incubate

August 18, 2023

Lyric Jorgenson, PhD
Acting Associate Director for Science Policy
National Institutes of Health Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD 20817

Dear Director Jorgenson:

On behalf of Incubate, the largest coalition of venture capital organizations that finance the early-stage life sciences ecosystem, we appreciate the opportunity to comment on the NIH's July 31 "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

Specifically, we are troubled by certain panelists' misguided claims regarding the balance between public discovery and private development within America's innovation ecosystem. Furthermore, there's growing concern about attempts to divert the NIH's primary mission of advancing science towards addressing systemic healthcare policy issues.

Efforts to develop effective new therapies that meet unmet medical needs rely on strong and predictable intellectual property protections. While basic NIH research leads to important early-stage discoveries, it is private capital that funds efforts to turn those promising discoveries into life-saving medicines. Without strong IP protections, companies and their investors simply would not be able to take such risks.

Prior to 1980, federally-backed research frequently yielded promising discoveries that never benefited the public. That's because the U.S. government owned the patents on those discoveries and rarely licensed them out to companies with the expertise to successfully commercialize them. As of 1980, just 5% of 30,000 government-held patents were licensed out for further development.[1]

Recognizing the urgent need to fix this broken system, Senators Birch Bayh (D-IN) and Bob Dole (R-KS) authored legislation permitting universities and other institutions to own, patent, and license federally-funded discoveries.

The Bayh-Dole Act, as it came to be known, helped ensure promising scientific discoveries no longer gathered dust. From 1996 to 2020, over 200 drugs and vaccines were developed through the technology transfer system Bayh-Dole established -- including the Covid-19 mRNA shots that have saved millions of lives.[2] [3]

[1] https://www.google.com/url?q=https://techtransfer.syr.edu/about/bayh-dole/&sa=D&source=docs&ust=1691639467985331&usg=AOvVaw0_6b7Bk1vtGBwZq9UDVqJY
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9975718/#:~:text=The%20US%20federal%20government%20invested,in%202020%20through%20March%202022.
[3] https://bayhdolecoalition.org/wp-content/uploads/2023/04/Driving-the-Innovation-Economy-Academic-Technology-Transfer-in-Numbers-2021.pdf

The economic impacts of the law are equally hard to ignore. Since 1996, the Bayh-Dole Act has added $1 trillion to U.S. GDP, supported 6.5 million jobs, and aided the formation of 15,000 start-ups.[4]

Unfortunately, we are seeing the Bayh-Dole system be misrepresented. The law's "march-in" provision should not be misused to impose price controls on life-saving medications. March-in is only permitted in rare instances, such as when a patent holder refuses to commercialize research altogether.[5] The law's authors never intended march-in to be used as a means of setting prices on successful products.[6]

More importantly, the suggested proposal would backfire by disincentivizing private companies from licensing government-backed research in the first place.

Developing a new medicine costs on average $2.6 billion and can take well over a decade.[7] [8] Some 90% of potential treatments fail during clinical trials.[9] Investors are able to fund so many drug development projects because one or two successful medicines can cover losses from dozens of failures. Robust and reliable IP protections allow private sector companies to recoup R&D costs and earn revenue to fund additional drug development activities for a defined period of time before generic and biosimilar competitors enter the market.

Allowing the government -- rather than private companies themselves -- to set prices on successful drugs undermines this entire system and will give life sciences investors no choice but to redirect their money elsewhere.

Another cause for concern is that certain lawmakers are asking NIH to insert "reasonable pricing" clauses in all future grants, licenses, and Cooperative Research and Development Agreements (CRADAs). This too amounts to government price-setting and would dissuade innovative life sciences companies from licensing early-stage research from the federal government.

This isn't theoretical. The NIH established a "reasonable pricing" requirement for CRADAs in 1989.[10] As a result of the policy, the number of private sector CRADAs with the NIH plummeted and the agency was forced to end the requirement in 1995.[11] [12] A year later, the number of CRADAs skyrocketed once again.[13]

History could not be clearer: "reasonable pricing" requirements led to reductions in public-private collaboration critical to developing life-saving therapies. It would be a mistake to revive these failed policies.

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[4] https://bayhdolecoalition.org/wp-content/uploads/2023/04/Driving-the-Innovation-Economy-Academic-Technology-Transfer-in-Numbers-2021.pdf
[5] https://www.law.cornell.edu/uscode/text/35/203
[6] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/
[7] https://pubmed.ncbi.nlm.nih.gov/26928437/
[8] https://ncats.nih.gov/about
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/
[10] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/
[11] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/
[12] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/
[13] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/

Incubate shares the NIH's desire to strengthen the U.S. technology transfer system while "promoting the application of knowledge to enhance human health."[14] Eroding IP protections and advancing mistaken "reasonable pricing" policies works directly against these goals.

In acknowledging the above, it's crucial to recognize that there are real and pressing concerns regarding access to and affordability of medicines. High out-of-pocket costs render essential medications unattainable for many American patients. But the solution isn't one that would reduce overall investment into these life-saving tools. Instead, the focus should be on improving the quality of insurance coverage, holding industry middlemen accountable, and ensuring that all patients have access to the medicines prescribed by their doctors.

When considering these broader healthcare challenges, it is also important to remember the distinct role of the NIH. Rather than modifying agency policies in ways that could stifle innovation, we should harness the NIH's capabilities to foster innovation and bolster competition. The value of strong public-private partnerships becomes evident here, as they serve as a bridge between research and real-world applications.

By fast-tracking groundbreaking innovations from the lab to the market, the NIH -- with the support of these public-private partnerships -- fosters a dynamic environment brimming with various therapeutic choices. Such diversity organically leads to more competitive pricing. Imposing restrictions will only hinder the very medical innovations vital for advancing public health.

Thank you again for the opportunity to comment. Please do not hesitate to email john@incubatecoalition.org or ashlyn@incubatecoalition.org with any questions.

Sincerely,

John Stanford
Executive Director
Incubate

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[14] https://osp.od.nih.gov/events/workshop-on-transforming-discoveries-into-products-maximizing-nihs-levers-to-catalyze-technology-transfer/