



February 6, 2024

Laurie E. Locascio, PhD
Director
National Institute of Standards and Technology
100 Bureau Dr.
Gaithersburg, MD 20899

Re: *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, Docket No.: 230831-0207

Dear Dr. Locascio,

The American Cancer Society Cancer Action Network (ACS CAN) is the American Cancer Society's nonprofit, nonpartisan advocacy affiliate. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. By engaging advocates across the country to make their voices heard, ACS CAN influences legislative and regulatory solutions that will end cancer as we know it, for everyone.

The advancement of our understanding of cancer and how it is treated and prevented is key to ending cancer as we know it, for everyone. Recently released statistics estimate that, since 1991, 4.1 million lives have been saved because of advances in treatment, screening and prevention made possible by research¹. The National Institutes of Health (NIH) and the National Cancer Institute (NCI) have been at the heart of major discoveries leading to transformations in cancer outcomes. While many of our foundational discoveries are made possible through NIH and NCI research funding, the translation of these discoveries into treatments and products has historically been the domain of the biopharma industry.

Industry, academia, and federal funders interact in an ecosystem that has been highly effective at generating advances, with an average of 25 percent of drugs approved over the past decade being oncology drugs. Key to the functioning of this ecosystem is the Bayh-Dole Act, which encourages entrepreneurship by empowering researchers with control of the intellectual property (IP) they develop while supported with government funding, thereby creating an incentive to see these discoveries developed and used by the public.

The objective of Bayh-Dole is public access and benefit from research advances, and, as a safeguard, Bayh-Dole included the concept of march-in-rights (MIRs) that could allow the federal government to compel licensing of IP developed with government support if those discoveries were not reaching and

¹ "Cancer statistics 2024: All hands on deck," CA, 17 January 2024, <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21824>

benefiting the American public. In the over forty years since the law was created, many MIR requests have been filed, but none of the requests have been acted on because the statutory threshold of a lack of public access was not met.

ACS CAN believes that patents and IP created as a result of federal funding should be fully developed into interventions that benefit all patients and the general public. No discovery that could improve public health should sit on a shelf or be inaccessible to Americans. It is wholly appropriate for MIRs to be exercised if an invention that can benefit public health has not been developed and commercialized. Much of the controversy about the current framework, however, has not been about addressing non-commercialization, but rather the use of march-in to address high prices of commercialized products. Non-commercialization/non-availability of a product and high product prices are two different issues. Since the statutory MIR criteria are about availability, the framework can only contemplate pricing if it is in the primary causal chain that leads to a lack of availability, and all MIR requests to date that have been driven by an interest in addressing prices have failed because pricing had not equated to non-availability. While high drug prices can create a significant burden for patients with cancer in the form of copays, coinsurance, deductibles, and higher insurance premiums, FDA approved oncology drugs—even expensive ones—are nearly universally available to all insured individuals.

While pursuing affordable prices for prescription drugs is a laudable goal, Bayh-Dole march-in rights are not designed for this purpose. ACS CAN believes that there is nothing in the proposed framework that would alter the longstanding statutory criteria's limitations on the ability to use MIRs to address price. However, promoting MIRs as a tool in addressing price risks would upset the well-established ecosystem that has led to steady advances in patient outcomes. In fact, the third evaluation question within the framework asks, "Does march-in support objectives of Bayh-Dole?" This question is further explored with the follow-on question, "What are the Wider Implications & Do They Conflict with Bayh-Dole Objectives?" ACS CAN believes that the wider implications of promoting the unlikely use of MIRs to address price may be reduced translation of discoveries made with the support federal research funding, and this outcome would be in stark conflict with core Bayh-Dole objective of promoting such translation.

In summary, while we share the administration's goal of lowering drug costs, we remain concerned about the utilization of march-in authority as an avenue to lower prescription drug costs as well as its long-term potential to deter the private and public research ecosystem that has been key to our nation's progress in the fight against cancer.

Fostering continued cancer discovery is critical to addressing today's unmet needs in cancer care and successfully combatting the more than 200 different diseases we call cancer by turning scientific advancements into effective therapies. We look forward to continuing to work with Congress and the administration in the pursuit of policy interventions that result in lowering the high costs of cancer by carefully balancing patient affordability and innovation.

Thank you for the opportunity to comment on the draft framework for considering March-In Rights. If you have any questions, please feel free to contact me or have your staff contact Nishith Pandya, Director, Federal Relations (nishith.pandya@cancer.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Lacasse". The signature is fluid and cursive, with the first name "Lisa" and last name "Lacasse" clearly distinguishable.

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network