



## Comments of the Regulatory Action Center

Re: [Rights to Federally Funded Inventions and Licensing of Government Owned Inventions](#)

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The Regulatory Action Center at FreedomWorks Foundation is dedicated to educating Americans about the impact of government regulations on economic prosperity and individual liberty. FreedomWorks Foundation is committed to lowering the barrier between millions of FreedomWorks citizen activists and the rule-making process of government agencies to which they are entitled to contribute.

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On behalf of our activists nationwide, FreedomWorks Foundation appreciates the opportunity to offer these comments regarding the notice and request for comments on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions (NIST-2021-0001-0001). This notice seeks comment on the proposed clarifications of the implementation of the Bayh-Dole Act and, in particular, federal “march-in” rights under this Act.

In July of 2019, while still on the campaign trail, then-Presidential Candidate Kamala Harris reportedly supported using march-in rights “to license a drug company’s patent to a lower-cost competitor.”<sup>1</sup> Since that statement, stakeholders in many industries, not only pharmaceuticals, have been left worrying about whether or not the Biden administration might force them to accept a detrimental license under march-in. President Biden’s use of emergency authorities under the Defense Production Act<sup>2</sup> and continued emphasis on federal control of supply chains have only added to this worry.<sup>3</sup>

This proposed rule promulgated by the National Institute of Standards and Technology (NIST) is a huge step toward providing those stakeholders with the regulatory certainty they deserve. This proposal includes several positive changes to the way we administer intellectual property protections, including procedural clarifications and streamlined requirements. Perhaps most important is the decision to clarify § 401.6 and affirm Congress’ intent that march-in is not to be used to implement a system of price controls.

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<sup>1</sup> David Siders. “How Kamala Harris would address rising drug prices.” *Politico*. July 16, 2019. <https://www.politico.com/story/2019/07/16/kamala-harris-2020-drug-costs-aarp-1416130>

<sup>2</sup> Rachel Roubein. “Biden to use Defense Production Act to increase supply of Covid-19 vaccines and tests.” *Politico*. February 5, 2021. <https://www.politico.com/news/2021/02/05/biden-defense-production-act-coronavirus-466130>

<sup>3</sup> “Remarks by President Biden at Signing of an Executive Order on Supply Chains.” *The White House*. February 24, 2021. <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/24/remarks-by-president-biden-at-signing-of-an-executive-order-on-supply-chains/>



One of the latest obsessions of politicians and pundits on both sides of the aisle is the utilization of some sort of price control mechanism in an attempt to lower the price of products -- pharmaceuticals in particular. Yet, as FreedomWorks Foundation has repeatedly asserted, such a system would likely exacerbate the problem of high drug prices.<sup>4</sup> The intent of such proposals -- to bring drug prices down -- is praiseworthy, but the reality of price controls is that they end up driving down investment and innovation and rarely have a positive effect on true pricing. Furthermore, federal price controls are a gross overextension of federal authority to artificially control the national and global economy.

We support any efforts, whether legislative or regulatory, that affirm the principle that price controls are both ineffective and an overreach of federal power. Although march-in has never been utilized, the existence of a scheme by which federal agencies can implement price controls on particular products should not be accepted. This proposed rule would finally make it clear that the federal government has no jurisdiction to implement price controls under the Bayh-Dole Act.

Additionally, this regulatory change would clear up much uncertainty about march-in rights and provide small businesses and universities with greater confidence about developing new innovations and products based on publicly funded research. As it stands, the uncertainty around intellectual property rights creates an undue burden on innovators. American inventors should be able to benefit from their inventions, even when federal funds are involved. Clearing up this uncertainty will undoubtedly have a positive impact on American innovation that President Biden claims is lacking in our country.<sup>5</sup>

We appreciate the opportunity to offer these comments on behalf of our activists, and look forward to continuing to work with the Institute in the future to cut red tape and provide regulatory certainty to the American public.

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<sup>4</sup> Stephen Moore. "Price Controls on Big Pharma Will Put the U.S. Last." *RealClearMarkets*. October 27, 2020. [https://www.realclearmarkets.com/2020/10/27/price\\_controls\\_on\\_big\\_pharma\\_will\\_put\\_the\\_us\\_last\\_582157.html](https://www.realclearmarkets.com/2020/10/27/price_controls_on_big_pharma_will_put_the_us_last_582157.html)

<sup>5</sup> "Biden-Harris Administration Launches American Innovation Effort to Create Jobs and Tackle the Climate Crisis." *The White House*. February 11, 2021. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/11/biden-harris-administration-launches-american-innovation-effort-to-create-jobs-and-tackle-the-climate-crisis/>



Respectfully submitted,

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