WE WORK FOR HEALTH

MARCH-IN RIGHTS FRAMEWORK EXPANSION THREATENS AMERICA'S LEADERSHIP IN MEDICAL INNOVATION

Background

WHAT IS NEW? The Biden Administration recently announced a new framework to expand its ability to exercise march-in rights. This is the latest in its attempt to undermine the U.S. leadership in biomedical innovation, this time also putting at risk all those who have contributed to a powerful public-private partnership that for decades has worked together to deliver new treatments for patients.

The administration's proposal is based on the faulty premise that price limits competition and product availability. It ignores the reality that turning patents into products requires multiple years of investment, numerous improvements, and billions of dollars.

Intellectual property (IP) protections are critical in ensuring America's leadership in healthcare and medical innovation. The complexities of research and development, regulatory approvals, and commercialization require strong IP, in addition to considerable investments, to provide needed medications to patients.

BOTTOM LINE: Without private industry investment and expertise, few patents would be expanded upon due to the complex and costly process of developing new products to improve America's health.

Public-private partnerships address important public health issues by taking moonshots against cancer and working to eliminate Hepatitis C. These collaborations — along with strong incentives and protections to develop a robust research and development ecosystem — support America's role as a leader in healthcare and medical innovation. The administration's recent framework puts that at risk, once again chipping away at the United States' ability to bring life-saving treatments to patients.

WHAT IS THE BAYH-DOLE ACT? The Bayh-Dole Act was passed in 1980 to ensure that research institutions receiving federal funds could patent and license inventions, ensuring these discoveries were not buried in research labs or academic papers. Prior to the bill, government-funded research often remained out of reach from prescribers and patients due to the complex, costly, and challenging process of developing, seeking regulatory approval for, and commercializing new treatments. These issues have been heralded as widely successful by leaders across the political spectrum and have contributed more than 200 new medications and vaccines since 1980.

WHAT ARE THE MARCH-IN RIGHTS AND HOW HAVE THEY BEEN USED? March-in rights ensured patents would be used and expanded upon. Only four circumstances were specified that could trigger the ability to license patents to others.

For 40 years, the National Institutes of Health has not exercised march-in rights.

WHY IS THE PROPOSED CHANGE IN CONFLICT WITH THE INTENDED PURPOSE? The Biden Administration asserts price should be considered a new factor that may limit product use and competition.

However, even the bill authors noted more than 20 years ago, *"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 government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."*