Bayh-Dole & Biopharmaceutical Innovation: Myths vs. Facts

MYTH #1: Bayh-Dole's "march-in" provision allows federal agencies to seize patents to set drug prices.

REALITY: This grossly misrepresents the text and intent of the law.

- Bayh-Dole's march-in provision was not intended to enable the government to set prices or revoke intellectual property protections.
- Rather, the march-in provision is applicable only under certain very limited and specified circumstances to ensure that grantees make efforts to make their licensed inventions useful for the benefit of patients and society.
- According to National Institutes of Health (NIH) Director Francis Collins, "The march-in approach does not appeal to us at all. And certainly, when I talk to expert legal advisors and they look at the language of the Bayh-Dole Act, it does not appear that march-in was contemplated to be used for an effort to adjust prices. It was basically, if a product is simply not available because somebody has locked it up, then the government has a right to step in." [1]
- In a 2002 commentary for the Washington Post, Sens. Bayh and Dole stated that "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."

MYTH #2: Lawmakers will need to "invoke Bayh-Dole" to ensure access to COVID-19 therapies.

REALITY: Bayh-Dole and other pro-innovation policies helped enable America's biopharmaceutical industry to engage in COVID-19 research at breakneck pace. Plus, many companies working on COVID-19 have promised that their medicines will be affordable and accessible.

- American researchers are moving towards treatments and vaccines faster than ever.
- Thanks to decades of pro-innovation policies, the nation's scientists already have a deep bench of innovations and technologies that might be helpful to draw from as they search for solutions to the COVID-19 pandemic.
- Bayh-Dole underpins America's research ecosystem by facilitating orderly and efficient technology transfer from institutions receiving government research funding to the private sector. Now more than ever, it's important to foster such collaboration.
- The NIH established a partnership between federal researchers and 16 pharmaceutical companies known as ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) to facilitate the discovery of coronavirus therapies. NIH Director Francis Collins noted, "Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic."[2]
- Johnson & Johnson, which hopes to have a vaccine ready for trials this fall, has promised to make 1 billion doses of its vaccine available on a not-for-profit basis, which will likely a price as little as $10.[3,4]
- Gilead is donating 1.5 million doses of remdesivir, its experimental anti-coronavirus drug, for compassionate use and expanded access to treat patients with severe symptoms.[5]

FOOTNOTES

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MYTH #3: Bayh-Dole allows private companies to profit off taxpayer-funded research.

REALITY: The NIH performs limited applied research. Private industry invests in applied biomedical science — and is responsible for the overwhelming majority of successful drug discoveries.

- While critically important, NIH-funded research focuses on basic science — not the costly, late-stage development and testing of patient-ready medicines.[6]
- Companies spend, on average, $2.6 billion to bring just one new medicine to market. Federal research grants typically amount to less than $3 million, or just one-tenth of one percent of what it costs to develop a new medicine and bring it to market.[7]
- Private companies invest the capital needed to translate scientific insights into medically useful innovations.
- In 2018, the private sector poured an estimated $129 billion into biomedical research and development in the United States.[8]

MYTH #4: Biomedical innovation would flourish with or without Bayh-Dole.

REALITY: American scientists lead the world in drug discovery and development because of Bayh-Dole. Misuse of Bayh-Dole threatens that reputation.

- In the early 1980s, only 10 percent of new drugs were first introduced in the United States.[9] Today, nearly 70 percent of new medicines are launched first in the United States. As a result, American patients have access to new medications before the rest of the world.[10]
- Early scientific discoveries resulting under Bayh-Dole has informed the research and development of more than 200 drugs and vaccines since 1980[11] — including treatments for HIV, HPV, and hepatitis B.[12]
- Bayh-Dole has facilitated the discovery of breakthrough vaccines in the past. For example, in December 2019, Merck finally announced FDA approval for its Ebola vaccine after years of research and testing.[13] Without strong IP protections, the company may have prematurely abandoned its research.[14,15]
- Misusing Bayh-Dole's march-in right to allow the government to enact price controls or confiscate an innovator's intellectual property will devastate the ability to eradicate COVID-19 — and chill research into other diseases. In fact, the National Institutes of Health adopted a "reasonable pricing" standard in 1989 medicines for medicines that benefited from Bayh-Dole — and had to revoke it just six years later because the evidence clearly demonstrated that it curtailed innovation.[16,17]

FOOTNOTES

6 Galkina Cleary, Ekaterina, et al. "Contribution of NIH Funding to New Drug Approvals 2010-2016." Proceedings of the National Academy of Sciences of the United States of America, National Academy of Sciences, 6 Mar. 2018, www.ncbi.nlm.nih.gov/pmc/articles/PMC5878010/.

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16 "Cooperative Research and Development Agreements." National Institutes of Health, 1994, www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf.

17 "NIH News Release Rescinding Reasonable Pricing Clause." National Institutes of Health, 11 Apr. 1995, www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.