



Treatment Action Group

April 4, 2021

National Institute of Standards and Technology  
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions  
Docket No.: 201207-0327  
Document ID: NIST-2021-0001-0001  
Federal Register 2020-27581

**RE: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, National Institute of Standards and Technology (NIST), United States Department of Commerce, Notice of proposed rulemaking. 86 FR 35, Agency/Docket Number: Docket No.: 201207-0327**

**Treatment Action Group (TAG) strongly opposes the National Institute of Standards and Technology (NIST)’s proposed changes to rulemaking: regulatory updates to 37 CFR Parts 401 and 404 Green Paper on Bayh-Dole Act regulations, regarding the “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements” and “Licensing of Government-Owned Inventions.”**

We are gravely concerned that the amendments suggested in the 37 CFR Parts 401 and 404 Green Paper, herein referred to as the “Green Paper,” gut key provisions that serve the public interest and make it impossible for members of the public to hold government contractors and their licensees accountable in their abuse of intellectual property which has been derived from government-funded research. The proposed amendments strip the Bayh-Dole Act of important public interest safeguards, including protections for public health and human lives, particularly for people living with HIV, tuberculosis (TB), and the hepatitis C virus (HCV).

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, TB, and HCV. TAG works to ensure that all people with HIV, TB, or HCV receive life-saving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

Congress passed the Bayh-Dole Act in 1980, resulting in incentivizing universities and small firms to do riskier basic science research with federal funding and creating policy space for technology transfer. It provides pathways to commercialization for the developed technologies. It’s been praised to have “unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers’ money...”<sup>1</sup> However, this legislation, aimed at bringing the benefits of science to the public, encourages the patenting and

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<sup>1</sup> The Economist “Innovations’ Golden Goose.” [Internet]. 2002 December 14. Available from: <https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose>



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exclusive licensing of innovations, such as life-saving medicines, which prevent other manufacturers from producing them during the life of the patent—20 years or longer. Unless contracts state otherwise, the patent holders can set arbitrarily high list prices on medicines, and the exclusion of other manufacturers from the market is an anticompetitive practice that keeps drug prices high.

The Bayh-Dole Act also enshrines important safeguards, such as march-in rights, the rights to appeal licenses, and provisions requiring that federally owned inventions be made available for non-exclusive licensing, which serve the public interest. Such safeguards provide avenues for the public to seek redress and demand accountability when government contractors and their licensees act in ways that harm public health, such as setting prohibitively high drug prices that limit or block people's treatment options and strain public finances.

NIST's proposed regulatory changes to eliminate these safeguards extend beyond its authority and subvert democratic enactment of legislation. March-in rights were included in the legislation to help correct market failures, such as when supplies cannot meet demand and when contracting other producers is needed. This has become all too apparent with the development of COVID-19 related technologies, including vaccines, with federal funding; yet supplies remain limited due to patent barriers and exclusive licensing. The use of march-in rights to scale up supplies during a pandemic is an option made available by the Bayh-Dole Act.

NIST has argued against this by speculating about the intent of the Bayh-Dole Act, when there is no specific language that excludes march-in rights for medicines or other biomedical technologies. In fact, in 1997, the original sponsor, former Senator Bayh, had even expressed support for using march-in rights in the Bayh-Dole Act to address drug prices.<sup>2</sup>

Four decades after the Bayh-Dole Act, drug prices continue to be a major obstacle to treatment access for people in the U.S. The Bayh-Dole Act holds an important safeguard—march-in rights—that could correct monopolistic and extortionate pricing on medicines by withdrawing the exclusivity and permitting additional licenses when the patented medicine is not made available on “reasonable terms.” In 2019, the Ways and Means Committee found that people in the U.S. pay nearly four times the average drug price of other high-income countries,<sup>3</sup> even when taking into account rebates and despite the majority of medicines being developed with public funding. The pharmaceutical industry argues that high prices are necessary to stimulate innovation. Yet, according to the Office of the Assistant Secretary for Planning and Evaluation, “The prices charged for drugs are unrelated to their development costs. Drug manufacturers set prices to maximize profits. At the time of marketing, R&D costs have already occurred and do not affect the calculation of a profit-maximizing price.”<sup>4</sup>

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<sup>2</sup> Knowledge Ecology International “Several march-in and royalty free rights cases, under the Bayh-Dole Act Bayh-Dole cases involving royalty free or march-in rights, 1997 Cellpro case” [Internet]. No date. Available from: <https://www.keionline.org/cl/march-in-royalty-free>

<sup>3</sup> Ways and Means Committee Staff, September 2019. A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf)

<sup>4</sup> Office of the Assistant Secretary for Planning and Evaluation, December 7 2016. Prescription Drugs: Innovation, Spending, and Patient Access Report to Congress.

The majority (79 percent) of Americans believe prescription drug costs are unreasonable, and one quarter (26 percent) are worried that they cannot afford the medicines they need.<sup>5</sup> Two-thirds (67 percent) of Americans support making federally funded prescription drugs available and at affordable prices for all Americans.<sup>6</sup> Unfortunately, important, life-saving medicines remain unreasonably priced and out of reach for many underserved, un-insured, or under-insured communities disproportionately affected by HCV, HIV, TB, and COVID-19 in the U.S. March-in rights in the Bayh-Dole Act offer a remedy that can ensure drug pricing is not a barrier to getting all people treated early and tested often.

Sofosbuvir (Sovaldi) is a prime example of how high prices result in poor treatment uptake. Sofosbuvir effectively cures 90 percent of people with HCV in three months (or 95 percent when used in combination with another direct-acting antiviral). The patents holder, Gilead launched it at the exorbitant list price of US\$84,000 for a three-month prescription. This triggered a U.S. Senate Finance Commission investigation in 2015, which found that Gilead had received US\$880 million in public funding for R&D on the drug.<sup>7</sup>

Facing these prices, the U.S. struggled to provide HCV treatment, particularly for Medicaid beneficiaries and incarcerated people, resulting in treatment rationing, restrictions based on disease severity, and required sobriety periods and prior authorizations that delay treatment, and contributing to ongoing preventable morbidity and mortality.<sup>8</sup> In 2017, after drug pricing negotiations with pharmaceutical corporations failed, the Governor of Louisiana and the former head of the state's Department of Health, explored using march-in rights under 28 U.S.C. Section 1498 as an option for addressing the extortionate pricing of the hepatitis C medication, sofosbuvir. The state budget could not cover the estimated US\$760 million cost it would take to treat all the estimated 90,000 people living with HCV in the state.<sup>9</sup> Ultimately, public pressure to address the hepatitis C epidemic, and the threat of a precedent setting use of Section 1498 resulted in an agreement on an exclusive voluntary subscription model which caps total state spending. However, the subscription model relies on significant scale up of and diagnoses to maximize annual treatment initiations and achieve promised cost-effectiveness. March-in rights are a direct, effective way to unlink R&D spending from pricing and to ensure pricing is set on reasonable terms, without the need for protracted brinkmanship between state officials and pharmaceutical manufacturers.

Billions of tax dollars have been directed to COVID-19 technologies in the past year. In just one example, the diagnostics corporation Cepheid, which received over \$250 million, including from

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<https://delaware.house.gov/sites/delaware.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf>

<sup>5</sup> Henry J. "Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation. [Internet]. 2020 October 16. Available from: <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>

<sup>6</sup> ASO/Lake Research Partners. Effective Messaging on Prescription Drug Pricing. Cheat Sheet. 2016.

<sup>7</sup> The Staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley. The Price of Sovaldi and its impact on the U.S. Health Care System.

[https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)

<sup>8</sup> Centers for Disease Control and Prevention (U.S.) (Press Release) Hepatitis C Kills More Americans Than Any Other Infectious Disease. 2016 May 4. <https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>.

<sup>9</sup> Rebekah E. "Louisiana's Journey Towards Eliminating Hepatitis C." Health Affairs [Internet]. 2019 April 1. Available from: <https://www.healthaffairs.org/doi/10.1377/hblog20190327.603623/full/>

the NIH and other government departments throughout its history, was awarded US\$3.7 million to develop a COVID-19 assay.<sup>10</sup> The GeneXpert platform is also widely used to run samples for diagnosing patients with TB, HIV, hepatitis B and C. Cepheid priced the COVID-19 test at \$36 per test in the U.S.

In 2012 Bedaquiline became the first new treatment from a novel class to be approved for TB in nearly five decades and is now a core component of the standard of care for multidrug-resistant TB.<sup>11</sup> Substantial public investments have also been made in the development of Bedaquiline, estimated at US\$455–747 million, of which direct clinical trial funding made up an estimated US\$120–279 million. It is estimated that public sector expenditures have exceeded expenditures by the originator, Janssen, a subsidiary of the pharmaceutical company Johnson & Johnson, by a factor of 3.1–5.1, or 1.6–2.2 when the cost of failures and costs of forgoing other investment opportunities are counted.<sup>12</sup> Yet, Janssen set the price for a six-month course of Bedaquiline at \$30,000 in the US.<sup>13</sup> The use of US taxpayer funding to develop technologies that are privately held or exclusively licensed, limits supply and creates price distortions, while preventing people from being diagnosed and treated quickly—effectively exacerbating the TB epidemic. It is in this scenario where march-in rights under the Bayh-Dole Act can be appropriately employed.

Truvada, commonly known as pre-exposure prophylaxis (PrEP), effectively lowers chances of HIV infection by more than 90 percent. Nearly a decade after Truvada was approved to prevent HIV, tens of thousands of Americans cannot access PrEP in part due to cost.<sup>14</sup> Truvada’s list price without insurance is between \$1,600–\$1,800 a month, meanwhile early animal studies to prevent and treat HIV with Truvada were conducted by researchers with the U.S. Centers for Diseases Control and Prevention (CDC).<sup>15</sup> The National Institutes of Health, along with the Bill and Melinda Gates Foundation, paid for multi-country clinical trials that showed PrEP protected against HIV in humans. In fact, the CDC holds patents for Truvada as PrEP, yet more than 40,000 new HIV infections occur in the U.S. every year, with a disproportionate impact on communities of color, transgender individuals, and populations in the South.<sup>16</sup>

While NIST is assessing revisions to regulations that support the Bayh-Dole Act, we strongly urge you to review the following information that allows using the Act’s march-in rights to address pricing affordability as part of the “reasonable terms.” We encourage NIST to review the revisions through a lens of equitable and affordable access to medicines, particularly those developed with taxpayer-funded research.

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<sup>10</sup> Forthcoming research.

<sup>11</sup> Gotham D., McKenna L., Frick M., & Lessem E. Public investments in the clinical development of bedaquiline. PLOS [Internet]. 2020 September 18 [cited 2021 April 1]; 15(9): Available from <https://journals.plos.org/plosone/article/peerReview?id=10.1371/journal.pone.0239118>.

<sup>12</sup> Ibid.

<sup>13</sup> McKenna L. “Reality Check: The Price of Bedaquiline.” Edited by Lessem E., Frick M. & Low M. Treatment Action Group. No date. (cited 2021 April 1). [https://www.treatmentactiongroup.org/wp-content/uploads/2018/10/reality\\_check\\_bedaquiline\\_10\\_16\\_18.pdf](https://www.treatmentactiongroup.org/wp-content/uploads/2018/10/reality_check_bedaquiline_10_16_18.pdf).

<sup>14</sup> Arnold Ventures “A Drug is 90 Percent Effective at Preventing HIV. It Cost Up to 1,800 Per Month” [Internet]. 2021 April 5. Available from: <https://www.arnoldventures.org/stories/a-drug-is-90-percent-effective-at-preventing-hiv-it-costs-up-to-1-800-per-month-1/>.

<sup>15</sup> Ibid.

<sup>16</sup> Centers for Diseases Control (U.S.) (Issue Brief) HIV in the Southern United States. 2019 September. <https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf>.



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In summary, TAG urges NIST to rescind the regulatory amendments to 37 CFR Parts 401 and 404 to safeguard public interests, particularly for people living with and affected by HIV, HCV, TB, and COVID-19 in the United States.

### Summary of proposed regulatory changes

1. The Green paper proposes eliminating:

#### *37 CFR § 404.4 Authority to grant licenses*

“Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest. Federal agencies having custody of federally owned inventions may grant nonexclusive, partially exclusive, or exclusive licenses thereto under this part.”

**Treatment Action Group position:** Keep *37 CFR § 404.4 Authority to grant licenses* to authorize non-exclusive and partially exclusive licenses as deemed appropriate in the public interest, such as facilitating generic manufacturing and competition of HIV, TB, HCV, and COVID-19 medicines, diagnostics, and vaccines, when available.

2. The Green paper proposes clarifying:

#### *37 CFR § 401.6 relating to the exercise of march-in rights*

Suggested amendment:

“The Green paper proposes providing additional guidance to agencies that, consistent with the Policy and Objective of Bayh-Dole in 35 U.S.C. 200, the price of goods and services arising from the practical application of the invention shall not be the sole basis for the exercise of march-in rights.”

**Treatment Action Group position:** Unreasonable pricing should remain part of the terms for using march-in rights. Exorbitant pricing on a federally funded innovation prevents the practical application and use of the technology. In the examples of Bedaquiline, Sovaldi, and Cepheid, pharmaceutical corporations charged exorbitant pricing that exceeded prices in other high-income countries, which are unreasonable terms. Removing the march-in rights provision prevents the public from taking action when a pharmaceutical corporation charges exorbitant pricing.

3. The Green paper proposes revising:

#### *37 CFR § 404.2 relating to Policy and Objective*

Original provision:

“It is the policy and objective of this subpart to use the patent system to promote the utilization of inventions arising from federally supported research or development.”

Suggested amendment:

“to clarify the link between establishing patent license financial terms and the goal of promoting commercial use, by noting that the government may consider licensing payments as a means to ensure commercialization by the licensee and thus promote the practical application of a subject invention.”

**Treatment Action Group position:** The privatization of the benefits of science developed in the publicly funded R&D system directly opposes the Policy and Objective set forth by Congress under this provision by failing to protect the public interest against nonuse or unreasonable use of a “subject invention.”

4. The Green paper proposes revising:

*37 CFR § 404.11 relating to Appeals*

Original provision:

“In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, interpretation, modification, or termination of a license:

- (a) A person whose application for a license has been denied.
- (b) A licensee whose license has been modified or terminated, in whole or in part; or
- (c) A person who timely filed a written objection in response to the notice required by §404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.”

Suggested amendment:

“...clarify who has standing to appeal the grant, denial, modification, or termination of a license by limiting a claim of damage by the agency’s granting of an exclusive license to that which denies a party the opportunity to promote the commercialization of an invention, and by requiring all agencies to establish procedures for considering appeals.”

**Treatment Action Group position:** The change means a person who may be damaged by an exclusive license must also show they were damaged by losing opportunities “to promote the commercialization” of a new technology. Yet there are other forms of harm, as demonstrated by how high prices of HIV, HCV, and TB medicines and technologies prevent people from timely diagnosis and treatment, and cause harm to the general public. People harmed in these ways should have public standing to comment on and appeal licensing decisions that harm them.

5. The Green paper proposes revising

*37 CFR § 401.14 relating to standard patent rights clauses*

Original provision:



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“Subject invention means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.”

Suggested amendment:

“...an invention that is conceived and reduced to practice by the contractor without the use of any federal funds is not considered a subject invention.”

**Treatment Action Group position:** Publicly funded R&D should be retained in the public domain, with the federal government having the ability to exercise rights to use and manufacture the benefits of this R&D. The amendment could result in firms receiving public funds and not claiming the developments from it as a “subject invention,” which, in turn, could encourage the underreporting of “subject inventions.” This practice impedes holding contractors accountable and works against the public interest.