



February 1, 2024

Laurie E. Locascio, Ph.D.
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Director Locascio,

On behalf of the Center for American Principles, I would like to thank you for the opportunity to comment on the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.

The Center for American Principles works tirelessly to protect the personal freedoms and civil liberties of Americans, including the free enterprise system that has made this country so prosperous.¹ Before serving as the president of this organization, I managed various issue advocacy and political campaigns fighting to preserve the U.S. system of free markets from misguided policy initiatives that undermine our prosperity and freedom.² This proposed new framework is among the greatest threats to American innovation I have ever encountered.

The newly proposed framework directly contradicts the plain language and intent of the Bayh-Dole Act of 1980 -- a law that has incentivized cutting-edge research and development for 44 years. By seeking to expand government march-in powers to include considerations of price, the proposed framework drastically encroaches on the free market system. If implemented, it would devastate research and investment into new and essential technologies.

Prior to the Bayh-Dole Act, the federal government licensed fewer than 5% of the 28,000 patents it held.³ Government offices were utterly ineffective in putting these discoveries to work for the taxpayers who funded them.

Bayh-Dole changed that by allowing universities and other research facilities to hold and license the patents on federally funded basic discoveries. The potential for licensing revenue created the incentives the old system lacked. Entrepreneurs licensed patented discoveries and commercialized them, secure in the knowledge that their licenses were securely protected.

¹ <https://www.centerforamericanprinciples.org/>

² https://www.centerforamericanprinciples.org/?page_id=218

³ <https://www.gao.gov/assets/rced-98-126.pdf>, p. 3

The proposed new framework destroys that confidence for inventors and investors across all industries -- not just the drug sector that framework proponents want to target. As the draft itself states, "The framework is not meant to apply to just one type of technology or product or to subject inventions at a specific stage of development."⁴

The implications of this statement are breathtaking. Across all sectors, the patent licensing system established under Bayh-Dole has led to the creation of 11,000 new startup companies from publicly funded research, resulting in more than 4.2 million jobs and contributing more than \$1.3 trillion to the U.S. economy.⁵

This proposed new authority for government intervention would not only deter pharmaceutical investors and cause partnerships with the National Institute of Health (NIH) to crumble, but also would undercut the entire American system of market-based public-private partnership for innovation.⁶

Ironically, the proposed framework would also work at cross purposes with the administration's own efforts to promote technological innovation. The CHIPS and Science Act, which President Biden signed into law in August 2022, is one notable example. In the words of the U.S. National Science Foundation, it "authorizes historic investments in curiosity-driven, exploratory research and use-inspired, translational research," which would "advance the most innovative ideas across all areas of science and engineering -- accelerating their translation to solutions for today's challenges and tomorrow's -- at speed and scale."⁷ The executive overreach of the framework imperils all of that.

The framework also fails to clarify how the government will assess prices in determining whether to march in. Beyond the word "reasonable," there is little discussion of what kinds of price-setting procedures, if any, would provide a "safe harbor" against march-in.⁸ Nothing in the framework would protect enterprises from essentially arbitrary government decisions that the price of a given product is unreasonable.

In proposing this new framework, the administration has tarnished the legacy of the late Sens. Birch Bayh and Bob Dole -- who stated explicitly that they never intended to allow price considerations to drive march-in authority.⁹

They have also sent a chill through the entire U.S. free market system: the government is actively considering a proposal that could lead to the downfall of American innovation.

⁴<https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the#:~:text=The%20objectives%20for%20the%20Draft,determining%20whether%20to%20march%2Din.>

⁵<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8577412/>

⁶<https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/>

⁷<https://new.nsf.gov/chips>

⁸<https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the#:~:text=The%20objectives%20for%20the%20Draft,determining%20whether%20to%20march%2Din.>

⁹<https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>

I, along with my colleagues at the Center for American Principles, implore the administration to withdraw the draft framework immediately.

Sincerely,

A handwritten signature in black ink, reading "Anthony Zagotta". The signature is fluid and cursive, with the first name "Anthony" written in a larger, more prominent script than the last name "Zagotta".

Anthony Zagotta
President
Center for American Principles