

EXPANDING ACCESS AND AFFORDABILITY TO TAXPAYER FUNDED DRUGS: THE USE OF MARCH-IN RIGHTS

The Biden Administration announced on Thursday, December 7 a framework for the exercise of certain government rights to federally-funded inventions.

These rights, sometimes referred to as **March-In Rights**, are a powerful tool for the federal government to ensure the public can afford and is not being price gouged for critical medicines the public itself has funded through taxpayer investments.

WHAT ARE MARCH-IN RIGHTS?

Under the Bayh-Dole Act, federal contractors can claim ownership of inventions made with federal funding, subject to key safeguards for the public interest.

One such safeguard, [March-In Rights](#), allows a federal agency to require the owner of a federally-funded invention to grant permission to a third party for the use of the invention.

A related, but distinct, safeguard is the [Royalty-Free Right](#), which gives the government an irrevocable, royalty-free license to practice the funded invention for or on behalf of the United States worldwide.

March-In Rights can be invoked only under certain conditions, including when the agency determines licensing is necessary because:

(1) the owner has not achieved practical application of the publicly-funded invention (practical application means that the invention is being used and **the benefits of the invention are available to the public on reasonable terms**), or

(2) there are health or safety needs not reasonably met by the owner of the federally-funded invention.

WHY ARE MARCH-IN RIGHTS IMPORTANT TO THE DRUG AFFORDABILITY CRISIS?

The U.S. Government pours more than [\\$50 billion](#) annually into biomedical research and development, primarily through grants from the National Institutes of Health (NIH).

Despite this support, prescription drug corporations routinely subject U.S. patients to the [highest prices](#) in the world.

When pharmaceutical companies charge extortionary prices on drugs invented with this public support, **March-In Rights can help curb these abuses.**

For example, the invention of the prostate cancer drug Xtandi relied on taxpayer-funded grants, but Americans were charged \$129,000 per year for the treatment, [multiple times](#) more compared to their peers in other high-income countries. Patients were [charged](#) hundreds of dollars in out-of-pocket costs just for filling one prescription of the drug.

March-in Rights are a powerful tool to curb prices for drugs relying on government-funded patents, but currently only about [11% of new drug approvals](#) have patents disclosing government support.

March-In Rights are not a panacea for price gouging by prescription drug companies relying on government support, but can be paired with other [powerful government authorities](#) to license generic competition and [contractual requirements](#) for fair prices to lower drug prices for millions of Americans.

HOW DOES THE GOVERNMENT EXERCISE MARCH-IN RIGHTS?

Agencies can commence [March-In proceedings](#) when they receive information that they believe warrants the exercise of these rights.

Then, the agency sends written notice to the contractor and requests an informal consultation to understand the situation and consider alternatives to March-In.

After informal consultation, the agency decides whether to continue with formal proceedings and notifies the contractor of its decision.

During formal proceedings, the owner of the publicly-funded invention can submit information and arguments in opposition to March-In.

During fact-finding proceedings before an agency official, the owner can appear with counsel, submit evidence, present witnesses, and confront witnesses presented by the agency.

The official prepares or adopts written findings of fact that are sent to the contractor and the head of the agency, or their designee, for making the ultimate decision. The agency and owner have 30 days to submit written arguments to the head of the agency/designee.

Finally, the head of the agency/designee makes a decision based on the record and the policy and objectives of the Bayh-Dole Act.

The owner of the taxpayer-funded invention can administratively [appeal](#) an adverse decision within the agency, or appeal the decision to the United States Court of Federal Claims. If the owner appeals, the agency cannot March-In on the invention until the appeals process is exhausted.

INDUSTRY CLAIMS ABOUT THE EXERCISE OF MARCH-IN RIGHTS ARE UNFOUNDED.

The drafters of the Bayh-Dole Act included March-In Rights very deliberately to protect the public interest when providing contractors ownership of publicly-funded inventions.

Exercising these rights to lower drug prices is fully consistent with Bayh-Dole's fundamental framework allowing contractors to commercialize federally-supported inventions. **Policymakers included these rights to ensure that the public is not abused** by corporations that wish to profiteer by charging Americans excessive amounts for products, including drugs, invented with taxpayer dollars.

Contrary to industry claims that March-In authority was not envisioned to address price gouging, the [Congressional Record](#) leading up to the passage of the Bayh-Dole Act reflected the understanding that March-In Rights were necessary to foster market competition and combat unreasonable profiteering on taxpayer-funded inventions.

As with Medicare drug price negotiation, drug corporations argue that exercising March-In Rights to rein in price gouging would chill innovation. These corporations would still be able to reap generous profits from selling medicines invented with taxpayer funds – but not profiteer by charging U.S. patients multiples more than prices paid by people in other high-income countries without risk of the government using its rights to license competition.

Profit incentives to commercialize government-subsidized inventions would still ensure that public science is translated into products to benefit consumers, including patients' health.

The bottom line is that so long as owners of drugs invented with federal funds do not price gouge the public, they have no reason to fear the government's March-In authority.