PORTAL
Program On Regulation, Therapeutics, And Law

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Via Electronic Submission

National Institutes of Health (NIH)
Office of Science Policy
6705 Rockledge Drive, Suite 630,
Bethesda, MD 20892

RE: Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

We are members of the Program On Regulation, Therapeutics, And Law (PORTAL) at Brigham and Women's Hospital and Harvard Medical School. PORTAL is one of the largest, non-pharmaceutical industry-funded academic research centers in the US devoted to investigating drug prescribing, outcomes, and policy. We support finalizing the NIH's Proposed Intramural Research Program Policy as proposed. This policy would require licensees who succeed in bringing a product to the market to submit an access plan outlining the steps they intend to take to promote patient access to those products. The NIH proposes a two-tier approach in which companies licensing products close to the market would have to provide a more detailed access plan. We believe effective implementation of such a policy can help improve access to products derived from public funding.

This submission provides some specific comments regarding key pieces of the proposed NIH Intramural Research Program Policy. Overall, we support the approach, and the issues raised here are meant to provide constructive feedback to help further strengthen the transparency and enforcement of this policy and minimize the risk of non-compliance.

Sincerely,

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Promoting approaches that support meaningful access.

The NIH could suggest the inclusion of specific commitments in companies' access plans to market the product at a reasonable price. For example, such a commitment could be drafted along the lines of the reasonable pricing clause that the Department of Health and Human Services (HHS) recently included in an investment contract with Regeneron to develop a monoclonal antibody therapy for COVID-19. In that case, Regeneron committed to choosing a list price (at wholesale acquisition cost) for commercial sales substantially equivalent to or less than the approved price for commercial sales in high-income countries outside the US, provided such sales are comparable sales within the same period.[1]

Previously, Senator Sanders had also put forward a similar proposal in the draft of the Pandemic and All-Hazards Preparedness Act (PAHPA), which suggested the use of a reasonable pricing clause in any contract, grant, license, cooperative agreement, or other transaction for medical product used against public threats funded or developed by the Biomedical Advanced Research and Development Authority (BARDA). The bill included a "most favored nation" provision, which provided that pricing could not exceed the lowest price for the same product offered in comparable countries, including Canada, France, Germany, Italy, Japan, and the United Kingdom.[2]

We recognize that pharmaceutical companies have long opposed attaching reasonable pricing clauses to government funding for drug research and development. For example, the NIH started to include reasonable pricing clauses in CRADA agreements in 1990 and reversed the policy in 1995 based on concerns raised by drug companies that reasonable pricing clauses had led to a decline in the number of CRADA agreements between the NIH and industry.[3] However, such concerns were not well-founded: the reasonable pricing clauses were not consistently implemented, plagued by vague wording, and empirical reviews of NIH-industry CRADAs issued during that era show no evidence that the new policy reduced the number of CRADAs.[4]

Thus, the NIH should suggest companies commit to reasonable pricing in their access plans. Reasonable pricing clauses could include more flexible language for products at an earlier stage of development and more specific language for products at a later development stage. To ensure licensees fulfill reasonable pricing requirements, NIH-approved access plans should include tangible commitments that can be readily and quantitatively measured by the agency, including commitments to not raise costs above inflation or cost-plus purchasing agreements with the US government or other

[1] Assistant Secretary for Public Affairs (ASPA), "HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies," Text, September 8, 2023, https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-monoclonal-antibodies.html.
[2] "Senate HELP Committee Release Staff Bipartisan Discussion Draft Legislation to Reauthorize the Pandemic and All-Hazards Preparedness Act » Senator Bernie Sanders," *Senator Bernie Sanders* (blog), accessed July 20, 2024, https://www.sanders.senate.gov/press-releases/news-senate-help-committee-release-staff-bipartisan-discussion-draft-legislation-to-reauthorize-the-pandemic-and-all-hazards-preparedness-act/.
[3] "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," November 15, 2021, www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.
[4] Ameet Sarpatwari, Alison K. LaPidus, and Aaron S. Kesselheim, "Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support," *Annals of Internal Medicine* 172, no. 5 (March 3, 2020): 348–50, https://doi.org/10.7326/M19-2576.

NIH-designated entities. These strategies would increase the likelihood that the benefits of NIH breakthroughs are accessible to a broad set of patients.

Providing flexibility while achieving clear policy objectives.

Access plans should provide clear and specific commitments from companies that benefit from NIH-funded research to prioritize taxpayers' access to the products. Given the public nature of the investment, the NIH should ensure that access plans proposed by pharmaceutical companies are made publicly available. We understand that companies might be worried that public disclosure of the access plans could reveal strategic or proprietary information relating to the development of the drug. However, the scope of access plans should not need to provide any proprietary information as to the development of the drug but rather describe policies such as approaches to fair pricing strategies that companies plan to take. The current draft does not require companies to disclose information other than a brief description of the licensed product; the anticipated patient population; other products, tools, facilities, or resources that would be necessary for the use of the licensed products; and one or more strategies to mitigate access challenges. None of these should invoke proprietary information.

Establishing licensee obligations depending on the stage of technology development.

The tiered approach proposed in the initial draft would provide reasonable flexibility to pharmaceutical companies in drafting the access plan according to the stage of development of the licensed product. We appreciate the need for flexibility for early-stage licenses, on which pharmaceutical companies may still need to make a substantial investment. The NIH should further consider other potentially relevant elements when evaluating access plans, such as the type and quality of patents licensed or whether the license is exclusive or non-exclusive.

While drugs typically start with a key patent on the active ingredient (a so-called "primary" patent), successful drug products usually end up being covered by many more—in some cases dozens or even over a hundred—patents covering other aspects of the drug, including secondary features such as metabolites, alternate formulations, or methods of manufacture or use ("secondary" patents). A recent study showed that many secondary patents are obtained even after initial FDA approval of the drug.[5] In evaluating access plans, the NIH should consider whether the licensed patent is the primary patent covering the drug's active ingredient or whether it covers ancillary features.

The NIH should also consider whether the license is exclusive or non-exclusive. If the patent has been licensed exclusively to a company, the NIH should allow less flexibility, given the impossibility of other companies to obtain a license. For example, access plans for NIH technologies licensed

[5] Caroline Horrow et al., "Patent Portfolios Protecting 10 Top-Selling Prescription Drugs," *JAMA Internal Medicine* 184, no. 7 (July 1, 2024): 810, https://doi.org/10.1001/jamainternmed.2024.0836.

exclusively could include commitments to sublicense the technology to other companies in situations of great public need, such as public health emergencies or in times of shortage.

Assessing policy impact.

The NIH already employs rigorous monitoring standards for research institutions that receive funding.[6] These standards include, for example, the submission of progress reports describing accomplishments toward the goal of the project and the description of challenges in achieving the goal. Similarly, companies that obtain NIH licenses should submit annual reports explaining how the policies described in their access plan have been practically implemented, whether any challenges have arisen in implementing the policies, or if different policies would be best suited to increase access. NIH should make summaries of these annual reports publicly available to provide stakeholders adequate insight into licensee progress. Metrics on the total number of licenses and licensees with agreed-to access plans, the development stage of the underlying technology (e.g., early or late-stage), the number of licenses with access plans in force or withdrawn, and other details should be incorporated into preexisting NIH technology transfer reporting.

To further enhance licensee accountability, all policies proposed in access plans should include concrete time horizons within which the licensee is expected to meet its access commitments, with the opportunity for revisions as the technology moves through clinical development. Systematic monitoring of access plans would allow the plans to be adapted and updated as necessary once the product is launched on the market.

[6] NIH, "Post-Award Monitoring and Reporting," accessed July 18, 2024, https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm.