



February 6, 2024

National Institute of Standards and Technology  
100 Bureau Drive  
Gaithersburg, MD 20899

**Re: Request for Information on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No.: 230831-0207)**

To whom it may concern,

Consumer Action for a Strong Economy (CASE) writes today in opposition to the proposed framework for the application of Bayh-Dole Act “march-in” rights, as recently outlined by the Biden administration. This misguided plan threatens consumers and represents an existential threat to American innovation and economic growth.

The Biden administration’s proposed expansion of the use of “march-in” rights to include product pricing as grounds for relicensing patents on products that benefited from federally funded research would chip away at America’s unrivaled position in leading global medical breakthroughs. The Bayh-Dole Act was passed in the first place in 1980 to help build this advantage.

The law turbocharges research and development (R&D) from universities and federally funded labs by drawing in private-sector investment and activity. Specifically, the law allows universities and labs to license patents to private companies and gives the government “march-in” rights to change these licenses only if companies are not actively working to develop commercially viable products.

Yet, proponents of government intervention are claiming that Bayh-Dole offers a backdoor into our free-market healthcare system for price controls. This could not be further from the truth. Bayh-Dole’s “march-in” rights are not supposed to be a free pass for government intrusion. Senators Birch Bayh and Bob Dole, the co-authors of the law, have already settled any debate around the law’s intent, explaining that government’s ability to relicense patents under the law should not be contingent on pricing.

The proposed modification would instead encourage the government to intervene in this very way, ramming through government price setting on prescription drugs and potentially disrupting the delicate balance that has driven advancements in medicine for decades. What’s more, the effects of this unprecedented abuse of the law would ripple throughout the economy beyond just healthcare.

Specifically, CASE’s concerns are outlined below:

1. **Intellectual Property (IP) Protections:** IP protections are central to the success of the Bayh-Dole Act. These protections encourage private partners to help take federally funded research and commercially develop products that have a real-world impact on patients and consumers. Private-sector participation is irreplaceable in this process. Abusing the Bayh-Dole Act’s “march-in” provisions to influence drug pricing would subvert these protections and discourage public-

private collaboration — investors would be unlikely to risk immense resources if they do not have faith that their IP rights will be upheld.

2. **Innovation & Economic Growth:** America's economy depends on a solid foundation of IP protections. The U.S. Patent and Trademark Office [reported](#) that IP-intensive industries accounted for 41 percent of the economy in 2019 and were responsible for more than 47 million jobs. However, as outlined above, the proposal to use "march-in" rights as a price setting tool threatens to drastically change the landscape for R&D in the United States. This could impact countless jobs and drag down the economy by discouraging the risks that make innovation possible and drive growth.
3. **Consumers' Interests:** Such modifications pose a direct threat to American consumers by deterring private collaboration and reverting us to a time when taxpayer-funded research often failed to yield tangible benefits for citizens. As outlined above, Bayh-Dole incentivizes private-sector development of discoveries made through federally funded research, leading to numerous breakthroughs. As a result, more than [200 new drugs](#) and vaccines have been developed through public-private partnerships since 1980.

Additionally, countless products that have improved consumers' lives and bolstered America's status as the world's leading economy — from Google and touch screen technology, to scanners at airports that keep travelers safe from threats — have all been [made possible](#) by the Bayh-Dole Act. Abusing the law would spell trouble for many industries and restrict consumers' access to products ranging from lifesaving drugs to new technologies that make daily life better and safer.

4. **Global Competition:** The U.S. economy benefits from leading the charge in building the industries and technologies of the future. However, China's aggressive investments in R&D underscore their dream of overtaking us on this front. Any weakening of our current advantages could have severe consequences well into the future. China's theft of American IP already costs us as much as [\\$600 billion a year](#). The Biden administration's plan would only add to the assault on American IP and create a hostile environment for our nation's innovators and entrepreneurs with threats from abroad and from our own government.

The National Institute of Standards and Technology (NIST) must consider the long-term implications of proposed modifications. America's economy would face irreparable damage under this plan and consumers would bear the brunt of the impact.

Sincerely,

**Consumer Action for a Strong Economy (CASE)**

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Consumer Action for a Strong Economy  
1800 Diagonal Road, Suite 600  
Alexandria, VA 22314  
@CASE\_forAmerica