

PATIENTS FOR AFFORDABLE DRUGS™

Patients For Affordable Drugs Comments on the National Institute of Standards and Technology's Proposed Rule Change to Bayh-Dole Act

Summary

Biomedical innovation is essential for the health and well-being of Americans and people all around the globe. It's important to recognize, however, that the U.S. government is an engine of innovation leading to new treatments for acute and chronic illnesses, new therapies, and new vaccines to prevent disease and death.

It is critical that those biomedical innovations are transferred to and used by the private sector with the paramount aim of improving public health. The goals of enriching shareholders of private corporations must be secondary. That is why Bayh-Dole protections must be maintained, and even strengthened.

As the COVID-19 pandemic has demonstrated, public access to taxpayer-funded inventions is crucial. Over the past year, the federal government has invested [more than \\$10 billion](#) in the research, manufacturing, and distribution of COVID-19 vaccines and treatments. The technology underlying two successful mRNA vaccines, those produced by Pfizer and Moderna, was [based on research](#) conducted years ago in federally funded laboratories. But as major vaccine makers have [indicated](#), prices will likely increase after the pandemic period, as [experts predict](#) the virus will become endemic. The government cannot allow Americans to be priced out of necessary taxpayer-funded vaccines and treatments without recourse; it would be an endangerment to public health and a capitulation to corporate pharmaceutical interests.

Bayh-Dole March-In Protections Are Essential

Bayh-Dole's march-in rights are included to protect American citizens — the end users of a government-funded invention. These rights exist to protect us from potentially harmful acts of a government contractor. Senator Bayh stated in comments before the National Institutes of Health during a review of these issues in 2004:

“If it can be shown that the health and safety of our citizens is threatened by practices of a government contractor, then Bayh-Dole permits march-in rights, not to set prices, but to ensure competition and to meet the needs of our citizens. However, such a procedure must be supported by hard evidence that the need exists.”

Those practices can precipitate government action under Bayh-Dole for four reasons, including these two:

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees.

Patients For Affordable Drugs strongly believes these two protections are essential and must be preserved. For example, if a new, improved drug were available as a result of a government-licensed invention, and the company controlling the drug sat on it to avoid competition with another more profitable alternative it owned, taxpayers would need the power to intervene.

The proposed rule changes to the Bayh-Dole Act would weaken the protections afforded to taxpayers in two harmful ways:

- I. First, the proposal compromises the very foundation of Bayh-Dole by narrowing the definition of “subject invention” — the definition relied on for every single safeguard provided to taxpayers through the Bayh-Dole Act. By adding an exclusion for companies that claim their invention was “conceived and reduced to practice without the use of any federal funds,” the proposed rule creates a loophole that will [allow](#) companies to accept public funding on their own terms without accountability to public interest.
- II. Second, the proposal weakens condition #1 (see above) for federal exercise of march-in rights by excluding price as the sole indicator of “practical application.” Currently, practical application is defined as “available to the public on reasonable terms.”¹ The proposed rule strives to narrow the definition of practical application by changing the definition to:

“March-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.”

This change further erodes guardrails designed to prevent private-sector contractors from pricing taxpayer-funded inventions out of reach for patients.

We strongly encourage NIST to reject the proposed changes, which would undermine taxpayer protections, impede accessibility and affordability of necessary drugs and vaccines, and threaten public health.

¹ See 35 U.S.C. § 201(f).

Patients For Affordable Drugs

Patients For Affordable Drugs is the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

The patients in our community care deeply about innovation and new drugs. Many are alive today because of new therapies and depend upon the science and research communities for new inventions that will extend their lives. But drugs don't work if people can't afford them. That is why it is essential to strike a balance between innovation and affordability and accessibility.