

Myths v. Facts Can Bayh-Dole March-In Rights Lower Drug Costs?

In 1980, the Bayh-Dole Act kickstarted a new era of American innovation by empowering universities, small businesses, and non-profit institutions to patent the federally-funded inventions they created and license them to private companies for further development.

The Economist Technology Quarterly <u>called</u> Bayh-Dole "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half century" — and for good reason. It's <u>bolstered</u> U.S. economic output by up to \$1.9 trillion, supported 6.5 million jobs, helped launch more than 17,000 startup companies, and led to the creation of thousands of new inventions.

The law includes a "march-in" provision that allows the federal government to mandate the relicensing of federally-funded patents under <u>four narrow circumstances</u>, such as if good faith efforts are not being made to develop a product. This provision <u>does not</u> authorize the government to impose price controls on resulting products.

Unfortunately, in December 2023, the Biden administration proposed a new <u>framework</u> that would allow government agencies to disregard that long-standing interpretation of Bayh-Dole and grant march-in petitions on the basis of price as a means to lower drug costs. It would not achieve this goal — but it would stunt research projects, startup development, and entrepreneurship across every U.S. industry.

Below, the Bayh-Dole Coalition debunks some common misconceptions about the government's new march-in framework.

Myth: Using march-in rights as a price control mechanism will lower drug costs.

Fact: It will stunt the development of desperately-needed treatments without lowering drug costs.



Nearly 98% of the new drugs and other therapies approved by the FDA between 1985 and 2022 are not march-in eligible.



According to the generic drug industry, "Rather than making a handful of brand medicines more affordable, it is likely that [the march-in] proposal would in fact undermine pre-existing incentives . . . for generic and biosimilar manufacturers."



According to the World Patients
Alliance, the proposal would also cause
"treatment options [to] become more
limited" and "progress against deadly
diseases [to] slow" — making future cures
"harder, not easier, to achieve."

Myth: Using march-in rights as a price control mechanism won't impact American innovation.

Fact: It will hurt innovative companies, especially small businesses, across every economic sector.



Nearly 75% of university patent licenses are to small businesses and startups.



The proposed <u>framework</u> would impact the commercialization of all government-funded inventions, not just drugs — including semiconductors, clean energy products, and other technologies that the government is trying to promote through laws like the CHIPS and Science Act.



According to the <u>National Venture</u>
<u>Capital Association</u>, "NIST's [march-in] guidance would unavoidably deter VCs from investing in inventions arising from federally funded research."