February 06, 2024

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

Re: Comments in response to NIST's *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*

Dear Director Locascio:

Thank you for giving us the opportunity to provide feedback to the National Institute of Standards and Technology and the Interagency Working Group for Bayh-Dole on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (MIR). We appreciate the opportunity to highlight some ideas we believe are critical to address.

California Life Sciences (CLS) represents the entire life science ecosystem in California, from early-stage innovators and startups to established industry leaders in the fields of biotechnology, pharmaceuticals, and medical technology. As integral components of a healthy and collaborative ecosystem, CLS also works closely with universities, academic and research institutions, the investment community, and other critical partners that promote this vibrant sector.

On behalf of our membership, we urge you to reconsider the recently published draft guidance. While we support lowering health costs for patients, this draft framework will not achieve this goal. Instead, this framework would create significant uncertainty in the innovation ecosystem, risking the investment in the study of new cures and harming small companies who face a challenging investment climate and rising costs.

The Bayh-Dole Act laid the foundation for America's world-leading, innovation-driven economy and the proposed guidance undermines the law's original intent and its proven effectiveness. Permitting the price of a product to be used as a criterion for march-in authority would not achieve the stated goal of addressing the cost of prescription medicines but would instead undermine the ecosystem of public-private partnership the Bayh-Dole Act has enabled to flourish for over 40 years. The law does not provide the government the authority to arbitrarily set prices for successfully commercialized inventions, nor does it include "price" as a consideration for the exercise of MIR. The authors of the Bayh-Dole Act themselves, Senators Birch Bayh (D-IN) and Bob Dole (R-KS), made clear that they intentionally omitted pricing as a consideration for use of march-in rights.[1] The absence of "price" or "pricing" in the underlying statute does not lend itself for its use in regulation, and does not authorize agencies to consider pricing to justify march-in.

[1] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=lk_inline_manual_11

Notably, the term “reasonable pricing" is not one that is defined in the law. This term is subjective and determining a workable definition will require fact intensive processes and dedicated resources that agencies are not equipped to handle. As there is no definition of what constitutes a “reasonable price," prospective licensees or those founding start-up companies around Bayh-Dole inventions have no idea what standards they will be judged by if they commercialize a product under these guidelines.

Every Administration that has considered a march-in petition on the basis of price since the enactment of Bayh-Dole has rightfully rejected it, including the Biden Administration last year. Pursuing this new framework abandons long-standing precedent and would not only undermine private-sector incentives for innovation but discourage public-private partnerships that have been responsible for spurring America’s leading role in global life sciences innovation. Allowing the government to impose price restrictions could jeopardize the delicate balance between protecting taxpayer investment in federally funded research and preserving incentive for the private sector to take on the risk of developing emerging technology into a commercially viable product.

Since the framework applies to all government-funded research and development, not just medical innovations but innovations from every discipline, it provides an apparatus for competitors or even our foreign adversaries to come after the innovative small companies that drive our technological progress. Even if filed march-in petitions are ultimately unsuccessful, the potential threat caused by their filing may deter potential funders or partners. While the framework purports to address the cost of pharmaceutical products, the Administration must consider that the broad nature of this change will impact research and innovation in nearly every sector.

CLS is proud to represent and advocate for the entire life sciences innovation ecosystem, including California universities that benefit from our state receiving the most funding awarded by the National Institutes of Health and National Science Foundation. This policy could have the negative effect of discouraging investment in our member companies that partner with these universities or accept federal funding in the form of SBIR grants.

Under the Bayh-Dole Act, partnerships between universities and industry have accelerated the progress of science and technology to the public’s benefit. The crux of the law is that it provides a legal infrastructure for these organizations with complementary skills to work together. However, the threat of subjective march-in will discourage partnerships between the private-sector and academic institutions.

Partnerships between industry and academic institutions are essential to ensure the American taxpayer benefits from scientific research that receive federal support. Successfully commercializing a product is the role of the private sector, not government. These partnerships allow nascent innovations from an academic lab to be further developed and translated into an actual product or service that can reach the marketplace and be used by the public. Prior to the

enactment of the Bayh-Dole Act, only five percent of patents resulting from federal investments in basic research were licensed, meaning 95% sat on agency shelves collecting dust.[2]

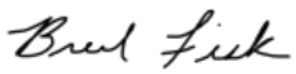
Another consideration is the outsized impact the draft guidance will have on rare disease research. Drug development for rare and ultrarare conditions is risky and challenging to fund, given the high costs of research and development for treatments targeting small patient populations. Public-private partnerships help reduce the risk for this process. Exposing patents for rare disease drugs developed with federal funding to march-in adds an additional element of uncertainty to an already high-risk sector. With 95% of rare diseases lacking a treatment today, U.S. policy should be aimed at eliminating barriers to drug development, not creating new ones.[3]

Another unintended consequence to consider would be the proposed guidance's effect on international competitiveness of U.S. academic institutions. As march-in would only apply to universities receiving funding from the U.S. federal government, partnerships with international institutions may be more appealing and risk-adverse for industry leaders. Moreover, we're seeing international initiatives, such as the European Union's "Rare Disease Moonshot" initiative, that have the goal of leveraging the sum of public and private knowledge and capabilities to find urgent solutions for patients with rare diseases.[4] The program seeks to bring together an ecosystem of rare disease experts and research to explore opportunities for collaboration through public-private partnerships.[5] While other countries and international collectives seek to scale up public-private partnerships for rare disease, the draft guidance would do the opposite and hamper opportunities for domestic innovation.

In summary, the draft framework will not be effective in lowering drug costs and will instead undermine the law that has enabled America's most influential academic institutions and forward leaning companies to be global leaders in innovation. CLS encourages the Administration to change course and work to implement real solutions that will protect patient access, help bring down health care costs, and support our ecosystem's work to develop new cures.

Thank you again for the opportunity to respond to your request for information. CLS welcomes any questions and further discussion on the topics above, and you can contact me at bfisk@califesciences.org.

Sincerely,



Brent Fisk
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California Life Sciences

[2] https://www.gao.gov/assets/rced-98-126.pdf
[3] https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf
[4] https://www.rarediseasemoonshot.eu/about-us/
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