

July 27, 2023

SUBMITTED VIA EMAIL to [sciencepolicy@od.nih.gov](mailto:sciencepolicy@od.nih.gov)

**RE: Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer**

Dear Dr. Jorgenson,

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to inform the proceedings of NIH’s Workshop on Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer. PhRMA believes that maximizing the timely transfer of federal investments in science and technology and attracting greater private sector investment to create innovative products, processes, and services as well as new businesses and industries, is critically important for America’s patients, the U.S. economy, and our national security.

PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to researching and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA’s member companies have invested more than \$1.1 trillion in the search for new treatments and cures, including an estimated \$102.3 billion in 2021 alone.<sup>1</sup>

The U.S. biopharmaceutical industry relies on a well-functioning, science-based regulatory system, strong and reliable intellectual property (IP) protections, and coverage and payment policies that support and encourage medical innovation to thrive. This framework, in addition to the collaborative biopharmaceutical research ecosystem that includes both the private and public sectors, yields more innovative medicines than any other country in the world. The American biopharmaceutical research ecosystem is among our country’s greatest strengths – largely due to policies enacted by Congress to ensure that federally funded inventions can move from the laboratory to the marketplace for the public good.

Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government funded early-stage research into useful products. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and the right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally funded inventions – and only 5% of those patents

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<sup>1</sup> 2022 PhRMA Annual Membership Survey, [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA\\_membership-survey\\_2022\\_final.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA_membership-survey_2022_final.pdf)

were ever licensed for use in the private sector.<sup>2</sup> Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research. Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D investment and innovation.<sup>3</sup> One study found that in the decade following an increase in NIH funding, private R&D spending grew by about eight times as much as the increase.<sup>4</sup> Another study found that each \$10 million increase in NIH funding resulted in private sector investment yielding a net increase of 2.7 patents.<sup>5</sup>

Although many medical discoveries have their origin in the research laboratories at the NIH or federally funded academic medical centers, technology transfer is what allows these discoveries to be developed, reduced to practice and made available to improve public health through licensing and collaboration agreements with the private sector. According to the NIH Office of Technology Transfer, “technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone.”<sup>6</sup> Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical R&D ecosystem. According to the Congressional Budget Office (CBO), “the complementary relationship between public and private R&D spending arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs and vaccines, whereas private spending focuses on applications of such research.”<sup>7</sup> While NIH plays an important role in fostering basic research in genomics, molecular biology and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies for patients. These discoveries only become fully developed therapies available to patients because of private industry contributions, both financial and technical.

The biopharmaceutical industry’s unique role in the research ecosystem is to utilize its scientific and industrial expertise and invest at risk to build upon and further advance basic science research to determine if safe and effective treatments can be developed and made available to patients. The federal government cannot research, develop and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing and

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<sup>2</sup> Mittal, A. K. (2009). *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*. Available at: <https://www.gao.gov/assets/gao-09-742.pdf>

<sup>3</sup> Schacht, Wendy H. (2012). *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Congressional Research Service Report RL32324.

<sup>4</sup> Toole, Andrew A. (2007). *Does Public Scientific Research Complement Private Investment in R&D in the Pharmaceutical Industry?* *Journal of Law & Economics*, 50(1) 81–104, <https://doi.org/10.1086/508314>.

<sup>5</sup> Azoulay, Pierre et al. (2019). *Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules*, *Review of Economic Studies*, 86(1)117–15. Available at: <https://academic.oup.com/restud/article/86/1/117/5038510?login=true>

<sup>6</sup> <https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer>

<sup>7</sup> <https://www.cbo.gov/publication/57126>

technological platforms and financial investment from private sector biopharmaceutical companies.

A rich body of research documented the nature of the complementary roles of the public and private sectors in advancing medical treatments. In 2001, the NIH concluded in a study for Congress that the biopharmaceutical industry was responsible for the discovery and development of 91 percent (43 out of 47) of all the top-selling marketed drugs in 1999.<sup>8</sup> A 2010 analysis of 252 drugs approved between 1998 and 2007 found that 76 percent originated in industry vs. 24 percent in academia.<sup>9</sup> A 2014 study of the most transformational drugs of the 25 prior years, as identified by over 200 physicians, found that the private sector was responsible for the vast majority of the work required to develop a therapy.<sup>10</sup> An analysis of the contribution of NIH funding to new drug approvals 2010 – 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.<sup>11</sup> And an analysis of 23,230 NIH grants awarded in the year 2000 that were ultimately linked through the reported patent filings to 18 FDA-approved therapies showed that NIH funding totaled \$0.670 billion, whereas private sector funding totaled \$44.3 billion.<sup>12</sup> Accordingly, the private sector makes a substantial investment in research and development of biopharmaceuticals that far exceeds the contribution of the public sector.

The NIH has certain rights and procedures when it considers licensing a patented invention for further development by the private sector. Companies that want to obtain a license to develop an NIH invention must complete an application, and if the applicant has requested an exclusive or partially exclusive license the NIH will publish a notice in the Federal Register, as required by law, and after review and evaluation of public comments will make a final determination regarding the license.

NIH considers several factors when determining whether to grant a license, and what kind of license. The criteria for consideration as to exclusive licenses include whether an exclusive license serves the best interest of the public and whether it is a reasonable and necessary incentive to promote the investment of risk capital to bring the invention to practical application

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<sup>8</sup> Department of Health and Human Services (DHHS), National Institutes of Health (NIH). (2001). *Report to the United States Congress, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*. Available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf>

<sup>9</sup> Kneller, R. (2010). *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*. *Nature Reviews/Drug Discovery*, 9, 867-82. Print.

<sup>10</sup> Chakravarthy R, Cotter K, DiMasi J, et al. (2016). *Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy*. *Ther Innov Regul Sci*. 2016;50(6):759-768.

<sup>11</sup> Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). *Contribution of NIH funding to new drug approvals 2010-2016*. *Proceedings of the National Academy of Sciences of the United States of America*, 115(10), 2329–2334. <https://doi.org/10.1073/pnas.1715368115>

<sup>12</sup> <https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/>

by a licensee. NIH can negotiate to ensure that exclusive or partially exclusive license terms and conditions are not broader than necessary.<sup>13,14</sup>

Private companies often understandably prefer exclusive licenses that allow them to be the sole user of a patented invention for certain uses for a specified period of time in order to provide a measure of certainty and predictability during the highly risky, lengthy, and costly drug development process. The investment necessary to develop a new medicine can cost an average of several billion dollars and take 10-15 years, and only 12% of medicines entering clinical trials ever obtain an FDA approval.<sup>15</sup> NIH is also aware of these risks when making licensing decisions. As part of licensing agreements NIH receives royalties from the private sector which can be reinvested in research and potential new discoveries by the agency. GAO has found that NIH received up to \$2 billion in royalties between 1991 and 2019.<sup>16</sup>

Given the high costs and length of time to research and develop new medicines and vaccines, as well as to invest in manufacturing facility enhancements and to invest in new facilities altogether, strong and reliable IP rights are critical for providing the potential for returns and spurring companies to make the needed investments needed to develop future medicines. Manufacturers seek the certainty and predictability provided by IP protections to make the decades long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities. Strong and reliable IP protections are also critical to fostering public-private partnerships and other forms of collaboration, including investment in emerging innovator companies.

Though the Bayh-Dole Act allows the federal government to “march-in” under a narrow set of circumstances, “march-in” was never intended to serve as a mechanism for regulating the pricing of any products, including prescription medicines. The provisions provide the right for the government to “march in” under a narrow set of circumstances and force patent holders to grant a license to a “responsible applicant” able to utilize the technology to address an unmet need. In the nearly four decades that the Bayh-Dole Act has been in place, NIH, after careful review, has rejected each of the seven march-in petitions based on pricing that have been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and met health or safety needs. Even in an instance where march-in was requested to respond to a manufacturing supply challenge, NIH concluded that the manufacturer was “working diligently to resolve its manufacturing difficulties”<sup>17</sup> and “no

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<sup>13</sup> <https://www.techtransfer.nih.gov/licensing>

<sup>14</sup> See 37 CFR § 404.7

<sup>15</sup> DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of health economics*, 47, 20-33.

<sup>16</sup> <https://www.gao.gov/products/gao-21-52>

<sup>17</sup> Thomas, J. (2016). March-In Rights Under the Bayh-Dole Act. CRS. Available at: <https://fas.org/sgp/crs/misc/R44597.pdf>.

remedy that is available under the march-in provision would address the problems identified by the requestors.”<sup>18</sup>

In an Op-Ed to the Washington Post, the bill’s authors, Senators Birch Bayh and Bob Dole, stated: “The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.”<sup>19</sup> Similar provisions cover the licensing of NIH inventions, which empower the NIH to terminate the license in whole or in part if the agency determines that the licensee is not executing its commitment to achieve practical application of the invention, the licensee is in breach of an agreement, termination is necessary to meet requirements for public use, or the licensee has been found by a court to have violated Federal antitrust laws in connection with its performance under the license agreement.<sup>20</sup> Changing policy on these provisions to allow price to be considered as a factor for action on the part of NIH could chill the private sector’s willingness to enter into contractual agreements and licenses with the agency.

PhRMA is also strongly opposed to any proposals to add “reasonable pricing” requirements to agreements between the NIH and private companies. Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed “reasonable pricing” conditions in all Cooperative Research and Development Agreements (CRADAs) between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.<sup>21</sup> In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D., said, “An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public.” Dr. Varmus further said, “Eliminating the clause will promote research that can enhance

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<sup>18</sup> National Institutes of Health (NIH). (2010). National Institutes of Health Office of the Director: Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation. Available at: <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf>.

<sup>19</sup> Bayh, B. and Dole, R. (2011). Our Law Helps Patients Get New Drugs Sooner. Washington Post op-ed. Available at: [https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=sr\\_1](https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=sr_1)

<sup>20</sup> <https://www.techtransfer.nih.gov/licensing>

<sup>21</sup> National Institutes of Health. (1994). Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. Available from: [https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH\\_%20CRADA\\_Report\\_on\\_Reasonable-Pricing\\_Clause\\_1994.pdf](https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf)

the health of the American people.”<sup>22</sup> After the removal of the clause, there was a subsequent rebound in CRADAs.<sup>23</sup>

Policies enabling the government to determine the “reasonable price” of medicines developed with support from NIH also fail to recognize that reducing the incentives for the private sector to invest in the future development of medicines could have serious unintended consequences for our national security and ability to respond to public health emergencies. The NIH and BARDA routinely partner with biopharmaceutical companies to support medical countermeasure (MCM) development through funding, technical assistance, and core services like clinical trial site management and manufacturing scale-up. Several MCMs, such as monkeypox vaccines, smallpox antiviral drugs, H5N1 influenza vaccines and anthrax vaccines are maintained in the strategic national stockpile, where they can be made available in the face of a public health threat.<sup>24</sup> Pipeline products being explored have potential but there is no guarantee they will ultimately receive FDA approval or have more than limited commercial utilization, and thus seeking to inject further uncertainty by setting an arbitrary price at the outset may simply serve to further chill critical R&D investments and collaborations between the public and private sectors with the end-result leaving the United States unprepared to quickly respond to emerging health threats.

As NIH considers the feedback from this Workshop’s proceedings, PhRMA suggests the agency can learn from other similar efforts from agencies such as NIST, who published a roadmap for “Unleashing American Innovation” in 2019 through its Return on Investment Initiative Green Paper.<sup>25</sup> Among other things, the authors of the report found that federal officials must better engage with the private sector, strengthen IP protections, and incentivize technology transfer.<sup>26</sup>

The biopharmaceutical industry is proud to be a key player in the U.S. biopharmaceutical research ecosystem. We rely on a well-funded and robust public research infrastructure to generate meaningful scientific exchange and partner with to advance science for the benefit of American patients. We look forward to ongoing dialogue on these issues. Please free to reach out to David Korn, Vice President, IP and Law at [dkorn@phrma.org](mailto:dkorn@phrma.org) or me at [julrich@phrma.org](mailto:julrich@phrma.org) with any questions or for additional discussion.

Sincerely,

Jocelyn Ulrich, MPH  
Deputy Vice President  
Policy and Research  
PhRMA

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<sup>22</sup> Press Release, NIH News, April 11, 1995. Available from:

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>

<sup>23</sup> <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>

<sup>24</sup> <https://aspr.hhs.gov/SNS/Pages/Requesting-SNS-Assets.aspx>

<sup>25</sup> <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>

<sup>26</sup> See page 5 at; <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>