types of risk that all startups and their investors must contend with – e.g., technology that works on a whiteboard or in the lab may not work at a scale feasible for commercial production; the executive team may fail to execute on the business plan; funding may be discontinued before the process is completed as some investors reassess the prospects for success; a newer and better technology may come along that nullifies some or all of the business assumptions; the ultimate cost of production may exceed the achievable selling price; etc. Add to this a particularly daunting risk facing the developers of any new drug or medical device - the enormous and highly unpredictable cost associated with the need for FDA approval. It is not unusual for a new drug to require years of experimentation and research and multiple clinical trials before the it can be proven to be both effective as a treatment and safe for humans and animals, during which time the developer receives little or no revenue from its investment.

Although overall costs often vary widely, but a new drug can easily require ten or fifteen years of development work and $2B or more from inception to final FDA approval. A new medical device typically requires nearly the same time horizon and will demand hundreds of millions of dollars in venture capital. A report entitled "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," published in the Journal of Health Economics 47 (2016) describes a study of 106 new drugs developed by 10 different companies. The study estimates the average cost per drug at $1.4B without considering the time-value of the out-of-pocket investments. If a market-based cost of funds is added, the total average cost is $2.8B per drug.[9] The time value of money is an important consideration for venture capital firms, which must show returns on their investments to remain in business. Moreover, only about 10% to 12% of the drugs on which

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[7] A study entitled "The US Ecosystem for Medicines: How new drug innovations get to patients," concludes that for the period 2011 to 2020, "55% of U.S. originated therapies were created by small biotech companies; 45% were created by large companies." https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients.

[8] Bayh-Dole-Coalition-Comments-on-NIST-Draft-March-in-Framework-2.pdf (bayhdolecoalition.org)

[9] https://pubmed.ncbi.nlm.nih.gov/26928437.

development work is initially commenced ever reach the point of market approval, meaning that close to 90% of the initial efforts at drug development fail for one of more of the foregoing reasons, even after the science itself is proven and promising, because clinical trials show that the product is either not safe or not effective or both.[10] The failure of the Framework to acknowledge and come to grips with these factual realities is one of several fundamental flaws.

IV. The Framework Ignores the Relatively Small Contribution That Government Funded Research Actually Provides.

Because federal labs can legitimately claim credit for funding the basic scientific research that leads to many new products, some academics and government officials argue that this contribution should give the U.S. government ownership of the technology, or at least the right to control the price and freely access to the product that is approved for sale or enters the market. This argument ignores the far larger contribution from private companies that is required to get technology from the basic research in a federal or university laboratory to commercialization. A study published in September 2022, entitled "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals," showed that upwards of 95% of the total cost of developing a new drug to the beginning of clinical trials is born by private investors, with the NIH contribution less than 5%.[11] For drugs that actually received FDA approval, the disparity is even more striking, with 98.5% of the total coming from private funding. And for oncology drugs, the private contribution to cost is almost 99%. That study was based on NIH records covering the period between 1984 and 2021, during which NIH made 23,230 extramural grants for drug research, which in turn led to a total of 8,126 patents that could be linked to discoveries funded by these grants. The study identified 41 therapies traceable to some portion of this universe of patents that reached the clinical trial stage successfully, and determined that 18 of the 41 received FDA approval. For the 41 therapies that underwent clinical trials, the aggregate contribution of NIH grants totaled $2.4B while the private contribution was $50.7B, or 95.5% of the total. In addition, those numbers do not include any post-approval contributions, which make the disparity even greater. For drugs that actually received FDA approval, NIH funding accounted for $670M of the total cost while private sector investment totaled $44.3B or 98.5% of the total.

The foregoing numbers powerfully illustrate just why the private sector is absolutely critical to bring about technology transfer from government labs and the labs of government contractors

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10 *Id* at p. 23.

11 Journal of Therapeutic Innovation & Regulatory Science (2023) Vol. 57:160 – 169. https://www.springer.com/journal/43441.

to innovative companies willing to undertake the risky and capital-intensive product creation cycle.

V. Federal Agencies Are Not Competent to Determine "Reasonable Prices" for Commercial Products.

Another glaring defect in the Framework is the suggestion that agencies use the product price paid by an end use as a factor in determining when and whether to exercise march-in rights and take back the exclusivity conferred by the patents owned by the contractor. The Framework contains 33 references to the word "price," most of them in suggesting that the price must be "reasonable." Nowhere, however, does the Framework provide any basis for determining what that actually means, nor could it do so with any credibility.

The Bayh-Dole Act does not include end user pricing as a factor supporting march-in, because the typical agreement for a research grant is between the government and a contractor (such as a university) that carries out the research leading to one or more patented inventions but the contractor will not be involved in the retail pricing of the product, leaving that to a licensee, its distributors or others. A typical university transfer of patented technology will be an exclusive license that requires the licensee to commercialize the invention(s) covered by the patent(s) and reserves the right to issue additional licenses if the exclusive licensee fails to meet milestones and objectives set forth in the license. The university is compensated by milestone payments and royalties on product sales by the licensee. A government decision to march-in based on pricing by a licensee-manufacturer in this situation would penalize the contractor over something it does not control. The Framework is extremely vague as to just how the government might want to analyze retail pricing where the contractor has no control.

The Framework is equally vague as to how a federal agency should determine whether a retail price is "reasonable." Prices in most all situations are established based on a constantly changing set of conditions that are different for every product and for every entity that the process touches along the way. For a federal agency to analyze the "reasonableness" of pricing for any commercial product, the agency will have to consider numerous of complex (and global) economic factors, including R&D cost, input costs from a global supply chain, size of the addressable market, costs of capital, the prices at multiple levels of the distribution chain, including manufacturers, wholesalers and other interim distributors, and, in the case of life science products, a multitude of insurance programs and providers, pharmacy benefit managers, retail pharmacies, hospitals, and more. Beyond that, the agency will have to consider, at each of these levels, whether the prices charged are reasonable.

Looking only at just one transaction in this chain, the prices charged by the manufacturer of pharmaceutical products are dependent on multiple variables, many of which change constantly and some of which are indeterminable. These include, without limitation, the price of

raw materials, the costs of manufacture, distribution and marketing, inventory levels, projected demand at particular prices, price elasticity, the prices of therapeutic substitutes, all of which require constant monitoring and revisions as economic conditions change. Many products are also sold in business-to-business channels, where prices may reflect more than one business purpose on the part of either of both parties.

The Bayh Dole Act was drafted with an appreciation of this market complexity, and for over 40 years it has worked incredibly well and shown the ability to evolve with very complex technologies and helped create thousands of U.S. companies. The current framework understands that the licensee-developer, i.e., the company that assumes the long-term risk and actually does the capital-intensive and time-consuming work of commercializing a technologically complex and often unproven product, must be the exclusive licensee of the contractor, allowing for risk-adjusted profit, which right now means that the developer can set the price according to market conditions. Market based pricing assures the developer and its investors that it will have at least the opportunity to be properly compensated for taking on the large long-term risks discussed above, IF the product is even successful. There really is no other way to determine a "reasonable price," and without assurances of the freedom to set their own prices, most small companies will refuse to undertake this type of development.

VI. The Framework Undermines the Basic Objectives of Several Biden Administration Programs and Priorities.

The Framework also appears to be at cross-purposes with other efforts by the Biden Administration to encourage and incentivize public/private collaborations to help reduce our nation's reliance on foreign suppliers for strategically critical products required for national security. As pointed out in the letter from the NVCA to President Biden, mentioned in fn. 2, the Chips and Science Act[12] specifically authorizes federal funding for both the creation of new semiconductor manufacturing facilities and for scientific R&D to reduce our nation's reliance of foreign suppliers. Given the breadth of the Framework – covering all technologies and all federal research grants – one must assume that any entity accepting the funding authorized by the Act will be subject to the same risk of march-in until its federally funded patents expire. For large companies with market power such as Intel, Micron, TSMC and others that will be constructing new production facilities, this may or may not be a problem. But for the geographically diversified startups and small companies, also envisioned as beneficiaries by the proponents of the Act through research grants, the adoption of the Framework will be a serious deterrent. Scientific research that leads to patents often provides a critical starting point for a new technology, but

[12] Pulic Law 117-167, enacted in 2022, has several short titles. https://www.congress.gov/bill/117th-congress/house-bill/4346/text. Reference in this letter to the Chips Act include the entire law.

the private capital required for bringing actual products to market normally exceeds the research costs by at least one or two orders of magnitude.[13] To allow the relatively small amount of initial seed funding from the government to control pricing of an end product fits the oft-heard aphorism of a "tail wagging a dog." It makes no sense to the investors and companies whose participation is needed to provide the essential private capital.

Other federal programs whose mandates will be undermined by the Framework are the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) programs. The Small Business Administration's website for SBIR/SBTT holds itself out as "America's Seed Fund" and explicitly states that a recipient is able to "Keep your equity and IP."[14] The National Science Foundation invests America's Seed Fund in about 400 companies annually that are pursuing a diverse range of new technologies.[15] The Framework, by making all federal funding subject to march-in rights, effectively revokes the promise made to small companies by SBA that they will own the IP generated by their efforts to create products from their technologies and to create viable businesses. Scenario 2 (pp. 85601-02) specifically refers to a small manufacturing company receiving SBIR grants being subjected to scrutiny to determine whether march-in rights would be appropriate, which is the antithesis of "Keep your equity and IP."

The foregoing are merely representative examples of high-profile programs whose missions will be thwarted by this government-wide proposal. The trust that inventors, entrepreneurs and venture capital investors place in the governmental institutions of this nation that protect intellectual property rights is already at an all-time low, and many have given up altogether on using patent portfolios as a reliable basis for building a business. The Framework proposal will exacerbate that trend. It will be a particularly egregious breach of trust for the federal government to reinterpret Section 203 – retroactively as is planned – as to companies and technologies whose development cycles have already commenced (or were completed) based on an assumption that the assignee or licensee of their patents would be free to set a price for the product based on market forces.

VII. Conclusion.

There is no more basis for the government to try and control the price of innovative new products enabled by the Bayh Dole Act and federal grants than there is for it to argue that use of the federally-funded interstate highway system entitles it to impose price restrictions on goods hauled to their destination by road; the suggestion is preposterous. This is particularly so in light

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[13] See fn. 10 and associated text for a discussion of the documentation of this disparity in the case of drug development. While the impact on other technologies may not be as dramatic as in the case of pharmaceuticals, it is still sufficiently high to deter investments for which the company's prices will be overseen by the government.

[14] https://beta.www.sbir.gov

[15] https://seedfund.nsf.gov/assets/files/applicants/combined-topics.pdf

of the cost and risk factors discussed above and the need to attract new capital in order to have new and innovative products at all. Apart from a brief (and unsuccessful) experiment in the early 1990s, all federal agencies have successfully resisted numerous invitations to reinterpret the intent of Congress as to "march-in rights" or to impose unmanageable price restrictions on the companies that work with universities and research labs to launch new products. The entirety of this proposal is based on the narrow, false premise that, by reclaiming patent rights from successful companies, the government can lower drug prices. This premise ignores the fact that the ability to "march in" on complex pharmaceutical products built on extensive patent portfolios is extremely limited, if applicable at all. But this lack of understanding is not the most egregious feature of this proposal. Its universal applicability, with "scanarios" that amount to overt threats to expropriate the intellectual property of U.S. startups, has already begun to undermine investment and discourage entrepreneurial activity in critical sectors. If the U.S. is going to compete and lead in areas like clean energy, advanced manufacturing, robotics, AI, semiconductors, materials science and yes, even life sciences, we will need our best ideas and research driving another generation of great companies with the support of private capital. In other words, the exact promise of Bayh Dole over 40 years ago.

Please do not destroy the innovation ecosystem that America has created and is still unique in the world.

Respectfully submitted,

Robert P. Taylor
General Counsel, USIJ
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