

United States Senate

WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

February 24, 2022

The Honorable Xavier Becerra
Secretary
Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write you today regarding calls by certain Congressional colleagues to misuse the government's march-in rights. It is hard to imagine a policy more toxic to America's biopharmaceutical innovation than the threatened misuse of march-in rights. March-in rights, exercised inappropriately, would destroy the development of new, innovative, and life-saving medications.

As you well know, Americans lead the world in biomedical research and biopharmaceutical innovation, and the Bayh-Dole Act is a central component of this success. Over 200 new drugs and vaccines have been developed through public-private partnerships facilitated in part by Bayh-Dole since its enactment in 1980.¹ Decades of pro-innovation policies have fostered an ecosystem often likened to a three-legged stool where government, universities, and private industries work collectively to fund and conduct basic science research, and then industry translates these pathways into lifesaving medicines.

At the highest level, the Bayh-Dole Act has succeeded by allowing universities and research institutes to license intellectual property rights to private actors with the expertise and capacity to develop and commercialize those technologies. March-in rights would destroy this delicate balance. As you may be aware, certain Congressional colleagues and activist groups have filed petitions to march-in on a pharmaceutical product purely based on its price. We strongly urge you, for both matters of law and public policy, to reject these requests.

Congress's explicit goal in creating march-in rights was to allow the government to intervene when a private actor failed to **commercialize** a technology. The purpose for the narrow grounds for intervention was to ensure that private actors developed and applied jointly funded technologies in a way that benefited the public. As you well know, the alternative and reality prior to Bayh Dole was that government funded research would many times simply languish unused.

¹ <https://autm.net/AUTM/media/Surveys-Tools/Documents/FY20-Infographic.pdf>

Stripping intellectual property rights for private actors simply because they are commercializing their applied research on terms opponents dislike contradicts the very purpose and function of the Bayh Dole Act. March-in rights were never intended to function as price controls nor does the statute allow it. The authors of the statute – Senators Bayh and Dole – have said as much. Every Republican and Democratic Administration dating back to President Clinton has agreed. The statute clearly doesn't sanction marching in to control prices of successfully commercialized products.

As policymakers, we want private industry to save American taxpayers money by commercializing and applying academic research. This commercializing ultimately benefits the public by allowing them to utilize the applications of this research and investment. But, if you were to use march-in rights in this context, it would create and add an unnecessary element of risk to the development of biopharmaceuticals, all of which would cause private firms to be reluctant to invest in the development of such products.

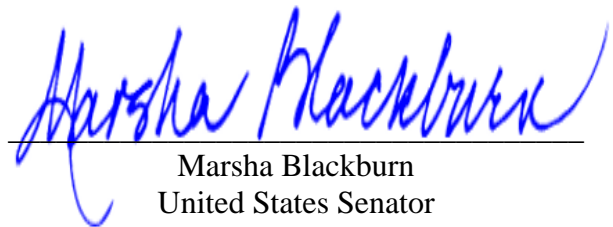
To be clear, we are concerned with the high prices of certain biopharmaceuticals and drugs. We are ready and willing to work with you on common sense measures that will reduce drug prices and preserve and promote American innovation. But, the disastrous policy pushed by some of our colleagues and private activist groups is not a solution to this complex, complicated, and emotional issue.

Accordingly, and for all these reasons, we ask that you protect public-private partnerships and maintain forty years of precedent by rejecting these petitions. Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact us.

Sincerely,



Thom Tillis
United States Senator



Marsha Blackburn
United States Senator