NATIONAL HEALTH COUNCIL

July 22, 2024

Office of Science Policy
National Institutes of Health
Department of Health and Human Services
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Submitted electronically to: https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/

RE: National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

To Whom It May Concern:

The National Health Council (NHC) appreciates the opportunity to provide comments to the National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning (RFI).

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 more than170 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.

The NHC believes that promoting equity in access to medical innovations requires a comprehensive strategy. While the current RFI focuses on the direct relationship between NIH and its licensees, it is crucial to recognize the broader market structure's role in patient access. This includes wholesalers, payers, and other entities involved in pricing and distribution, all of which significantly influence the availability and cost of medical products, including drugs, biologics, vaccines, and devices. Addressing these systemic factors is essential to ensure that taxpayer-funded innovations benefit all patients effectively. Although these considerations extend beyond the current RFI, the NHC believes they warrant attention. We support a broader conversation involving all relevant stakeholders to develop policies that address the entire value chain of medical product development and distribution. This inclusive approach will foster a more equitable and effective health care landscape. By considering the full spectrum of influences on patient access, we can create sustainable solutions that promote both innovation and accessibility in the health care system.

Promoting Meaningful Access Strategies

The NHC supports NIH's goal of ensuring that medical innovations, including those that were invented and developed with the help of taxpayer dollars, are accessible and affordable to all patients, particularly underserved communities. However, we are concerned about potential unintended consequences that could arise from the proposed policy.

One example of an unintended consequence NIH may wish to reflect upon is the changes NIH made to Collaborative Research and Development Agreements (CRADAs) between 1990 to 1995. To address concerns about patient access, NIH added a "reasonable pricing clause" to its CRADAs, requiring companies to demonstrate a reasonable relationship between the pricing of a product, the public investment in that product, and the health and safety needs of the public. However, after engaging with stakeholders, NIH leadership removed the clause, citing its deterrence of companies collaborating with NIH as a negative impact on innovation.[1]

It is crucial to ensure that the policy does not inadvertently recreate the kinds of disincentives observed in the CRADA example and hinder commercialization and development of new treatments, which are essential for advancing public health. While we appreciate NIH's intent to provide guidance on commercially reasonable approaches to promoting access, we urge caution to avoid imposing overly burdensome requirements that could disincentivize innovation. Access strategies should be flexible and adaptable to the unique challenges of each product and market.

Ensuring access should not impede the commercial viability of products, as each biomedical innovation faces unique development and market conditions. Rigid requirements could stifle innovation by adding significant compliance costs and administrative burdens. A balanced and flexible approach to access and innovation is necessary to tailor strategies to the specific challenges of each product and market, rather than a one-size-fits-all approach that could hinder progress.

NIH should seek input from stakeholders, including patient organizations, industry representatives, and health care providers, beyond this finite comment period, to develop ambitious yet feasible access strategies. Ongoing stakeholder input can help balance access objectives with the realities of product development and commercialization. Effective access strategies must address multiple dimensions, including affordability, availability, acceptability, and sustainability. These dimensions will often vary based on patients' unique circumstances and must be informed by patient engagement. By engaging patients and a wide range of stakeholders, effective strategies can be designed and implemented to meet the diverse needs of patient populations.

The NHC's work on patient-reported outcomes and real-world data, detailed in our resources on patient engagement, underscores the importance of incorporating patient

[1] National Institutes of Health. (1995, April 11). *NIH notice rescinding the reasonable pricing clause.* https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

insights into access planning.[2] Patients' unique experiences and preferences provide critical information that can inform more effective and equitable research and access strategies. Engaging with patients and patient organizations enables the development of truly patient-centered access plans, addressing specific barriers and challenges faced by different patient populations.

To operationalize these principles, NIH should establish mechanisms for ongoing stakeholder consultation. This could include regular forums for feedback, advisory committees with patient and industry representation, and transparent reporting on how stakeholder input shapes policy decisions. By institutionalizing stakeholder engagement, NIH can ensure that access strategies remain dynamic and responsive to emerging challenges and opportunities in the biomedical landscape.

Promoting Transparency in the Biomedical Research Enterprise and Return on Investment

Transparency in the biomedical research enterprise ensures that taxpayer-funded research benefits the public, fostering trust and accountability in the use of public funds.[3] However, it is essential to balance transparency with the need to protect proprietary information to maintain the commercial viability of new products. The NHC has emphasized that transparency should not place excessive burdens on licensees or provide competitors with undue advantages. [4] Implementing reasonable reporting requirements and streamlined processes can help minimize administrative overhead that does not detract from core research and development activities. Focusing transparency measures on outcomes and impacts rather than granular financial details can drive down innovation costs and clarify expense impacts on product pricing. This approach aligns with broader goals to ensure that public investments in research yield tangible societal benefits without undermining incentives for innovation. The NHC supports transparency initiatives that enhance understanding of the overall investment in biomedical research and its outcomes, such as the impact on public health, job creation, and economic growth.[5] By focusing on these broader metrics, transparency efforts can highlight the value of public investments while safeguarding proprietary information and promoting a competitive market.

[2] National Health Council. (n.d.). Patient-focused medical product development webinar series. Retrieved from https://nationalhealthcouncil.org/additional-resources/pfmpd-webinar-series/

[3] National Health Council. (2023). NHC statement for the record for Energy and Commerce Health Subcommittee on transparency. Retrieved from https://nationalhealthcouncil.org/wp-content/uploads/2023/03/NHC-Comments-on-Energy-and-Commerce-Health-Subcommittee-Hearing-on-Transparency-.pdf

[4] National Health Council. (2024). NHC comments on NIST draft march-in framework. Retrieved from https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-nist-draft-march-in-framework/

[5] National Health Council. (2020). NHC comments on transparency in coverage. Retrieved from https://nationalhealthcouncil.org/blog/nhc-comments-on-transparency-in-coverage/

Providing Flexibility while Achieving Clear Policy Objectives

Flexibility is essential to accommodate the diverse nature of biomedical innovations. Establishing clear and achievable benchmarks for access plans that consider the varying stages of product development is crucial. A nuanced approach that incorporates adaptability, outcome-focused goals, and stakeholder engagement can ensure that benchmarks for access plans are both effective and conducive to innovation and improved patient access. Benchmarks should be flexible to accommodate changes in the research and development landscape, allowing for adjustments based on new data, technological advancements, and shifts in market conditions. This adaptability ensures that benchmarks remain relevant and achievable as circumstances evolve. In addition to specific metrics, benchmarks should emphasize the desired outcomes of access plans. Setting goals aligned with improving patient access, affordability, and overall public health impact prioritizes outcomes that drive meaningful improvements in the biomedical sector.

Effective benchmarks should be developed in collaboration with a wide range of stakeholders, including patients, patient organizations, health care providers, industry representatives, and public health experts. Engaging these diverse perspectives ensures that benchmarks reflect the needs of those impacted by biomedical innovations, enhancing the legitimacy and effectiveness of policy measures.

Flexibility is also an important consideration to account for the differences in the licensed technologies and the specific terms of each license. Many NIH licenses pertain to research tools used in laboratories, which are integral to advancing scientific research but do not directly affect patient care or accessibility.[6] Additionally, most licenses are non-exclusive, promoting healthy competition among licensees; this diversity in license types and scopes highlights the need for access plans to be appropriately tailored to fit the specific circumstances of each license.[7] Furthermore, it is important to consider the relative contribution of NIH's licensed technology to the final product; an NIH invention might be a central component of a commercial product, or it may be a smaller part that needs to be combined with other, non-federally supported technology. As NIH aims to have a greater influence over the commercial strategy of its licensees through this new policy, it is worth considering that such influence should be proportional to the significance of NIH's technology in the final product.

Collaborative processes are more likely to gain widespread acceptance and drive positive outcomes.[8] By integrating these principles, NIH can establish benchmarks that are clear, achievable, adaptable, and outcome focused. This approach allows licensees to propose tailored solutions that align with their specific circumstances and market dynamics, enabling innovative and context-specific strategies for enhancing patient access. Encouraging

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[6] Office of Science Policy, National Institutes of Health. (2024, June 11). *Access Planning Webinar.* Retrieved from https://osp.od.nih.gov/wp-content/uploads/2024/06/2024.06.11_AccessPlanning_Webinar_FULL.pdf

[7] Ibid.

[8] Wirtz, B., Weyerer, J., Becker, M., and Müller, W. (2022). Open government data: a systematic literature review of empirical research. *Electronic Markets, 32,* 2381-2404. https://doi.org/10.1007/s12525-022-00582-8

collaboration between licensees and stakeholders ensures that input from patients, health care providers, and public health experts enhances the effectiveness and feasibility of access plans.

Helping Licensees Achieve Access Goals

NIH can support licensees by providing guidance, technical assistance, and resources to help develop and implement effective access plans. This support can include templates, best practice guides, and access to expert consultations. Additionally, capacity-building initiatives should be invested in to enhance the ability of licensees, particularly smaller companies and academic institutions, to meet access requirements. Training programs and workshops can equip them with the necessary skills and knowledge. Facilitating partnerships with patient organizations and other stakeholders to enhance patient access is also crucial. These collaborations can leverage existing infrastructure and expertise to expand reach and impact. Public-private initiatives that pool resources and expertise to address common access challenges should be promoted, creating synergies and driving innovation in access strategies.

Establishing Licensee Obligations Depending on the Stage of Technology Development

Tailoring access obligations to the stage of technology development is a reasonable approach. Implementing more defined provisions for late-stage inventions, while allowing flexibility for early-stage inventions, is essential. Late-stage products have clearer pathways to market, making it feasible to set more specific access requirements. Using milestone-based obligations that correspond to key development and commercialization stages ensures that access commitments are aligned with the progress of the innovation. Recognizing the inherent uncertainties of early development and providing flexibility accordingly is crucial. Early-stage inventions face higher risks and variability, requiring adaptable and supportive frameworks. Introducing progressive obligations that evolve as the innovation advances through development stages allows for adjustments based on emerging data and market conditions.

Assessing Policy Impact

Evaluating the policy's effectiveness is crucial to ensuring it meets its objectives without unintended consequences. The NHC advises careful consideration to prevent potential negative impacts on the research and development ecosystem. Specifically, it is important to ensure that the policy does not inadvertently create barriers or disincentives for conducting vital research, especially in areas where treatment needs are acute. Maintaining a stable and supportive funding environment is imperative; studies show that an increase in 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.[9]

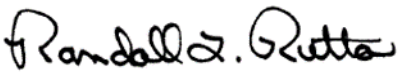
[9] Sussex, J., Feng, Y., Mestre-Ferrandiz, J., Pistollato, M., Hafner, M., Burridge, P., and Grant, J. (2016). Quantifying the economic impact of government and charity funding of medical research and development funding in the United Kingdom. *BMC Medicine, 14(32)*, https://doi.org/10.1186/s12916-016-0564-z

Best practices include periodic reviews and data collection, both qualitative and quantitative, to evaluate access plans. Engaging stakeholders – patients, health care providers, and industry representatives – through advisory committees and public forums is essential to gather diverse perspectives and ensure the policy remains relevant and effective. Comprehensive metrics covering affordability, availability, acceptability, and sustainability should be used, with stakeholder involvement to ensure they reflect real-world experiences. Continuous improvement should be facilitated by regularly updating criteria and metrics based on feedback and new data. Incorporating publicly available case studies and best practices can provide guidance for future policy development, and regular transparent reporting on policy assessments is vital for maintaining accountability and trust among stakeholders.

Conclusion

The NHC appreciates the opportunity to provide comments to NIH in response to its RFI. The NHC supports NIH's efforts to ensure that medical products resulting from federally funded research are accessible to all patients. However, we urge NIH to carefully consider the potential unintended consequences of the proposed policy. It is essential to strike a balance that promotes patient access while fostering an environment conducive to innovation and the commercialization of new treatments. NIH's past experience with similar policies can introduce complexities and hesitations in partnership with NIH and ultimately impact research and development of new treatments. We look forward to collaborating with NIH and other stakeholders to refine and implement this policy. 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.

Sincerely,



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