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MYTHS VS FACTS: EXPANDING MARCH-IN RIGHTS AND SEIZING PATENTS

The Biden administration's new proposal to expand march-in rights under the Bayh-Dole Act hurts innovation and puts at risk all those who have contributed to powerful public-private partnerships that for decades have delivered new treatments for patients. The Bayh-Dole Act was enacted to allow research laboratories, including those at universities, to retain patent rights in inventions stemming from federally funded research. These research organizations could thereafter license these patents to third parties with the resources to develop and commercialize products incorporating these inventions.

As a condition for allowing federally funded research laboratories to retain these patents, however, the Bayh-Dole Act provided the federal government with march-in rights, which may be exercised under four limited and defined statutory circumstances. Emphasizing the facts and raising awareness about the looming threats of expanded march-in rights is critical to the technologies we use today and the lives and livelihoods of millions of Americans in and beyond the biopharmaceutical ecosystem.

INNOVATION

MYTH: The government funds the development of new medications.

FACT: Over the past decade, only **1% OF ALL FDA-APPROVED PRODUCTS** have key patents covering what are often referred to as "subject inventions," which received federal support. **JUST 8% OF ALL MEDICATIONS** have received any amount of public funding. Private sector investment is essential to transform discoveries into medicines. On average, **$67 IN PRIVATE INVESTMENT** is provided for every $1 in public funding.

MYTH: Drug companies already make a lot of money, so march-in rights won't hurt their operation.

FACT: The biopharmaceutical sector allocates more revenue to research and development than any other industry. Companies reinvest these earnings into developing future medicines and finding new diseases that can be treated by these drugs to address patient needs. The process of discovering new medications costs **MORE THAN $2 BILLION ON AVERAGE, AND ONLY 1 OUT OF EVERY 10 DRUGS** that makes it to clinical trials is ultimately approved by the FDA. The proposal to expand march-in rights poses a detrimental threat to the biopharmaceutical R&D pipeline.

MYTH: The march-in rights proposal will impact only prescription drugs that the government targets – not all current and future medicines available and in development.

FACT: Expanded march-in rights threaten manufacturers' ability to collaborate with the federally funded researchers, which helps ensure early phase and basic research discoveries develop into products. Because development decisions are made many years before a potential product is approved by the FDA and eligible for march-in rights, this uncertainty will deter collaboration to advance discoveries supported with *any* public funding. Expanded march-in rights do not prioritize innovation and patient access.

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PATIENT COST

MYTH: March-in rights will lower prescription drug costs for patients.
FACT: The proposed march-in right framework does nothing to address external factors that distort patients' out-of-pocket costs, including insurance deductibles, co-pays, co-insurance, and pharmacy benefit manager interference.

MYTH: Patients are in favor of march-in rights because they are supposed to lower costs at the pharmacy counter.
FACT: **MORNING CONSULT POLLING** found twice as many respondents would be inclined to vote for an electoral candidate who stands for preserving the Bayh-Dole Act in its current form than one who advocates for substantial changes to the law. The survey also noted 77% of voters fear the use of the Bayh-Dole Act as a price control could decrease their access to innovative treatments for myriad conditions, including cancer, Alzheimer's and rare diseases.

PATIENT ACCESS

MYTH: Expanding march-in rights will improve patients' access to prescription drugs.
FACT: Quite the opposite: If research discoveries remain stuck in laboratories, they are out of reach for patients. Prior to the Bayh-Dole Act, numerous patents based on research conducted with some federal support existed, but few became products for public use. No medication was ever approved.

MYTH: Price controls are the only way the government can help counter high drug prices.
FACT: Failed attempts to regulate pricing in licensing agreements **IN THE 1990S** drove investments and industry away from collaborations to expand upon and commercialize the discoveries. Rather than setting price controls, the government should focus on the many factors that fuel skyrocketing costs in healthcare. Pharmacy benefit managers, for example, currently have little government oversight regarding the rebates and discounts they negotiate but do not pass to patients to lower costs.

LEGISLATIVE INTENT AND IMPACT

MYTH: Reinterpreting march-in rights as a tool for price setting will protect government interests and investments by ensuring a "reasonable price."
FACT: Including price in march-in rights contradicts the intent of the Bayh-Dole Act. It was never supposed to serve as a mechanism for price controls. The legislation authors **NOTED THE OMISSION** of price in the criteria for march-in rights because they knew it would deter private-sector investment in federally funded research and send us back to a time when government-funded research sat idle, not benefiting anyone.

MYTH: Reinterpreting march-in rights as a mechanism to control prices will only impact patients and the healthcare industry by targeting the costs of certain medicines.
FACT: The proposal covers any research institution receiving federal funds in any field, so march-in rights threaten discoveries across technologies that have developed airport scanners, cloud computing, firefighting drones, and biopharmaceuticals. Chipping away at the research ecosystem would affect all the communities, universities, and economies these industries support.