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Docket No. NIST-2023-0008

Dr. Laurie E. Locascio
Director and Undersecretary of Commerce for Standards & Technology
National Institute of Standards and Technology
Attention: Mojdeh Bahar, Associate Director for Innovation and Industry Services
100 Bureau Drive
Gaithersburg, MD 20899

Re: National Venture Capital Association's Comments on the National Institute of Standards and Technology's *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*

The National Venture Capital Association (NVCA) offers the following comment in response to the National Institute of Standards and Technology's (NIST) request for information regarding its *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, 88 Fed. Reg. 85,593 (Dec. 8, 2023).

Venture capital (VC) fuels the future of the American economy: It helps transform novel ideas and painstaking research into revolutionary products and services that grow new companies. Venture-backed companies have scaled, gone public, and generated millions of high-skilled jobs and trillions of dollars for the U.S. economy. Through high-risk investments, venture capital works in tandem with government funding to fill gaps that would otherwise stymie American innovation. When visionaries seek to change the status quo, it is often venture capital that provides critical financial support and mentoring guidance.

NVCA promotes the interests of venture capital firms and the entrepreneurs they support. NVCA writes to express its absolute opposition to NIST's draft guidance. Since the Bayh-Dole Act's enactment more than 44 years ago, agencies have—without exception—refrained from exercising march-in rights, recognizing the catastrophic impact doing so would have on innovation and investment. NIST's guidance signals a dramatic shift from this steadfast history, going so far as to encourage agencies to exercise march-in rights in certain circumstances. As NVCA explains below, NIST should completely abandon this approach.

First, the critical importance of venture capital investments cannot be understated. Venture capital investments jumpstart entrepreneurs and startups through high-risk, high-reward investments. A centerpiece of any willingness to invest is the certainty of the patent rights

underlying the venture. An innovator's patents thus play a central role in fostering the investment a fledgling company needs to turn its ideas into meaningful products and services.

Second, the Bayh-Dole Act recognized that enforceable patent rights are an essential asset in any innovator's business and a key contributor to investors' willingness to fund innovative ventures. Realizing that federal research funds often resulted in inventions that did not reach the American public, Congress placed patent ownership with the innovative researcher to ensure commercialization. It prescribed only exceedingly narrow circumstances under which an agency could take those rights away. Over the 44 years since the statute's enactment, no agency has ever needed to exercise those rights. The draft guidance is irreconcilable with this history—and Congress's manifest purpose. Any increase or threat to increase the use of march-in rights will erode venture capital's trust in the U.S. patent system, undermining the Act's purpose and the administration's otherwise laudable investments in private research and development. This erosion will disproportionately burden entrepreneurs and innovation in emerging technologies that uniquely depend on federal funds in early research and VC funding to achieve commercialization, inordinately damaging development where the American public needs it most.

Third, the draft guidance's sweeping pronouncements about march-in rights are not appropriately the subject of non-binding guidance; instead, given the enormous stakes, changes like those NIST proposes should be promulgated through notice and comment rulemaking.

For these reasons, NVCA urges NIST to abandon this draft guidance and consider the realities of how this patent-forfeiting regime will stifle our nation's entrepreneurial economy, domestic venture investment, and private sector trust in the American patent system. Moving forward, we ask that NIST consult with the venture capital community to understand the downstream impact of policies like this on private investment in American companies.

I. Venture-capital investments fuel innovation and the nation's entrepreneurial economy but depend on a strong and predictable patent system.

Venture-capital funds are essential to American innovation. Through high-risk investments, venture capital enables untested entrepreneurs and startup businesses to bring new products and services to market. Companies including Bloom Energy, Modern Meadow, Apple, Tesla, Vir Biotechnology, Vivint Solar, Microsoft, and Amazon are the product of venture capital.¹ "VC-backed companies account for 41% of total U.S. market capitalization," including by "generating 92% of R&D spending and 93% of patent value."² These contributions further "'spill[] over' into the wider market," with studies showing that "knowledge spillovers from VC-financed firms are at least nine times larger than those from general corporate R&D."³ The market has thus recognized

¹ Will Gornall and Ilya A. Strebulaev, *The Economic Impact of Venture Capital: Evidence from Public Companies 2* (Working Paper June 2021), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2681841.

² *Id.* at 3 (focusing on companies that went public after ERISA's enactment).

³ Kjartan Rist, *VC's Outsized Economic Impact Will Power a New Golden Age*, *Forbes* (Jul. 28, 2021), <https://www.forbes.com/sites/kjartanrist/2021/07/28/vcs-outsized-economic-impact-will-power-a-new-golden-age/?sh=7e4568a23204> (citing Martin Watzinger and Monika Schnitzer, *Spillovers from Venture Capital Investment*, *VoxEU* (Oct. 31, 2017), <https://cepr.org/voxeu/columns/spillovers-venture-capital-investment>).

the crucial role venture capital plays; indeed, “the venture capital industry appears to be a bright spot in an increasingly troubled global innovation landscape.”⁴

The rapid growth associated with VC-backed firms also produces enormous employment benefits. Between 1990 and 2020, employment at VC-backed companies grew 960%, compared to only 40% growth in private sector employment generally.⁵ This change reflects an annualized growth rate of 8.2% for VC-backed firms, compared to 1.1% for private-sector employment. These employment benefits have broad geographic impact across the United States, with 62.5% of VC-backed jobs located outside of the hub states of California, Massachusetts, and New York.⁶

These enormous investments can only happen through careful balancing. Venture-capital funds incentivize investors with an attractive return on capital and provide entrepreneurs with the support they require to scale their business toward success—but the model only works if the investments’ assets are worth the risk.⁷

To allocate limited funds among inherently high-risk, untested investments, VC firms assess an investment’s security and growth potential, with intellectual property ranking as the most valuable of assets. Estimates are that 84% of the value of S&P 500 companies comes from intangible assets like patents, trademarks, and proprietary information.⁸ Patent rights fuel investment by “enabl[ing] firms to increase their expected profits from investments in research and development, thus fostering innovation that would not occur but for the prospect of a patent.”⁹ Startups with an approved patent application are 59% more likely to obtain VC funding within three years of obtaining the patent.¹⁰ In addition, “the effect of patents on VC funding is strongest for startups liable to the greatest frictions.”¹¹ Not only that, but “patents filed by VC-backed startups are of higher quality and economic importance than the average patent.”¹² Such companies “are also disproportionately likely to have more original patents, more general patents, and patents

⁴ *Id.* (quoting Bloom, Nicholas, Charles I. Jones, John Van Reenen, and Michael Webb (2020), “*Are Ideas Getting Harder to Find?*”, *American Economic Review*)

⁵ Gregory W. Brown, David Fisher, Lu Yi, and Michael J. Chow, *An Analysis of Employment Dynamics at Venture-Backed Companies Between 1990 and 2020* 1 (Feb. 2022), available at: <https://nvca.org/employment-dynamics/>.

⁶ *Id.*

⁷ Mark Flickinger, *Venture Capital Fundamentals: Why VC is a Driving Force of Innovation*, *Forbes* (Mar. 29, 2023), <https://www.forbes.com/sites/markflickinger/2023/03/29/venture-capital-fundamentals-why-vc-is-a-driving-force-of-innovation/?sh=22681f994128>.

⁸ *2019 Intangible Assets Financial Statement Impact Comparison Report*, Ponemon Institute LLC, available at <https://www.aon.com/getmedia/60fbb49a-c7a5-4027-ba98-0553b29dc89f/Ponemon-Report-V24.aspx>

⁹ *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Federal Trade Commission 2 (Oct. 2003).

¹⁰ Joan Farre-Mensa, Deepak Hegde, and Alexander Ljungqvist, *Do Patents Facilitate Entrepreneurs’ Access to Venture Capital?* 3 (Oct. 6, 2016).

¹¹ *Id.*

¹² Sabrina T. Howell, Josh Lerner, Ramana Nanda, and Richard R. Townsend, *How Resilient is Venture-Backed Innovation? Evidence from Four Decades of U.S. Patenting*, Nat’l Bureau of Economic Research 2 (Working Paper Oct. 2023).

more closely related to fundamental science,” all of which “is consistent with VC-backed firms playing a disproportionately important role in terms of job creation and productivity growth.”¹³

Because patent ownership is such a critical factor motivating VC funding, reductions in the predictability and dependability of the patent system directly and immediately disrupt VC-driven innovation. Perceived vulnerabilities to patent rights have caused venture capital to “sh[y] away from patent-intensive startups over most of the last two decades,” with “[t]he share of venture capital funding received by the most patent-intensive businesses dropp[ing] from over 50% in 2004 to 28% in 2017.”¹⁴

NIST’s proposed guidance encouraging agencies to exercise march-in rights will exacerbate these trends, upsetting VCs’ reliance on stable and predictable patent rights and discouraging them from funding the very startups that federal research and development dollars should be encouraging.

II. The draft guidance will upend venture-capital trust in the patent system, undermining the very innovation the Bayh-Dole Act and the administration seek to encourage.

Through the Bayh-Dole Act, Congress intentionally sought to ensure that government-backed inventions reached the American public by shifting patent rights to inventors to attract private funding for commercialization. Consistent with that purpose, Congress included in the Act a narrow provision allowing the government to “march in” and revoke contractors’ exclusive patent rights when such exclusivity did *not* serve the Act’s aims—that is, when important inventions remained uncommercialized. Reflecting that narrow purpose, not one agency has exercised march-in rights in the 44 years the Act has benefited the American economy. If agencies begin exercising march-in rights in the way the guidance advises—or even if agencies threaten to do so—it will upend the predictability of patent rights, undermining the very incentive structure the Act created to drive innovation.

A. March-in rights are meant only to address the exceedingly narrow problem of non-commercializing federally funded innovation.

Congress understood the direct relationship between secure patent rights and innovation when it crafted the Bayh-Dole Act, and recognized the need to incentivize the private sector to carry products inspired by federally funded basic research to market.

Historically, the nation lacked a uniform approach to patent rights in inventions arising from federal funding, but agencies generally held title.¹⁵ As a result, “many inventions resulting

¹³ *Id.*

¹⁴ Russ Krajec, *Venture Capital Investments in Patent-Heavy Companies is Down Substantially*, Blue Iron (Aug. 4, 2020), <https://blueironip.com/venture-capital-investments-in-patent-heavy-companies-is-down-substantially/>.

¹⁵ S. Rep. No. 96-480 at 2 (“In general, the present patent policies require contractors and grantees to allow the funding agency to own any patentable discoveries made under research and development supported by the Federal Government unless the contractor or grantee successfully completes lengthy waiver procedures.”).

from federally funded scientific research were not being commercialized.”¹⁶ Of the billions of government dollars funding research at universities, hospitals, and nonprofit organizations at that time, much of it funded “basic research,” that is, research “not specifically geared to producing new inventions” but rather “expand[ing] the frontiers of knowledge.”¹⁷ Although patentable inventions would stem from such research, “[t]he founding agency [was] rarely in a position to develop these reported inventions,” which would “cost[] 10 times as much as did the basic research itself.”¹⁸

Facing severe economic hardships in the 1970s—including “industrial stagnation and a lack of significant technological innovations”—an advisory committee to President Carter identified “diminished patent incentive” as playing a central role in stagnation.¹⁹ Congress swiftly responded with the Bayh-Dole Act, Pub. L. No. 96-517, which revolutionized innovation at research organizations—including entrepreneurs, nonprofit organizations, and universities—that rely on federal funding for research and development. The Act sought to place federally funded inventions on equal footing with American innovation generally by placing ownership over patents arising out of federally funded research with the innovators performing that research.²⁰ Congress expressly intended to promote “utilization of inventions arising from federally supported research or development,” including by “ensur[ing] inventions... are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.”²¹ Put another way, by allowing inventors to retain an exclusive license for inventions arising from federally funded research, Congress meant to incentivize private actors to carry inventions through commercialization, mitigating the waste stemming from federally funded research being left unutilized.²²

The Act was a resounding success. It “fostered university-industry partnerships that helped lift the economy out of the doldrums of the 1970s, re-establishing America’s [technology] leadership.”²³ Its lasting impact is profound—“[s]ince it was enacted in 1980, the Act has led to over \$1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country,

¹⁶ Charles R. McManis and Suheol Noh, *The Impact of the Bayh-Dole Act on Generic Research and Development*, Wash. U. Sch. of Law – Legal Studies Research Paper Series 5 (May 2011); *see also* S. Rep. No. 96-480 at 2 (noting that, before the Bayh-Dole Act’s passage, “of the more than 28,000 patents in the Government patent portfolio, less than 4 percent [were] successfully licensed”).

¹⁷ S. Rep. No. 96-480 at 19.

¹⁸ *Id.*

¹⁹ National Academies of Sciences, Engineering, and Medicine, *Best Practices in State and Regional Innovation Initiatives: Competing in the 21st Century* 104 (2013) (quoting Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (October 2003); and Advisory Committee on Industrial Innovation, Report on Patent Policy ISS (1979)).

²⁰ 35 U.S.C. § 202(a)

²¹ *Id.* § 200.

²² S. Rep. No. 96-480 at 3.

²³ Sujai Shivakumar and Thomas Howell, *Proposed Federal Use of March-in Rights Would Weaken American Innovation*, Ctr. for Strategic & Int’l Studies (Dec. 20, 2023), <https://www.csis.org/blogs/perspectives-innovation/proposed-federal-use-march-rights-would-weaken-american-innovation> (quoting Joseph Allen, *Universities: Fallen Angels or Stewards of Bayh-Dole?*, IP Watchdog (Oct. 29, 2018), <https://ipwatchdog.com/2018/10/29/universities-fallen-angels-stewards-bayh-dole/id=102772/>).

and contributed to the success of over 11,000 new startup companies from universities throughout America.”²⁴ In short, it was—as one commentator put it—“[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.”²⁵

To account for limited circumstances in which innovations fueled with federal dollars were not being put to use, the Act created “march-in rights,” authorizing a contracting agency—in very limited circumstances—to compel a contractor to “grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants.”²⁶ Were the contractor to refuse, the statute empowers the agency to revoke the contractor’s exclusivity and grant the license itself. The statute enumerated the four narrow circumstances in which an agency could exercise march-in rights—only where “necessary” to “achieve practical application,” “to alleviate health or safety needs” not being satisfied; to “meet requirements for public use” not being satisfied, or because a section 204 agreement was not reached.²⁷

When Congress passed the Act, it intended only that march-in rights “prevent companies from licensing academic know-how merely to block rival firms from doing so.”²⁸ That is, the Act’s principal goal was to prevent under-commercialization of federally funded inventions. The reservation of march-in rights ensured that contractors did not abuse the exclusivity rights conferred by a patent by refusing to commercialize the innovation and by blocking others from doing so. Thus, agencies would retain march-in rights “when the invention *is not being used* and it appears that there is a public need to use the invention.”²⁹ March-in rights were *not* intended—as Senators Bayh and Dole themselves later made clear—to control by government fiat the market for a particular invention when it *had* been commercialized.³⁰

Consistent with the exceedingly narrow purpose Congress intended march-in rights to serve, *not one* agency has exercised such rights in the 44 years since the Act’s passage. This utter dearth of use of march-in rights proves the inconsistency of the draft guidance with the statute: march-in must be reserved only for highly limited applications because any conclusion otherwise would gut the Bayh-Dole Act.

²⁴ Gabrielle Athanasia, *The Legacy of Bayh-Dole’s Success on U.S. Global Competitiveness Today*, Ctr. for Strategic & Int’l Studies (Jan. 12, 2022), <https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today#:~:text=A%20Lasting%20Impact%20on%20U.S.%20Innovation&text=Since%20it%20was%20enacted%20i n,companies%20from%20universities%20throughout%20America>.

²⁵ *Innovation’s Golden Goose*, *The Economist* (Dec. 12, 2002).

²⁶ 35 U.S.C. § 203(a).

²⁷ *Id.*

²⁸ *Innovation’s Golden Goose*, *supra* note 25.

²⁹ S. Rep. No. 96-480 at 18 (emphasis added).

³⁰ Birch Bayh and Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, *Wash. Post* (Apr. 11, 2002), perma.cc/538T-NHDA (“The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.”).

B. The draft guidance will eviscerate the Bayh-Dole Act’s promotion of the patent system.

The draft guidance expressly “[e]ncourage[s] the consistent and predictable application of the Bayh-Dole Act’s march-in authority” against a backdrop of complete agency restraint.³¹ Agencies have properly treated march-in rights as a remedy solely in the event that inventions unjustifiably remain uncommercialized by private parties. To date, there have not been circumstances in which important innovations have lacked commercialization, and NIST has identified no evidence otherwise to explain or justify the need for new guidance.

The draft guidance’s march-in approach will severely harm VC confidence in the American patent system. Uncertainty about whether and when agencies might exercise march-in rights fundamentally alters the risk calculus VCs make when deciding whether to invest in a new entrepreneur or startup. The decision to fund a new venture that depends on its patented innovations must be built on the assumption that those patents are exclusive unless licensed according to the companies’ business judgment. The threat that agencies might exercise march-in rights frequently, *even where an invention is already commercialized*, directly upends that most basic assumption, hindering VCs’ interest in already risky investments.

NIST’s guidance would unavoidably deter VCs from investing in inventions arising from federally funded research—directly contrary to the innovation environment the Act meant to foster. The increased risk directly disrupts existing investors’ reliance interests. And it further makes any future technologies backed by federal funds potentially toxic for VC investment. This outcome “frustrate[s] the policy that Congress sought to implement” through the Bayh-Dole Act³²—that is, to *encourage* private investment in government-funded inventions.

Innovators who used public funding will be unable to secure VC support, making public funding effectively meaningless to produce commercially viable products and services. The draft guidance’s apparent intent to disincentivize investments in federally funded projects directly undermines the administration’s express and laudable endeavors to support public-private partnerships elsewhere—particularly programs supporting entrepreneurial innovation. In fact, the administration just announced \$150 million in research funding for 18 states, including to various centers comprising “one of the single largest broad investments in place-based research and development in the nation’s history.”³³ This effort builds on the president’s marquee legislation, the American Rescue Plan, which “reauthorized and expanded the State Small Business Credit Initiative (SSBCI) and will provide nearly \$10 billion in funds,”³⁴ and granted \$1 billion for Build Back Better Regional Challenge winners “to rebuild regional economies, promote inclusive and equitable recovery, and create thousands of good-paying jobs in industries of the future such as

³¹ *Id.* at 85,594.

³² *Mylan Lab ’ys Ltd. v. FDA*, 910 F. Supp. 2d 299, 306 (D.D.C. 2012) (quotations omitted).

³³ Eva Dou, *Biden Wooing Battleground States and Red States with Research Funds*, Wash. Post (Jan. 29, 2024), <https://www.washingtonpost.com/technology/2024/01/29/biden-innovation-research-funds-battleground/> (quoting the National Science Foundation).

³⁴ *The State Small Business Credit Initiative and Rebuilding the U.S. Manufacturing Base*, The White House (May 2023).

clean energy, next-generation manufacturing, and biotechnology,”³⁵ among other things. Along similar lines, the CHIPS and Science Act allocated billions to semiconductor and scientific R&D, which the administration credits for “spur[ring]” companies to invest billions more.³⁶ The administration has further touted the “\$640 billion in clean energy and manufacturing investments” private companies have announced since the president took office,³⁷ including at least \$110 billion under the Inflation Reduction Act.³⁸

The VC community has supported these efforts, along with other programmatic initiatives supporting business stimulation like the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which are meant to bolster technological innovation “through the investment of Federal research funds” and “[i]ncrease[d] private-sector commercialization of innovations derived from Federal research and development funding.”³⁹ But the risk that agencies will more expansively exercise march-in rights against inventions backed by government funding is already cautioning VCs away from these otherwise critical partnerships, undermining the administration’s objectives in these spaces and driving away the funds necessary to realize broader economic initiatives.

The unreliability in the patent system will also extend to university technology transfer offices, despite this being against the original intent of Bayh-Dole. Under the legislation, universities that receive federal grants can patent and license their inventions to US companies, which led to the creation of companies like Google (Stanford TTO), Genentech (University of California TTO), and Akamai Technologies (MIT TTO). The march-in framework would call into question inventions spun out of university TTOs leveraging federal dollars, thus limiting the innovation coming out of these commercializing arms.

The draft guidance’s march-in approach effectively precludes all but the largest of companies from innovating. The draft guidance’s harms will fall particularly hard on entrepreneurs, who have little hope of commercializing new innovations without VC support. The guidance signals the government’s openness to exercising march-in rights more freely,

³⁵ *President Biden to Announce 21 Winners of \$1 Billion American Rescue Plan Regional Challenge*, The White House Briefing Room (Sept. 2, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/02/president-biden-to-announce-21-winners-of-1-billion-american-rescue-plan-regional-challenge/>.

³⁶ *FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China*, The White House Briefing Room (Aug. 9, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chains-and-counter-china/>.

³⁷ *FACT SHEET: Biden-Harris Administration Announces Innovation Engines Awards, Catalyzing More than \$530 Million to Boost Economic Growth and Innovation in Communities Across America*, The White House Briefing Room (Jan. 29, 2024), <https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/29/fact-sheet-biden-harris-administration-announces-innovation-engines-awards-catalyzing-more-than-530-million-to-boost-economic-growth-and-innovation-in-communities-across-america/>.

³⁸ *FACT SHEET: One Year In, President Biden’s Inflation Reduction Act is Driving Historic Climate Action and Investing in America to Create Good Paying Jobs and Reduce Costs*, The White House Briefing Room (Aug. 16, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/16/fact-sheet-one-year-in-president-bidens-inflation-reduction-act-is-driving-historic-climate-action-and-investing-in-america-to-create-good-paying-jobs-and-reduce-costs/>.

³⁹ *See generally Mission - The SBIR and STTR Programs*, SBIR-STTR - America’s Seed Fund, <https://www.sbir.gov/about>.

incentivizing large, established companies to use march-in petitions to stymie competition from smaller entities who must then either license their patents or expend limited resources responding to and defending against march-in proceedings. Indeed, the draft guidance itself contemplates this precise circumstance.⁴⁰

C. The draft guidance’s march-in approach will stymie development in critical industries.

The draft guidance will be felt the hardest in emerging fields that uniquely rely on government-funded intellectual property, stifling research and development in renewable energy, defense, telecommunications, agriculture, healthcare, and more.

In the energy sector, for example, the Advanced Research Projects Agency-Energy (ARPA-E) has provided over “\$3.68 billion in R&D funding for more than 1,530 potentially transformational energy technology projects.”⁴¹ The program focuses on jumpstarting ideas too early in development to attract private funding. Among this program’s successes, “218 teams have together raised more than \$11.8 billion in private-sector follow-on funding to continue to advance their technology toward the market,” including by attaining 1073 patents to date.⁴² Similarly, the Department of Energy’s Lab-Embedded Entrepreneurship Program (LEEP) funds fellowships “to enable the most promising clean tech entrepreneurs to develop game-changing technologies for a clean energy future.”⁴³ These programs’ success in bringing new clean-energy technology to market depends on entrepreneurs receiving follow-on funding from the private sector, including VC. Indeed, as DOE announced just last year, more than *\$1 billion* in follow-on funding for LEEP projects has allowed the program to become “a hub for innovations vital to building a clean energy economy.”⁴⁴ But the march-in framework in the guidance would disincentivize private-sector participation in these critical projects by injecting uncertainty regarding the rights flowing from these inventions, compromising America’s clean-energy future.

As another example, military technology startups are revolutionizing national defense, particularly by meeting growing demand for software-based tech and AI systems. To compete globally, the Defense Department “has increased the speed at which it procures and integrates emerging technologies” to “ma[ke] it possible to spread commercial software to the government.”⁴⁵ To ensure America charts the course on emerging military technologies, VCs have been principally driving development in this space by funding startups that develop “products from first principles, focusing on the mission’s core requirements rather than rigid specifications, . . .

⁴⁰ See 88 Fed. Reg. at 85,601 (Scenario 2).

⁴¹ *Our Impact*, U.S. Dep’t of Energy, ARPA-E, <https://arpa-e.energy.gov/about/our-impact>.

⁴² *Id.*

⁴³ *Lab-Embedded Entrepreneurship Program*, U.S. Dep’t of Energy Off. of Energy Efficiency & Renewable Energy, <https://www.energy.gov/eere/ammto/lab-embedded-entrepreneurship-program>.

⁴⁴ *Innovators from DOE’s Lab-Embedded Entrepreneurship Program Surpass \$1 Billion in Follow-on Funding*, U.S. Dep’t of Energy Off. of Energy Efficiency & Renewable Energy (Mar. 13, 2023), <https://www.energy.gov/eere/ammto/articles/innovators-does-lab-embedded-entrepreneurship-program-surpass-1-billion-follow>

⁴⁵ Jeff Decker & Eric Li, *How Software Companies Can Enter the U.S. Defense Market*, Harvard Bus. Rev. (July 14, 2023), <https://hbr.org/2023/07/how-software-companies-can-enter-the-u-s-defense-market>.

allow[ing] for greater adaptability and innovation.”⁴⁶ In this way, VC funds are “reshap[ing] the defen[s]e and military technology landscape . . . fostering a more agile, technology-centric, and mission-focused approach to modern warfare.”⁴⁷ Inventions that received government funding for R&D, such as through the Defense Advanced Research Projects Agency (DARPA), the draft guidance incentivizes established companies that have historically “monopolized” this industry to utilize the march-in petition process to exact pressure upon new competitors.⁴⁸

In the healthcare space, VC has deployed billions of dollars to thousands of startups developing cutting-edge medical devices and cures.⁴⁹ NVCA has long supported robust government funding to R&D and technology transfer programs to jumpstart commercialization in this industry,⁵⁰ like through NIH’s Small business Education and Entrepreneurial Development (SEED) program. Unfortunately, the march-in guidance would undermine these critical partnerships - half of the guidance’s scenarios pertain to the biotech or pharmaceutical industries, revealing NIST’s outsized focus on this space. Disincentivizing entrepreneurs and their VC backers from further developing necessary medical technologies would severely harm Americans nationwide who desperately need these treatments.

The draft guidance itself confirms its likely immense impact on technological innovations across industries. NIST deploys the example of a manufacturing startup developing “improved 3-D printing technology for construction materials” that “received Phase I and Phase II SBIR grants.”⁵¹ It forecasts that a large construction company that wants to launch its own 3-D printing initiative might petition the government to march-in on the startup’s patent portfolio if the startup took too long to successfully launch a commercial product. Although the guidance suggests that “[t]he mere fact that a potential competitor might be able to bring a subject invention to market more quickly” is not necessarily grounds to exercise march-in rights, it *does* indicate that exercising march-in rights or having the agency closely “monitor” product development might be appropriate depending on how the startup allocates its more limited resources.⁵² Even the threat of march-in under these circumstances—and the need to expend resources responding to march-in-related inquiries—will deter startups from utilizing federal funds for R&D. That risk touches all corners of technological innovation.

NIST’s instruction that agencies “assess whether march-in is warranted” when a “contractor or licensee has commercialized the product, but *the price or other terms* at which the product is currently offered to the public are not reasonable”⁵³ exacerbates this concern because it expands march-in rights beyond their narrow purpose and is otherwise vague and indeterminate.

⁴⁶ Josipa Majic Predin, *VCs Fuel the Boom in Defense and Military Startups Amid Global Conflicts*, Forbes (Nov. 2, 2023), <https://www.forbes.com/sites/josipamajic/2023/11/02/vcs-fuel-the-boom-in-defense-and-military-startups-amid-global-conflicts/?sh=3b099a55bdd5>.

⁴⁷ *Id.*

⁴⁸ *See id.*

⁴⁹ *Healthcare Innovation*, NVCA, <https://nvca.org/healthcare-innovation/>.

⁵⁰ *See id.*

⁵¹ 88 Fed. Reg. at 85,601 (Scenario 2).

⁵² *See id.* at 85,602.

⁵³ *Id.* at 85,598 (emphasis added).

Agencies must “‘articulate a comprehensible standard’ for assessing the applicability of a statutory category.”⁵⁴ That is, “[i]f a ‘purported standard is indiscriminate and offers no meaningful guidance’ to affected parties, it will fail ‘the requirement of reasoned decision-making.’”⁵⁵ Notably, neither the guidance, existing march-in regulations, nor the statute define what makes a price or term “reasonable” or how an agency might go about determining reasonableness. Contractors—and the VCs considering whether to invest—lack any ability to predict whether or under what circumstances an agency might decide to march in on patents for market-based reasons. Such a vague standard—if it can be called a standard at all—invites arbitrary decision-making. And any such invitation inevitably upends VCs’ ability to make the high-risk investments necessary to commercialize innovative new products, especially in these critical industries.

At bottom, the draft guidance turns the Bayh-Dole Act’s incentive structure on its head, injecting confusion and uncertainty into a patent system that was supposed to stabilize these rights and encourage entrepreneurs and their chosen partners to invest in and commercialize inventions arising from federally funded research. Its effect will be to discourage VC and other private funding necessary to commercialize inventions stemming from federally funded research—the Act’s core aim. Innovation driven by startups who most depend on VC funding will ultimately pay the greatest price.

III. Reimagining the framework for exercising march-in rights through generally applicable informal policy guidance would be highly destabilizing.

As we have described, expanding the exercise of march-in rights will undermine the trust between government and private-sector industries collaborating to innovate. NIST’s approach to fundamentally reshaping march-in rights through generally applicable draft guidance is also unlawful and particularly ill-suited to industry needs—and it would have highly destabilizing effects in industries where investment-backed expectations should be maintained.

First, the APA requires any agency issuing a rule to provide prior notice and an opportunity for public comment,⁵⁶ and agencies cannot avoid this process by mere labels.⁵⁷ When an agency’s pronouncement “binds private parties or the agency itself with the ‘force of law,’” the agency must follow notice-and-comment rulemaking procedures.⁵⁸ As the D.C. Circuit has recognized, one way that private parties can be effectively bound by the directives contained in an agency document is “if the affected private parties are reasonably led to believe that failure to conform will bring adverse consequences.”⁵⁹

⁵⁴ *ACA Int’l v. FCC*, 885 F.3d 687, 700 (D.C. Cir. 2018) (quoting *U.S. Postal Serv. v. Postal Regulatory Comm’n*, 785 F.3d 740, 754 (D.C. Cir. 2015)).

⁵⁵ *Id.* (quoting *Postal Regulatory Comm’n*, 785 F.3d at 754-755).

⁵⁶ *See* 5 U.S.C. § 553(b), (c).

⁵⁷ *Am. Mining Cong. v. MSHA*, 995 F.2d 1106, 1109–1110 (D.C. Cir. 1993); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1024 (D.C. Cir. 2000).

⁵⁸ *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002).

⁵⁹ *Id.* at 383 (quoting Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 *Duke L.J.* 1311, 1355 (1992)).

Here, the draft guidance advises several circumstances where the government should march in on exclusive patent rights. Parties holding these rights will thus conform their behavior to avoid the risk of an agency's march-in. If implemented, the guidance will shape markets as innovators face credible fear that any given regulator may have arbitrary considerations or think their prices are "unreasonable" and take away their hard-earned patent rights to share them with competitors.

Second, industry-nonspecific, informal policy guidance is a poor vehicle to bring about the changes NIST proposes. Public funding drives R&D in emerging fields ranging from renewable energy to telecommunications to healthcare; NIST's broad, generally applicable march-in guidance will have correspondingly far-reaching impacts *without* accounting for individualized industry needs, only increasing the unpredictability of how different agencies might apply the guidance. The failure to account for nuances in how inventions develop within various industries—and particularly the heavy reliance on government funding in some critical industries—is deeply problematic.

Agencies should take such action only through rulemaking—not informal policy guidance—to ensure fulsome notice and comment from affected parties on the novel concept of an agency exercising march-in rights. Rulemaking would also ensure comprehensive analysis under the Regulatory Flexibility Act, which is exceedingly important in this context because of the severe risk of harm to the private-sector interests directly injured by march-in. At the end of the day, such a radical approach to desecrate a law that has served so well for over forty years should only be considered by Congress itself. We urge NIST, and the Biden Administration more broadly, to refrain from overreaching and inserting itself into what should be a legislative matter.

IV. Conclusion

NIST's draft guidance fundamentally contradicts the Bayh-Dole Act's core purpose and the administration's priorities to revitalize the American economy through entrepreneurship. NIST's encouragement of agencies to exercise march-in rights under the circumstances discussed is a marked departure from the serious restraint Congress originally intended agencies to demonstrate in this arena by limiting march-in to the rare circumstances in which a federally funded invention was not being commercialized. The draft guidance would disrupt the long-standing predictable trust in patent rights supported by federally funded research. Adoption of this guidance would deter further investment in companies leveraging these patents, thus stifling public-private collaboration to further drive American competitiveness and innovation.

NVCA thus urges NIST to immediately abandon the draft march-in framework.

Sincerely,

A handwritten signature in black ink that reads "Bobby Franklin". The signature is written in a cursive, slightly slanted style.

Bobby Franklin
President and CEO
National Venture Capital Association