February 6, 2024

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

Dear Director Locascio,

The Council for Innovation Protection (C4IP) welcomes the opportunity to respond to the December 8, 2023, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights from the National Institute of Standards and Technology (NIST) (Docket Number 230831-0207) (referred to herein as the "NIST RFI," and the guidance as the "draft guidelines").

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. Founded and chaired by former directors of the U.S. Patent and Trademark Office from previous Democratic and Republican administrations, our nonprofit organization aims to be a valued partner to those considering policies impacting America's intellectual property system.

C4IP has serious concerns about how these draft guidelines, if implemented, will impact the innovation ecosystem by undermining a singularly successful law -- the Bayh-Dole Act. This act has successfully incentivized private investment into federally-funded inventions, bringing early-stage research concepts into the commercial sphere as new products or services with immediate benefits to Americans: improving the quality of life, creating new startups, small businesses, and high-paying jobs.

As will be explained in greater detail below, the draft guidelines presented in the NIST RFI will convert Bayh-Dole's simple and highly successful system in which the private sector takes license to federally-funded patents and makes further investments in the hopes of creating commercial products, into a complex one where the government can pull back the deal at any time under an expansive and vague set of circumstances. In fact, the more successful a private company is, the more likely it is to get ensnarled into the complicated process the draft guidelines provide for the federal government to "march-in" and let another company produce and sell a product.

The draft guidelines are not limited to a single agency, a single area of technology, or a single point in time in the development lifecycle. They will cause a sea change in how private industry views engagement with the federal government or any entity conducting research with the federal government. Federally-funded research will again be viewed as "contaminated" and untouchable by the private sector, the very problem the Bayh-Dole Act set out to solve.[1]

Investors will halt funding for early-stage, developing technologies that take federal government funding or license federally-funded patents. The many recently passed laws and federal programs that use research grant money to achieve their policy objectives -- the CHIPS and Science Act (semiconductor research),[2] the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs,[3] the Cancer Moonshot,[4] and the Inflation Reduction Act (green research),[5] to name a few -- will inevitably lose their effectiveness.

Conversely, the draft guidelines, if adopted, will incentivize large companies to monitor risk-taking startups and small businesses working with federal inventions to identify those that become successful. The draft guidelines, especially their scenarios, provide a roadmap for established companies to petition federal agencies to march-in on a startup because those established companies will produce the startup's new product faster and less expensively (particularly because they did not bear the risk or expense of developing the federally-funded invention).

This ever-present yet uncertain threat of federal take-over means that, in the future, an unknown number of startups and small businesses simply will not be formed, leaving an unknown number of federally-funded inventions unused and undeveloped. In effect, these draft guidelines will take our country back to the pre-Bayh-Dole Act era. This benefits no one -- not the taxpayers whose money will be wasted, not our country, which will see other countries take advantage of our

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[1] Vicki Loise and Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, Science Translational Medicine (2010), https://www.science.org/doi/10.1126/scitranslmed.3001481.
[2] The White House, *FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China* (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/.
[3] The Small Business Administration, *The SBIR and STTR Programs*, https://www.sbir.gov/about.
[4] The National Cancer Institute, *About the Cancer Moonshot* (Dec. 4, 2023), https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/about (describing the latest set of goals for the program).
[5] *See, e.g.*, National Oceanic and Atmospheric Administration, *Inflation Reduction Act: Climate Data and Services*, https://www.noaa.gov/inflation-reduction-act/inflation-reduction-act-climate-data-and-services (describing climate data research funding).

undeveloped R&D, and certainly not the American people, who will lose out on benefiting from the fruits of federally-funded research that were never fully developed into new products and technology they can use.

I. The Bayh-Dole Act Has Benefited Americans Tremendously by Unlocking the Potential of Federally-Funded Research

The Bayh-Dole Act has been a feature of the American innovation ecosystem for over four decades, with many federal grant programs relying on it. It is easy to take its operation and attendant success for granted. The Act transformed the utilization of inventions arising from federally-funded research. Before the Act, less than four percent of patents resulting from federal funding were licensed and put to work.[6] After the Act, it is estimated that the tech transfer it enabled from universities alone has added over $1.9 trillion to U.S. gross industry output and $1 trillion to U.S. GDP (both in 2012 dollars) between 1996 and 2000, along with countless life-changing innovations.[7] The success of the Act has led other countries to adopt it as a best practice.[8]

The Bayh-Dole Act is effective because it incentivizes the private sector to risk the commercial development of federally-funded research -- often early-stage, mission-driven, "head-end" research[9] -- in other words, basic research not necessarily undertaken with the intent of immediately useful commercial

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[6] Loise & Stevens, *supra* note 1.

[7] Lori Pressman, Mark Planting, Carol Moylan and Jennifer Bond, *Economic Contributions of University/Nonprofit Inventions in the United States: 1996 – 2020*, Biotechnology Innovation Organization (BIO) and AUTM (2022), https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf; *see also* Walter Copan, *Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation*, IPWatchdog (Nov. 2, 2020), https://ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/id=126980/ (stating that the Bayh-Dole Act has added over $1.3 trillion to U.S. GDP).

[8] AUTM, *Landmark Law Helped Universities Lead the Way*, https://autm.net/about-tech-transfer/advocacy/legislation/bayh-dole-act (listing other countries that have adopted a version of the Bayh-Dole Act).

[9] Rebecca Mandt et al., *Federal R&D Funding: The Bedrock of National Innovation*, MIT Science Policy Review (2020), https://sciencepolicyreview.org/2020/08/federal-rd-funding-the-bedrock-of-national-innovation/ ("federally-funded R&D focuses heavily on use-inspired basic research and supporting work which is in line with the missions of federal agencies, missions that prioritize societal needs"); National Center for Science and Engineering Statistics, *The State of U.S. Science and Engineering 2020*, National Science Foundation, https://ncses.nsf.gov/pubs/nsb20201/u-s-r-d-performance-and-funding ("the federal government is the second-largest funder of R&D and funds the largest share of basic research").

application, as that is often not the mission of the researching entity. But with an investment of additional time and money, such research may translate into useful products with commercial applications.

The licensing scheme of the Bayh-Dole Act takes advantage of the patent system to grant an exclusive license under a federally-developed invention, incentivizing a private entity to make further investments. For example, federal money funded approximately 55% of the research at universities in fiscal year 2022.[10] Under the Bayh-Dole Act, universities may secure title to the patents resulting from this research and then license them for further commercial development to startups, small businesses, or other private entities.[11] This system has met with enormous success -- 9,884 licenses and options with universities were executed, and 998 new startups were formed in 2022 alone.[12]

By allowing universities and other research institutions to license federally-funded inventions, the Bayh-Dole Act also decentralized the process of technology transfer. Before the Act, there were 23 tech transfer offices across the country; now, they are at virtually every major research university.[13] This decentralization has fostered the creation of research hubs around universities, in turn enabling the researchers who are closest to the patented inventions to form startups and small businesses that further develop their discoveries.[14]

While the Bayh-Dole Act has impressive numbers to back up its success, not every licensed federally-funded patent turns into a successful product; not all capital

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[10] Michael T. Gibbons, *R&D Expenditures at U.S. Universities Increased by $8 Billion in FY 2022*, National Center for Science and Engineering Statistics (Nov. 30, 2023), https://ncses.nsf.gov/pubs/nsf24307.

[11] For greater readability, these comments will refer to "licensees" to mean both licensees and contractors, which are defined as the entities accepting government funding, except where otherwise stated.

[12] AUTM, *Driving the Innovation Economy: Academic Technology Transfer in Numbers*, https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf.

[13] Loise & Stevens, *supra* note 1.

[14] Gabrielle Athanasia, *The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today*, Center for Strategic and International Studies (Jan. 12, 2022), https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today; *see also* Meredith Asbury, *How a Lab Incident Led to Better Eye Surgery for Millions of People*, The Golden Goose Award (2021), https://www.goldengooseaward.org/01awardees/lasik (describing how federal funding following a laser accident led to a startup spun out of the University of Michigan with some of its scientists and the development of LASIK); Mandt, *supra* note 9 ("federal funding is often responsible for the key centers around which technology hubs form and lead to regional economic growth; examples include Silicon Valley in California; Boston, Massachusetts; the Research Triangle Park in North Carolina; the Boulder-Denver corridor in Colorado; and Madison, Wisconsin").

expenditures pay off.[15] Additionally, the additional private investment is usually significantly higher than the federal funds initially expended; estimates suggest it takes at least $10,000 to bring one dollar of academic research to market.[16] Investing in federally-funded research, like any research, is risky.

The Bayh-Dole Act -- until now -- has provided the incentive to take that risk, thanks to the federal government's appropriate reluctance, following the letter of the law, to march-in on a licensee. Win or lose, the licensee could rest assured of its rights without government intervention if it had exclusively licensed a federally-funded patent and had not egregiously neglected to try to develop it. As explained further below, the draft guidelines will upset this paradigm and consequently threaten to upset all that the Bayh-Dole Act has fostered -- from the new technologies and products available to Americans to the new jobs created at startups and small businesses to the additional licensing money universities can reinvest in research, to name a few.

II. The Uncertainty Caused by the Draft Guidelines Will Undermine the Successful Public-Private Partnerships Fostered by the Bayh-Dole Act

The Bayh-Dole Act was drafted with four narrow exemptions allowing for the government to "march-in" and reclaim control of the patent.[17] Although Bayh-Dole has always allowed the federal government to march-in and issue additional licenses to federally-funded inventions, administrations under both parties have never exercised this right, understanding that the Act's intent was to allow seizure only for substantial failure to engage in developing federally-funded patents.[18]

The draft guidelines upend this paradigm. Although they largely restate the statutory language of these narrow exceptions, they then describe scenarios that

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[15] Faisal Hoque, *Why Most Venture-Backed Companies Fail*, Fast Company (2012), https://www.fastcompany.com/3003827/why-most-venture-backed-companies-fail (approximately 75% of venture-backed startups fail).

[16] *Innovation's Golden Goose*, Economist Technology Quarterly (2002), https://bayhdolecoalition.org/wp-content/uploads/2023/05/The-Economist-December-14-2002-Innovation_s-Golden-Goose-Article.doc.pdf; *see also* Wayne Winegarten, *Giving the Gov't Drug Patent March-In Authority Is Bad Policy*, Law360 (Dec. 13 2023), https://www.law360.com/ip/articles/1776564.

[17] 35 U.S.C. § 203(a)(1)-(4).

[18] *See* Birch Bayh and Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, Washington Post (2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ ("The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.").

would dramatically expand when the federal government would march-in, compared to the well-understood meaning of the statute that reserved marching-in for exceptional circumstances. Perhaps the clearest example of the draft guidelines' overreach is the inclusion of "reasonable" pricing as a factor that should be considered -- a consideration that is contrary to the language of the statute,[19] and which, in practice, is likely to be highly subjective.

The real import of these new guidelines, then, is that although the federal government has never exercised march-in rights in 43 years under the Bayh-Dole Act, march-in was considered in eight out of the eight scenarios the guidelines describe and characterized as likely the best path forward in four -- which stands in diametric contrast to how the federal government has implemented the act to date.[20] The scenarios, coupled with the balance of the draft guidelines, paint a picture of a new regulatory landscape in which march-in is frequently justified, setting in motion a highly subjective, fact-intensive inquiry to be undertaken by federal government bureaucrats.

The guidelines' scenarios give agencies the clear direction that, in comparison to past practice, they should be leaning in to monitor licensees' businesses and second-guessing them at every step of the business lifecycle. As the draft guidelines' examples cover a wide range of technology, from water filtration to reflective coatings for highway safety to face mask technology, it is also plain that agencies across the federal government -- indeed, any that give research grants -- should be preparing to step up their surveillance. Given that until now, march-in petitions have only been filed with NIH,[21] this guidance marks a significant expansion of federal agencies that are expected to suddenly second-guess the minutiae of their licensees' activities. Agencies such as the Departments of Defense, Agriculture, Energy, and Transportation will also become recipients of the new wave of petitions encouraged by the draft guidelines.

In sum, the fact-intensive and subjective nature of the proposed draft guidelines will make it uncertain if and when the federal government will march-in. C4IP is

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[19] NIST, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, 88 Fed. Reg. 85598 (Dec. 8, 2023) [hereafter "NIST RFI"] ("If the 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, agencies may need to further assess whether march-in is warranted.") (proposed guidelines for 35 U.S.C. § 203(a)(1)); *id.* at 85599 ("Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?") (proposed guidelines for 35 U.S.C. § 203(a)(2)).

[20] NIST RFI, *supra* note 19, at 85601-05.

[21] *See* Bayh-Dole Coalition, *Digital Library*, https://bayhdolecoalition.org/digital-library/ (collecting filed march-in petitions to-date).

concerned that this new approach, with its attendant uncertainty, will cause potential licensees and their investors to abandon the development of government-funded inventions. This shift will disrupt the enormously fruitful innovation arising from public-private partnerships over the past 40+ years, which grew in reliance on the federal government's appropriate restraint in exercising its march-in rights.

a. Dispositive Consideration of Pricing is Both Illegal and Unwise

The plain text of the Bayh-Dole Act does not provide for price as a consideration for marching-in.[22] That this factor was not included as part of the four limited exemptions was entirely intentional, as the senators responsible for the passage of the Act wrote: "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional[.]"[23] Executive guidance cannot rewrite this clear statutory language.[24]

But even if it could, including consideration of pricing in march-in is bad policy, injecting uncertainty into licensees' business decisions. Licensees trying in good faith to comply with the guidelines as currently drafted would simply be guessing whether a given price might cross the line.

With respect to § 203(a)(1), for example, which requires that contractors take steps to achieve practical application of their inventions, the draft guidelines would further specify that if the "licensee has commercialized the product," the federal agency should now consider whether the price is "not reasonable" as part of determining whether practical application has been realized.[25] "Not reasonable" can take many meanings in different contexts, making it a highly subjective inquiry and consequently unpredictable for licensees.[26]

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[22] *See* 35 U.S.C. § 203(a)(1)-(4) (no mention of price).

[23] Birch Bayh and Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASHINGTON POST (2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

[24] *See* Chevron USA Inc. v. Natural Resources Defense Council, Inc., 467 US 837, 843-44 (1984) ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.").

[25] NIST RFI, *supra* note 19, at 85598.

[26] The description of pricing relevant to the second factor under § 203(a)(2), which asks whether march-in is necessary to "alleviate health or safety needs," fares no better. The draft guidelines direct an agency to ask whether the licensee is "exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances." NIST RFI, *supra* note 19,

Moreover, attempting to anticipate the federal government's preferred pricing will distract licensees from doing what is best for their companies. This distracted focus, in turn, will reduce the competitiveness of America's most innovative startups and small businesses, harming the future of innovation in our country. Given these risks, potential future licensees are likely to simply pass on licensing federally-funded inventions. Public-private partnerships will deteriorate as a result.

Finally, beyond the harm to individual licensees, this "reasonable pricing" criteria will effectively turn the Bayh-Dole Act into a mechanism for government price control, distorting the marketplace for investment into new innovation and technology. By having the government pick winners and losers, we risk forfeiting a key strength of the American economic system -- its decentralized process of allowing the marketplace to direct investment to where it will produce the most benefit -- and, instead, take our system closer to that of the state-driven economies of some our economic rivals. Whatever the short-term allure of government price control may be, it has no comparable history of long-term success in driving the progress of innovation.

b. The Open-ended Nature of the Draft Guidelines Will Invite Frequent Petitions and Regular Federal Intervention at Great Expense to Contractors and Licensees

The draft guidelines make clear that the federal government is empowered to march-in at any stage of a licensee's business activities for nearly any reason. Again, the requirement under § 203(a)(1) that a contractor take steps to achieve "practical application" of the invention is instructive -- there can be a failure of practical application despite there being a product if the licensee is selling it at the "wrong" price, as discussed above. Alternatively, if there is "no product," per the guidelines, "agencies may need to further assess whether march-in is warranted."[27] The licensee faces scrutiny whether or not it is successful, and something as common as a setback in research and development could be the basis for the federal government reclaiming the patent through march-in.

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at 85599. Licensees trying to set prices in the health or safety space are left with hoping that no one will argue that they are "exploiting" anyone or that their price is too "extreme and unjustified" given the "totality of the circumstances" -- several criteria that are susceptible to motivated argumentation that will ultimately turn on a subjective decision, and which are thus of little help in achieving business certainty.

[27] *Id.* at 85598.

March-in decisions will fall to a federal official -- an agency head who, per the guidelines, may delegate the responsibility.[28] Critical decisions about a licensee's fate will rest on the shoulders of someone who likely has no experience in the particular industry or even experience as an adjudicator. While the statute itself provides that the ultimate decision to march-in falls to an agency head, the draft guidelines remove the statute's carefully crafted guardrails by broadening the bases on which an agency is directed to consider marching-in, putting a thumb on the scale of more frequent federal intervention by whomever the agency head designates.

These changes would give rise to several negative effects: (1) creating a roadmap for established companies and competitors to regularly petition the federal government to march-in, to the detriment of our countries' innovative startups and small businesses in particular; (2) embroiling innovative startups and small businesses in lengthy, expensive bureaucratic proceedings; and (3) putting the decision whether to march-in in the hands of unqualified federal workers.

i. The Draft Guidelines Will Benefit Large Industry Incumbents and Hurt New Entrants and Small Businesses

Companies, startups, and small businesses that are lucky enough to be successful in commercializing federally-funded inventions will have a target on their back, especially from established, larger competitors, who will often be able to argue that they could bring a product to market more quickly and with less expense -- particularly given that they did not bear the research and development costs. With little disincentive and great windfall opportunity for entities making a request to the government to exercise march-in rights, the process could devolve into a free-for-all where established companies frequently petition the government to march-in on the operations of their smaller competitors. This would embroil startups and small businesses in lengthy, expensive proceedings and enable our economic adversaries, such as China, to mount state-backed campaigns against innovative U.S. companies, both of which are discussed further below.

Several of the examples discussed in the draft guidelines bear out these concerns. In Scenario 3, for example, the (smaller) licensee would likely be subject to march-in by several interested petitioners if the licensee did not present a plan to meet product demand satisfactory to the federal government.[29] Tellingly, even in a scenario where the draft guidance cautions against march-in simply because the

[28] *Id.* at 85596.
[29] *Id.* at 85602.

petitioner is more established, the guidance directs the agency to monitor the licensee in case march-in might still be appropriate going forward.[30] The scenarios clearly contemplate frequent petitions, followed by fact-intensive inquiries leading to march-in or ongoing federal oversight. This is the exact opposite of how the federal government has behaved under the Bayh-Dole Act until now and directly contravenes the narrow limits for intervention set forth in the act itself.

ii. Under the Draft Guidelines, Contractors and Licensees Will Bear a Heavy Burden in Responding to Petitions

The guidelines emphasize that "march-in considerations are extremely fact-dependent and any decision to exercise march-in will be made based on the totality of the circumstances."[31] In other words, the draft guidelines contemplate extensive agency fact-finding both in response to petitions and where the agency determines independently that march-in may be appropriate. The draft guidelines set forth an informal consultation period, followed by a formal proceeding before the designated fact-finder, which may involve counsel and witnesses, formal findings, and an opportunity to challenge them, followed by an internal agency appeals process.[32] An adverse decision may then be challenged in the Court of Federal Claims by the contractor or an exclusive licensee.[33]

While such an extensive process may be necessary for due process considerations, it certainly will impose a substantial burden on a contractor and its licensee. Even an informal consultation is a process that any sensible licensee would take seriously and feel compelled to involve counsel, even if not required. The expenses and time required would only multiply from there, compounded by how the uncertainty caused by the proceeding would negatively affect the licensee's ongoing work and ability to attract additional funding. The prospects for the licensee will be even worse if an established company's petition led to the march-in proceeding -- such a petitioner would likely be willing to spend significant resources mounting a challenge in exchange for access to an innovative technology with proven marketplace potential.

Given that the draft guidelines contemplate marching-in simply where progress seems to have "stalled," the fact that a licensee could ultimately prevail in showing that it had merely experienced a normal research setback is little comfort if the licensee must endure a lengthy administrative process to prove that. Likewise, for a

[30] *Id.* (Scenario 2).
[31] *Id.* at 85597.
[32] *Id.* at 85596.
[33] *Id.*; 35 U.S.C. § 203(b) (allowing appeal by any adversely affected contractor, inventor, assignee, or exclusive licensee).

licensee to prevail against a well-funded competitor may come at the cost of near-bankruptcy -- if the licensee can survive that long. The prospect of facing this administrative fight at any time during the licensee's business lifecycle will be a significant deterrent for any entity to develop federally-funded inventions.

iii. Federal Bureaucrats Are Not Well-Positioned to Assess the Adequacy of a Licensee's Progress

When faced with a march-in petition, or on their own initiative, the draft guidelines would empower federal bureaucrats to second-guess the business strategy and adequacy of a licensee's marketplace progress, overriding the judgment of both the licensee and university or research institute that actually developed the technology and understands it, and which university or research institute already has all the safeguards and incentives in place to terminate or reform licenses to its commercialization partners when called for.

For example, in fiscal year 2022, about 55% of research at universities was funded by the federal government. These universities often license their federally-funded patents to startups and small businesses.[34] These resulting partnerships have led to world-renowned incubation hubs such as Silicon Valley and Research Triangle Park in North Carolina, as well as technology incubators and research parks in nearly every city and state in America. The Biden Administration itself recently named 31 "Tech Hubs" across 32 states that will share $500 million in grant funding from the CHIPS and Science Act.[35]

Currently, it is these research institutions and universities that have contractual relationships with start-up licensees with defined milestones, understand the technology and the relevant markets, and can gauge the adequacy of progress. Likewise, university tech transfer offices have developed expertise in executing tailored, appropriate licenses to facilitate productive working relationships with licensees. These licenses include extensive coverage of licensee progress towards marketplace introduction and success, enabling the university licensor to monitor and audit progress, provide expert input, and terminate or modify the license if the licensee fails to make adequate progress. Universities stand to benefit from a licensee's success through milestone payments and royalties, so they have every incentive to ensure a licensee's diligence, but also have the experience to know when a startup is no longer viable. The resulting symbiotic relationship between

[34] Gibbons, *supra* note 10.
[35] U.S. Economic Development Administration, *Biden-Harris Administration Designates 31 Tech Hubs Across America* (Oct. 23, 2023), https://www.eda.gov/news/press-release/2023/10/23/biden-harris-administration-designates-31-tech-hubs-across-america.

American research universities and innovative startups and small businesses is one of America's most profound competitive advantages.

The draft guidelines would undermine this established system of innovation, advancement, and job creation with a new layer of oversight from the federal government, coupled with a new open invitation for petitions interfering with university-licensee relationships. Licensees of federally-funded inventions would have no way of knowing who will make a decision to march-in, which could happen years in the future. Yet they will be subject to interminable second-guessing of their venture. In the face of this unquantifiable risk, we expect many companies to take a pass on federally-funded research, leaving our nation's research universities holding the bag with stranded research results and no party interested in taking them forward to the marketplace.

III. History Demonstrates that the Draft Guidelines Cannot Provide the Certainty That Capital Investment Requires

The layers of uncertainty described above -- the meaning of new terms in the guidelines, the invitation of well-funded march-in petition challenges, the interposition of federal arbiters -- only compound the risk calculations venture capitalists and others already consider when deciding whether to fund a young company. Unfortunately, history suggests that the additional uncertainty of active federal intervention will cause investment money to go elsewhere, leaving federally-funded inventions gathering dust on laboratory shelves.

Two past periods in U.S. history are instructive. First, before the Bayh-Dole Act, the federal government had a policy of issuing non-exclusive licenses to federally-funded inventions. The result was that by 1978, the federal government had obtained approximately 28,000 patents but had licensed fewer than four percent.[36] The draft guidelines raise the very real risk of a government "exclusive" license becoming non-exclusive in practice when the government marches-in and grants a license to another party. Private industry, in other words, is likely to react as if the federal government has gone back to the practice of non-exclusive licensing, with the potentially disastrous results seen before 1978 of little private sector engagement with federally-funded research.

Likewise, after the passage of the Bayh-Dole Act, the U.S. National Institutes of Health (NIH) inserted "reasonable pricing" clauses in its model Cooperation, Research and Development Agreement between 1989 and 1995. This contractual change is functionally similar to the inclusion of pricing considerations in the draft

[36] Loise & Stevens, *supra* note 1.

guidelines. The resulting lack of engagement by the private sector led to the cessation of this practice, with the then-NIH Director stating, "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 [Public Health Service] scientists without providing an offsetting benefit to the public."[37]

There is no good reason to repeat the mistakes of the past, particularly when the federal government has already committed public funds to meet some of our country's greatest challenges -- the many green energy research projects funded by the Inflation Reduction Act, for example.[38] If the private sector declines to accept this money or to contract with those universities and research entities that do -- as it has in the past -- the federal government's effectiveness in driving innovation policy through research funding will be significantly diminished.

Under the draft guidelines, no matter how low a licensee sets price, or how much effort it puts into developing a product, or how fast it develops a product, there will always be the risk of some other company petitioning the federal government to march-in or the federal government marching in on its own accord. And, of course, the more successful the product, the higher the incentive for a me-too competitor to present a march-in petition as a means to gain windfall access to another's technology. Without the ability to meaningfully plan for this risk, federally-funded patents will become lower-priority investment targets.

IV. The Draft Guidelines Will Not Lead to Lower Drug Prices, But Will Hurt Universities and Small Businesses in Other Fields

Much of the press around the draft guidelines has focused on drug pricing and the use of federal march-in rights to lower drug prices.[39] As discussed above, consideration of price is not a permissible basis for the federal government to

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[37] National Institutes of Health, *NIH News* (1995), https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIHNotice-Rescinding-Reasonable-Pricing-Clause.pdf.

[38] *See* The White House, *Inflation Reduction Act Guidebook*, https://www.whitehouse.gov/cleanenergy/inflation-reduction-act-guidebook/.

[39] *See, e.g.*, Sydney Lupkin, *White House Proposes to 'March in' on Patents for Costly Drugs*, NPR (Dec. 7, 2023), https://www.npr.org/sections/health-shots/2023/12/07/1217882958/white-house-proposes-to-march-in-on-patents-for-costly-drugs; Jocelyn Kaiser, *Biden Wants NIH to Have 'March-in' Power to Override Patent Rights for High-priced Drugs*, SCIENCE (Dec. 7, 2023), https://www.science.org/content/article/biden-wants-nih-have-march-power-override-patent-rights-high-priced-drugs; Liz Seegert, *March-in Rights Are Key to Biden's Push to Lower Excessive Drug Prices*, FORTUNE (Dec. 21, 2023), https://fortune.com/well/2023/12/21/march-in-rights-biden-lower-excessive-drug-prices/.

march-in. Moreover, it would not have the intended effect because the federal government does not have sufficient rights in patents covering drugs. A recent study reviewing drugs approved between 2011 and 2020 found that 92% of approved drugs were not covered by any patents resulting from federally-funded research.[40] Seven percent were covered by some, but not all, federally-funded patents, making them ineffective march-in targets per the draft guidelines.[41] That leaves only five out of 361 drugs (one percent) as viable potential march-in targets because all the relevant patents were federally-funded.[42]

While drug prices will not be improved, the entire innovation ecosystem surrounding federally-funded research will be decimated. For example, universities and research entities that use federal funds for life sciences research will be harmed because the patents they acquire will be licensed for far less, if at all. Their patented early-stage, head-end research would become devalued to an "unblocking" license level -- having the value of a non-exclusive license that permits research and development that would be covered by the patent without liability but which otherwise confers no marketplace protection. As a result, we expect to see universities and research entities receiving far lower value for their head-end patents, leaving them unable to fund further basic research -- a true lose-lose scenario.

The remaining impact of the draft guidelines will be felt by startups and small businesses in other areas of technology that are often created around the commercialization of a single federally-funded patent or small set of them. Unlike drug development, which takes tremendous additional research beyond the basic government-funded research, these small companies rely on their federally-funded patent or patents to provide protection for their research and development investments. It is these innovative areas of the economy that are most vulnerable to disappearing if the draft guidelines are not withdrawn.

V. The Draft Guidelines Will Hurt U.S. Competitiveness in the Global Innovation Marketplace

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[40] Gwen O'Loughlin and Duane Schulthess, *March-in Rights Under the Bayh-Dole Act & NIH Contributions to Pharmaceutical Patents*, VITAL TRANSFORMATION (Nov. 30, 2023), https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

[41] NIST RFI, *supra* note 19, at 85600 ("Agencies may also need to consider whether there is intellectual property (beyond the subject invention(s)) that could possibly prevent other licensees from making the product or offering the service in question. A complicated intellectual property landscape could reduce the likelihood of successful licensing and weigh against march-in.") (emphasis removed).

[42] O'Loughlin & Schulthess, *supra* note 40.

The draft guidelines, if finalized, will chill private investment in federally-funded patents just as the U.S. is fighting to maintain its global technological leadership. America's market-based economy relies on private capital to drive further research and development of early-stage innovations that result from federal funding. Without this partnership, federally-funded research will not lead to broader innovation as it does currently. Initiatives like the CHIPS and Science Act will not succeed because private industry will not invest to turn "contaminated" federally-funded research into commercial products.

The U.S. system historically relies on the market picking winners and losers -- not the federal government, as the draft guidelines would dictate. This change would undermine one of our country's greatest advantages over our economic competitors, such as China, with its centrally-directed investment in technological development.

While federally-funded U.S. patents are likely to languish as they did before the Bayh-Dole Act, there is one critical difference now versus 40+ years ago -- today, the unlicensed patents' public disclosures will provide a blueprint to develop next-generation technologies in state-driven economies. China, for example, can direct its enormous state-run apparatus to mine unused U.S. federally-funded patents and develop them into commercial products, enabling it to become the first-mover in new areas of technology. This is the opposite of smart competition with other would-be world technological leaders.

At bottom, undermining the Bayh-Dole Act threatens American technological leadership, just as we face mounting competition from abroad.

* * *

At the outset of the draft guidelines, NIST states that one of its goals in providing these draft guidelines is to ensure "consistent and predictable" application of march-in rights.[43] As has been explained, there are many reasons why application of the guidelines will not be predictable, leading to the breakdown of public-private partnerships and the innovation emanating from them. The only "consistent" outcome of the guidelines will be the heightened sense that federal march-in is around the corner, particularly if a product incorporating a subject invention is successful. This looming shadow will deter private sector engagement with the federal government. Whatever the intention of these guidelines, history and common sense teach that they will not deliver more innovation at a better price but will instead waste federal money on inventions whose potential will be abandoned,

[43] NIST RFI, *supra* note 19, at 85594.

to the detriment of us all -- lost new technologies and products, lost startups and small businesses, lost jobs, and lost American competitiveness.

C4IP urges NIST to publicly withdraw these draft guidelines, a necessary step to assure public-private partnerships that they can count on a reliable public partner in the future.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

cc:
The Honorable Gina M. Raimondo, Secretary of the Department of Commerce
The Honorable Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
The Honorable Monica M. Bertagnolli, M.D., Director of the National Institutes of Health
The Honorable Isabel Casillas Guzman, Administrator of the U.S. Small Business Administration