



NATIONAL HEALTH COUNCIL

February 6, 2024

The Honorable Laurie Locascio  
Under Secretary of Commerce for Standards and Technology  
Department of Commerce  
1401 Constitution Avenue, NW  
Washington, DC 20230

**RE: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights; Docket No: 230831-0207**

Dear Under Secretary Locascio:

The National Health Council (NHC) appreciates the opportunity to respond to the National Institute of Standards and Technology (NIST) *Request for Information (RFI) Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of 170 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

At the forefront of our interests is the availability, accessibility, and affordability of health care, including medications developed through public-private partnerships. Research underscores the pivotal role of public support in spearheading the development of new treatments and therapies, especially for chronic conditions, where ongoing medication

can have significant effect on a patient's health and wellbeing.<sup>1,2,3,4,5,6</sup> While we share the Administration's goal of ensuring treatments are affordable, we are concerned by the potential unintended consequences that could diminish the value of publicly funded research by discouraging the translation of it into treatments. Therefore, we urge NIST to carefully assess potential repercussions that might compromise public health and hinder the advancement of new medical solutions. The NHC would like to underscore the following considerations as NIST seeks to balance innovation with the accessibility of results from publicly funded research endeavors.

## **The Role of Public-Private Partnerships in Health Care Innovation and Public Health**

The NHC recognizes the indispensable role of public-private partnerships in advancing medical research and development. Notably, government funding plays a critical role in supporting independent clinical research in areas characterized by market deficiencies due to inadequate incentives such as in rare disease research – clearly illustrating the

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<sup>1</sup> National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Forum on Drug Discovery, Development, and Translation. (2021). *Innovation in drug research and development for prevalent chronic diseases: proceedings of a workshop*. The National Academies Press. <https://doi.org/10.17226/26291>.

<sup>2</sup> Aiyegbusi, O., Macpherson, K., Elston, L., Myles, S., Washington, J., Sungum, N., Briggs, M., Newsome, P., and Calvert, M. (2020). Patient and public perspectives on cell and gene therapies: a systematic review. *Nature Communications*, 11(6265). <https://doi.org/10.1038/s41467-020-20096-1>

<sup>3</sup> Cummings, J., Reiber, C., and Kumar, P. (2018). The price of progress: funding and financing Alzheimer's disease drug development. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*, 4, 330-343. <https://doi.org/10.1016/j.trci.2018.04.008>

<sup>4</sup> Austin, C. (2021). Opportunities and challenges in translational science. *Clinical and Translational Science*, 14(5), 1629-1647. <https://doi.org/10.1111/cts.13055>

<sup>5</sup> Seyhan, A. (2019). Lost in translation: the valley of death across preclinical and clinical divide – identification of problems and overcoming obstacles. *Translational Medicine Communications*, 4(18). <https://doi.org/10.1186/s41231-019-0050-7>

<sup>6</sup> National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Committee on Ensuring Patient Access to Affordable Drug Therapies. (2018). *Making medicines affordable: a national imperative*. National Academies Press.

essential role of federal funding in fostering advancements in medical research for these conditions.<sup>7,8,9,10,11,12,13</sup>

Furthermore, federal science funding, while a catalyst for academic research, also attracts additional investment from various sectors, thus contributing to the overall health ecosystem.<sup>14,15</sup> The current health care system is structured to motivate for-profit entities to play a significant role in pioneering innovation, working in tandem with federal research efforts.<sup>16</sup> This collaboration is vital, fostering a landscape where innovation thrives under a balance of incentives and safeguards, as established by the Bayh-Dole Act. Commercialization of medical research through mechanisms established by the Bayh-Dole Act is not merely a pathway to innovation but a lifeline for patients awaiting new treatments. For people with chronic diseases and disabilities, these treatments can be their best options to improve quality of life, safeguard their health and well-being, and potentially cure them. Recognizing the imperative to address public health needs, it is

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<sup>7</sup> Cleary, E., Jackson, M., Zhou, E., and Ledley, F. (2023). Comparison of research spending on new drug approvals by the National Institutes of Health vs the pharmaceutical industry, 2010-2019. *JAMA Health Forum*, 4(4). doi:10.1001/jamahealthforum.2023.0511

<sup>8</sup> National Center for Science and Engineering Statistics. (2021). Survey of federal funds for research and development, 2021. Retrieved from <https://nces.nsf.gov/surveys/federal-funds-research-development/2021>

<sup>9</sup> Verbaanderd, C., Rooman, I., and Huys, I. (2021). Exploring new uses for existing drugs: innovative mechanisms to fund independent clinical research. *Trials*, 22(322). <https://doi.org/10.1186/s13063-021-05273-x>

<sup>10</sup> Farooq, F., Mogayzel, P., Lanzkron, S., Haywood, C., and Strouse, J. (2020). Comparison of US federal and foundation funding of research for sickle cell disease and cystic fibrosis and factors associated with research productivity. *JAMA Network Open*, 3(3). doi:10.1001/jamanetworkopen.2020.1737

<sup>11</sup> Nayak, R., Avorn, J., and Kesselheim, A. (2019). Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *BMJ*, 367. doi: 10.1136/bmj.l5766

<sup>12</sup> Dakwins, H., Draghia-Akli, R., Lasko, P., Lau, L., Jonker, A., Cutillo, C., Rath, A., Boycott, K., Byanam, G., Lochmüller, H., Kaufmann, P., Le Cam, Y., Hivert, V., Austin, C., and International Rare Diseases Research Consortium. (2018). Progress in rare diseases research 2010-2016: an IRDiRC perspective. *Clinical and Translational Science*, 11(1), 11-20. doi: 10.1111/cts.12501

<sup>13</sup> Kaufmann, P., Pariser, A., and Austin, C. (2018). From scientific discovery to treatments for rare diseases - the view from the National Center for Advancing Translational Sciences - Office of Rare Diseases Research. *Orphanet Journal of Rare Diseases*, 13(196). <https://doi.org/10.1186/s13023-018-0936-x>

<sup>14</sup> Azoulay, P., Li, D., Zivin, J., and Sampat, B. (2019). Public R&D investments and private-sector patenting: evidence from NIH funding rules. *The Review of Economic Studies*, 86(1), 117-152. doi: 10.1093/restud/rdy034

<sup>15</sup> Biotechnology Innovation Organization. (2017). *The economic contribution of university/nonprofit inventions in the United States: 1996-2015*. Retrieved from [https://www.autm.net/AUTMMain/media/Partner-Events/Documents/Economic\\_Contribution\\_University-Nonprofit\\_Inventions\\_US\\_1996-2015\\_BIO\\_AUTM.pdf](https://www.autm.net/AUTMMain/media/Partner-Events/Documents/Economic_Contribution_University-Nonprofit_Inventions_US_1996-2015_BIO_AUTM.pdf)

<sup>16</sup> Lanahan, L., Graddy-Reed, A., and Feldman, M. (2016). The domino effects of federal research funding. *PLOS ONE*, 11(6). <https://doi.org/10.1371/journal.pone.0157325>

essential that NIST's interpretation of the Bayh-Dole Act's provisions recognizes, supports, and nurtures an environment where such transformative research can flourish and reach patients effectively. This balance is critical to ensure that march-in rights are strategically employed to tackle substantial public health issues, such as unmet medical needs or access barriers, without impeding the innovation imperative for medical advancement.

### **Adherence to Bayh-Dole Act Principles**

The NHC strongly reaffirms the necessity of adhering to the foundational principles of the Bayh-Dole Act, which has been instrumental in the commercialization of federally funded research, including translation of medical research into treatments, ensuring public access to resulting innovations.<sup>17</sup> In crafting the Bayh-Dole Act, legislators aimed to prevent scenarios where dominant companies might block the commercialization of licensed inventions that pose a threat to their existing products. This concern led to the inclusion of the march-in provision, empowering the government to mandate additional licensing by the patent holder – often academic institutions under this Act – if necessary efforts towards development are lacking, or if production fails to meet public health demands or federal usage requirements. This legislation has been successful in facilitating a balance between advancing public welfare and stimulating economic growth through the utilization of federally funded inventions. As NIST considers its interpretation of the Bayh-Dole Act's provisions, the NHC recommends a comprehensive evaluation to maintain this delicate balance, ensuring that the exercise of march-in rights remains in alignment with the original intent of the Bayh-Dole Act. To maintain the integrity of the Bayh-Dole Act and its original intent, the NHC urges NIST to ensure that any exercise of march-in rights strictly adheres to the Act's foundational principles of advancing public welfare through the utilization of federally funded inventions, while also fostering innovation and respecting intellectual property rights. This includes promoting public accessibility to inventions and safeguarding public interests without hindering the commercialization process that is vital for innovation. Any interpretation of the Bayh-Dole Act should provide a clear commitment to and mechanism for evaluating whether march-in rights are used in ways that align with the Act's goals, ensuring that these rights are not used in a way that inadvertently hampers innovation or the development of new technologies.<sup>18</sup> This approach should balance the need for public access to federally funded inventions with respect for the intellectual property rights that drive private investment in research and development.<sup>19</sup>

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<sup>17</sup> Link, A. and van Hasselt, M. (2019). On the transfer of technology from universities: the impact of the Bayh-Dole Act of 1980 on the institutionalization of university research. *European Economic Review*, 119, 472-481. <https://doi.org/10.1016/j.euroecorev.2019.08.006>

<sup>18</sup> Feldman, A. (2015). The Bayh-Dole Act, a lion without claws. *Clinical and Translational Science*, 8(1), 3-4. doi: 10.1111/cts.12262

<sup>19</sup> Atkinson, R. (2019). Healthy funding: the critical role of investing in NIH to boost health and lower costs. Retrieved from <https://www2.itif.org/2019-healthy-funding.pdf>

## Unintended Consequences

It is crucial that NIST's interpretation of the Bayh-Dole Act's march-in provisions carefully considers and avoids unintended consequences that could hinder translation of research into essential treatments. Specifically, it is important to ensure that NIST does not inadvertently create barriers or disincentives for conducting vital research, especially in areas where treatment needs are acute. Additionally, it is imperative to maintain a stable and supportive funding environment. Studies show that an increase in National Institutes of Health (NIH) funding levels leads to a substantial rise in private pharmaceutical research and development spending, highlighting the catalytic effect of federal funding in medical research.<sup>20</sup>

The NHC advises careful consideration to prevent potential negative impacts on the research and development ecosystem. Specifically, we recommend ensuring NIST's interpretation of the Bayh-Dole Act's march-in provisions does not inadvertently increase regulatory uncertainty or perceived risk among private sector entities engaged in federally funded research. This caution is essential to maintain robust public-private partnerships, which are vital for the translation of NIH-funded basic research into practical applications. The commercialization of medical research, as facilitated by the Bayh-Dole Act, is fundamental to delivering therapeutic innovations to patients, marking significant progress in health care and improving patient health outcomes. Additionally, we urge NIST to consider the indirect implications that its interpretation may have on NIH funding decisions and overall research policy, ensuring that it supports rather than hinders private investment in research and development. Our recommendation is aimed at preserving a balanced innovation ecosystem that fosters collaboration and sustains the momentum of medical advancements.

## Comprehensive Stakeholder Involvement and Transparency

While acknowledging the intent behind the draft framework, the NHC underscores the need for substantial revisions to ensure its effectiveness and viability, which will require comprehensive stakeholder engagement and transparency beyond this brief comment period, particularly given the complexity of the issues surrounding the framework. Decisions regarding the development and accessibility of treatments profoundly impact patients, making it essential to involve a wide range of stakeholders, including patient advocacy groups, in the policymaking process. The NHC advocates for a decision-making process that incorporates diverse perspectives, ensuring that policies are well-informed, balanced, and aligned with patient needs. Involving stakeholders in the conversation not only enhances the quality of decision-making but also ensures that the policies developed are responsive to the real-world challenges faced by patients and the health care system. This inclusive approach can lead to more effective and sustainable health policy outcomes. Stakeholder involvement should be an ongoing process, allowing for continuous input and adaptation of NIST's interpretation of the

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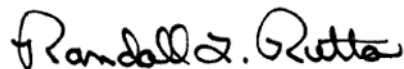
<sup>20</sup> Sussex, J., Feng, Y., Mestre-Ferrandiz, J., Pistollato, M., Hafner, M., Burridge, P., and Grant, J. (2016). Quantifying the economic impact of government and charity funding of medical research and development funding in the United Kingdom. *BMC Medicine*, 14(32), <https://doi.org/10.1186/s12916-016-0564-z>

Bayh-Dole's march-in provisions to address emerging issues and challenges in health care.<sup>21,22,23,24</sup> By ensuring a transparent process and broad stakeholder engagement, the framework can be more responsive to the evolving health care landscape and better equipped to address the diverse needs and perspectives of those affected by its implementation. This inclusive approach will also contribute to building trust among stakeholders, fostering a collaborative environment conducive to addressing complex health care challenges.

## Conclusion

The NHC values this opportunity to engage in this critical dialogue on march-in rights. We believe that our suggestions will enhance the Bayh-Dole Act's capacity and NIST's goal to serve the best interests of patients while fostering an environment conducive to health care innovation. We look forward to collaborating on initiatives that enhance patient-centered health care policy and practice. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,



Randall L. Rutta  
Chief Executive Officer

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<sup>21</sup> Frank, L., Morton, S., Guise, J., Jull, J., Concannon, T., Tugwell, P., and the Multi Stakeholder Engagement Consortium. (2020). Engaging patients and other non-researchers in health research: defining research engagement. *Journal of General Internal Medicine*, 35(1), 307-314. doi: 10.1007/s11606-019-05436-2

<sup>22</sup> Concannon, T., Grant, S., Welch, V., Petkovic, J., Selby, J., Crowe, S., Synnot, A., Greer-Smith, R., Mayo-Wilson, E., Tambor, E., Tugwell, P., Multi Stakeholder Engagement Consortium. (2018). Practical guidance for involving stakeholders in health research. *Journal of General Internal Medicine*, 34(3), 458-463. doi: 10.1007/s11606-018-4738-6

<sup>23</sup> Agency for Healthcare Research and Quality. (2014). Defining the benefits of stakeholder engagement in systematic reviews. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK196184/>

<sup>24</sup> National Health Council. (n.d.). Patient engagement: capturing and including the patient voice. Retrieved from <https://nationalhealthcouncil.org/issue/patient-engagement/>