February 6, 2024

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

Dear Director Locascio:

The Incubate Coalition writes to express concerns regarding the new Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. Our network consists of life-science venture capitalists who seek to educate policymakers on the role of venture capital in bringing promising, innovative treatments to patients in need.[1]

We'd like to respond to the first, fourth, and fifth questions you've posed in your request for information to make the case for amending this framework to better serve the public interest.

Before submitting those answers, however, it may be helpful to give context about our role in the life-science ecosystem and the important guidance that venture capitalists require from governments. Drug development is among the riskiest of ventures in the innovation economy. Most investments fail -- many before they even reach the clinical trial stage. Of the drug candidates that are promising enough to enter clinical trials, only about one in 10 ultimately receives regulatory approval.

The federal government has, for decades, admirably funded basic science research, largely through National Institutes of Health (NIH) grants to university and non-profit researchers who lay the theoretical groundwork for medical discoveries.

But when NIH and academic labs make discoveries, it is merely the beginning of a long and expensive journey to turn those good ideas into products that benefit patients.

Venture capitalists fund effectively all early-stage drug development at the start of that journey. We are financiers with a high tolerance of risk -- far higher than any other actors like banks or other private capital. No one else -- in government or the private sector -- is interested in funding the early days of translating academic discoveries to real-world drugs.

Life-science investors typically consider three variables before committing their capital.

First, we study the likelihood that a discovery will yield proven medical benefits. That is why so many of the employees at venture firms are doctors or trained scientists.

Second, we consider the amount of resources needed to validate our theories. We might need hundreds of millions of dollars before we know if we are on the right track -- or even billions in the case of well-documented mRNA investments.

[1] https://incubatecoalition.org/about-incubate/

Third, we must consider the likelihood of generating a positive return on that invested amount. We have a fiduciary responsibility to our investors, known as limited partners, who are often pension funds, university endowments, and philanthropic foundations. As such, we cannot simply invest in any scenario, but only when all three aspects of the investment make sense. For example, we would not invest in the following situations:

- A project with shaky science at its core.
- A project that requires an uncertain amount of investment over next 10-15 years.
- A project that features sound science and a predictable upfront investment, *but uncertainty about the ability to recoup investment and profit.*

It is the final criteria that explains why Incubate advocates so strongly for robust intellectual property protections and clear reimbursement policies, and why we are concerned about this framework. Simply put, the framework would fundamentally weaken investors' confidence in generating returns, thereby calling their investment thesis into question when evaluating potential lines of research.

With that in mind, we offer the following thoughts on the posed questions:

> *(1) How could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?*

If private-sector companies and investors know that the government can forcibly relicense patents on any product developed using federal funds, they'll be more likely to refrain from commercializing those early-stage inventions altogether.

The framework's lack of a clear directive on how federal agencies decide if a product is "too expensive" only aggravates their uncertainty.

Disincentivizing investment into early-stage research would deprive future generations of revolutionary inventions across virtually every industry. As just a few examples, the Bayh-Dole Act is directly responsible for advances in mRNA and immunotherapy technologies, HIV medicines, and countless technologies that underpin our phones, computers, and televisions. Google would not exist if it were not for the Bayh-Dole Act.

Of course, the academic technology transfer system established by Bayh-Dole is especially crucial when it comes to drug development, given that the federal government funds a considerable share of basic science research at universities nationwide. But federal dollars alone aren't enough to bring a new drug to market.

Consider an analysis from Vital Transformation[2]:

[2] https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/

A cohort of research projects linked to 23,230 NIH grants awarded in the year 2000 was audited to account for patents, where the project led to a product in clinical development and potentially FDA approval. A total of 8126 associated patents led to the identification of 41 therapies that registered clinical trials; 18 of these therapies received FDA approval.

NIH funding for the 18 FDA-approved therapies totaled $0.670 billion, whereas private sector funding (excluding post-approval funding) totaled $44.3 billion.

Put in simpler terms, the private sector's contribution to commercialized medicines is about 66 times higher than the public funding from all linked NIH grants.

If venture capitalists who finance post-academic R&D lose confidence that they'll be able to recoup their sizable investments, they will increasingly move their capital elsewhere -- either to "safer science" or toward another industry.

Ultimately, patients lose.

We have no doubt that your proposed march-in framework represents a good-faith attempt to make transformative, federally-backed research more accessible to the public. But in practice, it would do just the opposite -- all while exercising authority found nowhere in the Bayh-Dole Act itself.

(4) Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?

This proposed framework would undermine the central objective of the Bayh-Dole Act. As Senators Birch Bayh and Bob Dole clarified, "The law makes no reference to a reasonable price that should be dictated by the 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."[3]

Changing more than four decades of precedent and reinterpreting the Bayh-Dole Act in a way that allows federal agencies to march in on the basis of the price of commercially available products would deter, rather than entice, private investment into publicly funded research. Bayh-Dole does include a provision that allows federal agencies to "march in" and relicense patents under certain specific circumstances, but only if a company is sitting on a patent to a much-needed product it has failed to commercialize.[4]

To ensure that groundbreaking inventions reach ordinary Americans for generations to come, we urge you to withdraw this framework in its entirety – or alter it to explicitly clarify that a price

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

[4] https://bayhdolecoalition.org/wp-content/uploads/2023/02/BDC-Issue-Brief-March-in-Rights.pdf#new_tab

cannot be a trigger for march-in -- as both Bayh-Dole's authors and decades of bipartisan consensus have already determined.[5]

> *(5) 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. Does the framework ask questions and capture scenarios applicable across all technology sectors and different stages of development? How could any gaps in technology sectors or stages of development be better addressed?*

As we've referenced before and as you note, this framework is technology agnostic and its scope extends far beyond the pharmaceutical industry, to everything from software to agriculture. Yet the discourse surrounding this new framework entirely revolves around drug pricing. The White House announcement was even titled "Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition."[6]

Your agency is admirably soliciting public comments on whether the framework is understandable and whether it captures the full range of applicable scenarios. It is therefore important to highlight the fact that this framework would have the biggest detrimental impact on the earliest stages of research, *including* basic scientific research that *doesn't* involve the private sector.

The framework would discourage companies and their investors from licensing the "composition of matter" patents that tend to originate in academic. This will ultimately make academic institutions' composition of matter patents relatively less valuable, thereby leading to lower royalty and licensing revenues and fewer resources for schools to reinvest in their own research efforts.

Life-science venture capital is our expertise. The only competition that exercising march-in rights on the basis of reasonable price will promote is competition with our adversaries overseas, should the government signal to would-be investors that the U.S. pharmaceutical ecosystem does not value intellectual property protections.

Without the stalwart support of the government to protect intellectual property rights, private capital will increasingly cease to flow to publicly funded research. Without the backing of private capital, technology -- especially drugs in development -- stand little chance to find a path to commercialization.

Sincerely,

/s/ John Stanford

Executive Director
Incubate Coalition

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[5] https://bayhdolecoalition.org/digital-library/

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/