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Dear Dr. Tabak and Ms. Rives,

**Comment on NIH Proposed Rule for Increasing Access to NIH-Owned Innovations**

Universities Allied for Essential Medicines (UAEM) appreciates the opportunity to comment on the National Institutes of Health (NIH) proposed rule aimed at increasing access to NIH-owned innovations. As an advocacy organization dedicated to promoting access to medicines and medical innovations, we believe that our perspectives and recommendations will contribute significantly to the refinement and success of this policy. Below, we present our detailed comments and suggestions.

**Introduction**

UAEM is a student-driven organization that works to change norms and practices in academic patenting and licensing, empowering students to advocate for a biomedical research and development system that benefits all. Since our founding in 2001, we have grown into a global network of more than 100 student chapters in 20 countries. Our mission is to ensure that health products developed in university labs with public funding are accessible to the people who need them. We have a longstanding commitment to adding affordability provisions within university licenses for inventions developed with public funding, as demonstrated through our policy

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vehicles, the Equitable Technology Access Framework (ETAF)\(^1\) and the Affordable Access Plan (AAP).\(^2\)

Before diving into the proposals as outlined in the Request for Input and model policy, UAEM offers the following general comments on the agency's licensing approach. Transparency in licensing processes would help foster greater accountability and public trust, and allow for monitoring of the use and uptake of access plans as proposed. Key areas to address in transparency include:

1. **Application Disclosure**: Disclose the number of companies applying for each license to provide insight into the agency's leverage and decision-making process.
2. **Rationale for Exclusivity**: Publish detailed justifications for granting exclusive licenses, as required by statute, to promote innovation only when necessary and reasonable bring attention to the need for the agency to improve transparency around licenses granted by the agency.

**Proposal 1: Promoting Meaningful Access Approaches**

The draft policy's initial agreement terms for access planning are intentionally flexible and non-prescriptive, which has a risk of resulting in vague commitments and a lack of concrete action. This lack of specificity might hinder the establishment of clear guidelines and expectations for stakeholders, potentially undermining the policy's effectiveness in ensuring access.

The policy highlights that access obligations should not hinder commercial development. This approach aims to maintain a balance between innovation and financial viability but might inadvertently place commercial interests above equitable access to medications, potentially compromising the policy's goals. To address pricing and affordability, we propose following a formula. For instance, looking at the median price in the seven largest economies that have at least 50% of the U.S. population as a ceiling on U.S. pricing. Alternatively or in addition, a target total revenue should be set for products; if exceeded, measures such as reducing exclusivity periods, or extending a royalty-free license to generic manufacturers could be permitted.

We recommend the agency incorporate a pricing or affordability review standard into the guidance, ensuring that medication costs do not impede patient access to necessary

\(^1\) Available on our website at [https://www.uaem.org/tools/efat](https://www.uaem.org/tools/efat).

treatments. Including a detailed plan for pricing, similar to the aforementioned formula, could provide clearer guidelines and improve affordability.

While the policy indicates that additional guidance will be provided, it currently lacks specific examples and strategies for promoting access, which leaves licensees without clear directives. Incorporating examples from various industry partners, both internal and external, could offer practical insights and clearer implementation paths, thereby enhancing the policy’s effectiveness. Moreover, the policy should include plans for different aspects of access, such as supply chains and pricing, to provide comprehensive and actionable guidance. We recommend holding a public comment period to gather more examples for use.

The annual review and modification process outlined in the policy might not be frequent or rigorous enough to ensure continuous compliance and adaptation to emerging access issues. To improve this, it is suggested to include, at a minimum, a public comment period in these reviews, allowing civil society to raise concerns and propose improvements, thus fostering a more transparent and responsive policy framework. However, we would recommend instead convening an advisory board to provide perspective and seek comments where needed on access plans that are proposed. Additionally, for Lower-and Middle-Income Countries, the policy should include specific requirements to ensure access and affordability.

We suggest that the NIH take the following approaches to ensure meaningful action:

1. Define Access: Break down the term "access" into specific components such as supply chain issues, shortages, and pricing. Create detailed plans for each aspect to ensure a comprehensive approach.
   a. These issues have slightly different solutions in the known literature.

2. Set Pricing Standards: Implement a pricing/affordability review standard. For instance, use the median price in the seven largest economies that have at least 50% of the U.S. population as a ceiling for U.S. pricing.
   a. We have additionally joined a letter with Public Citizen and other members of Civil Society that include further language on pricing standards.

3. Institute an Advisory Board:
   a. At a minimum, the NIH should include a public comment period in the annual review process to allow civil society to raise issues and propose improvements.
   b. However, comment periods have downsides (pull example).
   c. We suggest implementing an advisory committee to help assess annual affordable access plans and provide expert guidance. One possible structure of the advisory board would be to mimic the structure of state Prescription Drug
Affordability Boards. This structure includes appointed board members who do not work directly for a licensee, or recuse themselves in the case that they have a conflict of interest. The board members should have relevant expert experience, in the Michigan legislature, proposed legislative language for a PDAB describes those members as "The board consists of 5 members, appointed by the governor 11 with the advice and consent of the senate. The members of the board 12 must include individuals who have expertise in health care 13 economics, health policy, health equity, and clinical medicine."3

4. Create Clear Guidance and Examples: We recommend the agency provide specific examples and strategies for promoting access, drawn from various industry partners, to offer practical insights to licensees. We suggest the agency bring forward a future Request for Input on examples and strategies for access licenses. We have included in our comment an appendix with suggested language and table of model licenses.

5. Separate Criteria for LMICs: Clearly distinguish access requirements between domestic (US) and LMIC contexts to ensure both are adequately addressed.
6. Resource-Limited Settings: Include specific strategies for adapting innovations to resource-limited settings to ensure they are accessible and affordable. This may include requirements or incentives for heat-stable formulations, access provisions around materials and distribution, or licensing terms to rein in costs.

Proposal 2: Promoting Transparency in the Biomedical Research Enterprise and Return on Investment

The current policy proposes several mechanisms to improve transparency, primarily through mandatory disclosure of specific information to the NIH upon request. However, the absence of a requirement for public disclosure of detailed cost breakdowns and financial data poses significant limitations, particularly concerning transparency for end-users. This deficiency impedes comprehensive assessment of the true economic impact and return on investments derived from NIH-funded research. The NIH should seek transparency at the full limit of statutory authority. Additionally, the policy must specify penalties for non-compliance in reporting, including the withholding of future funds from the agency licensing the technology, denied eligibility to receive future licenses, or a royalty-based penalty.

Traditionally, government licensed technologies will have a lower royalty rate, around 4.0%, than their corporate counterpart licenses, which average closer to 8.0%. The NIH could consider reverting to a higher licensing royalty rate in the case that a licensee fails to comply with the

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access planning provisions in this rule, or with transparency requirements.

We recommend that the NIH establish a publicly accessible return on investment dashboard to systematically track and evaluate the efficacy of access to biomedical innovations over time, relative to the NIH’s research investment. This dashboard would provide stakeholders with critical insights into the societal benefits and cost-effectiveness of NIH-funded research.

Furthermore, including per-clinical trial cost information is crucial to enhancing transparency regarding research expenditures and enabling more informed decision-making. These measures collectively aim to strengthen accountability, transparency, and public trust in the NIH’s stewardship of biomedical research funding, thereby optimizing the impact of taxpayer dollars in advancing public health and scientific knowledge.

Transparency is crucial for public trust and accountability. We recommend:

1. **Public Disclosure**: Require public disclosure of detailed cost breakdowns and financial data to assess the true economic impact and return on investments. Include a penalty for that disclosure.
2. Return on Investment Dashboard: The NIH should develop a publicly accessible dashboard to track the efficacy of access over time compared to the cost of NIH’s research investment. It should include digestible metrics, and a simple report out. The U.S. Food and Drug Administration created a dashboard to track compliance with clinical trial reporting requirements, and a similar format would provide clear, comprehensive information to the public about return on investment from NIH-licensed technologies. This could be done retroactively to show the impact of technologies licensed to date.
3. Community Outreach: Partner with civil society organizations to implement community outreach and transparency initiatives.

**Proposal 3: Providing Flexibility While Achieving Clear Policy Objectives**

We commend NIH’s commitment to balancing the need for flexibility in product development and commercialization with the imperative for transparency in policy enforcement through “Providing Flexibility While Achieving Clear Policy Objectives,” so long as the balance of flexibilities are clearly defined and prioritize the public interest. Below are detailed comments and suggestions aimed at enhancing the clarity and effectiveness of this draft policy. The current draft policy lacks specificity regarding the scope of the "standards". It is essential to

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4 See, for example U.S. FDA Pre-Notices for Potential Noncompliance, available at https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/pre-notices-potential-noncompliance
clearly delineate which components of these standards will be subject to flexibility and under what criteria. Specifically, a detailed clarification is needed on which components are subject to flexibility and the criteria for such flexibility. The agency should specify the extent and boundaries of the said flexibility to ensure that the goal of the policy's core objectives are not compromised.

A transparent set of guidelines allowing all stakeholders to understand the basis for granting flexibility, and a structured process for licensees to request flexibility in policy implementation is crucial.

To maintain the integrity of the policy while allowing for flexibility, robust monitoring and enforcement mechanisms are necessary to monitor licensee compliance with the policy's standards and the conditions of any granted flexibility, assess the impact of flexibility on equitable access and transparency goals, making adjustments as necessary to uphold these core objectives. While narrowly targeted products might warrant exceptions, exceptions should not be based on orphan drug status alone, as orphan drug status has been repeatedly used to extend monopolies and keep prices high.⁵

To help allow flexibility and ensure efficacy, the agency could introduce a default access plan in its policy. This plan would take effect if a licensee wishes not to create their own plan, or fails to submit a satisfactory plan through the processes outlined by the agency. This would ensure some form of access planning takes place, even in the worst case scenario.

The policy should balance flexibility with clear objectives to avoid compromising core goals. We suggest:

1. **Structured Flexibility Request System**: Establish a transparent and structured process for licensees to request flexibility, ensuring alignment with policy goals and including public feedback.

2. **Stage-Specific Guidelines**: Develop comprehensive, stage-specific guidelines outlining mandatory obligations for licensees at each phase of technology development.

3. **Default Access Plans**: Introduce a default access plan that NIH can enforce if licensees fail to submit satisfactory plans.

Proposal 4: Helping Licensees Achieve Access Goals

Much like our own university-specific Affordable Access Plan language, the draft policy does not provide detailed or specific support mechanisms for licensees to overcome access challenges, leaving them to navigate complex issues independently. Without such mechanisms, licensees might struggle to address key access issues like supply chain disruptions, pricing, and distribution effectively. The agency should develop a menu of recommendations including guidelines, best practices, and case studies to help licensees develop comprehensive access strategies. If resources are made available, the agency could establish a dedicated support team to assist licensees in overcoming specific access challenges, ensuring they are not left to handle these issues alone.

The draft policy allows for licensees to request waivers or modifications to access planning provisions, but it does not outline clear criteria or a transparent process for these requests, potentially leading to inconsistent support. The absence of a well-defined process could result in arbitrary decisions, causing confusion and uncertainty among licensees. Specifically, the policy stipulates that a "maximum of one meeting" will be held with licensees about access planning. We firmly believe this should be turned into a minimum, unless a waiver is granted.

The waiver policy should additionally establish clear criteria for waiver and modification requests, including specific conditions under which they can be granted. Furthermore, a transparent review process should be implemented, involving public disclosure of decisions and the rationale behind them. A public comment period would also be preferred before any waiver is granted so that patients, providers, insurers, and other stakeholders can voice concerns over access planning waivers whenever those concerns may exist. This approach would ensure consistency, fairness, and accountability, providing licensees with a clearer understanding of their options and the steps they need to take to secure necessary modifications.

The draft policy’s tiered approach provides more specific provisions for late-stage inventions, potentially neglecting early-stage inventions that could benefit from early access planning and support. This oversight might prevent early-stage innovations from reaching their full potential in terms of accessibility and impact. To mitigate this, the policy should include specific clauses for early-stage inventions, drawing from successful licensing models. We have included below a table and other resources outlining model licenses for early stage inventions at 10 universities across the United States as examples that could be pulled from, originally documented in a white paper released earlier this year.6

6 Tess McMullin, Robert Hunter, Nicholas Merrill. (2024). Early Action for Equitable Access: Protecting Access to Medicine in University Licensing. iPIP and UAEM. Available at:
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<th>University</th>
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Model Licenses
For each license, the following information is provided:

**Background Information**
- The location of the university
- Amount of federal funding received in 2023
- Whether the university is private or public.\(^7\)

**Bayh-Dole Requirements**
- **Objective:** If the licensing agreement commits to the objective of Bayh-Dole: “to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions...and protect the public against nonuse or unreasonable use of inventions.”\(^8\)
- Federal License: If the agreement acknowledges the Federal agency’s right to a nonexclusive, non transferable, irrevocable, paid-up license.\(^9\)
- Progress Reporting Requirement: The frequency of licensees reporting commercialization progress to the university required.
- Small Business Preference: If the agreement acknowledges Bayh-Dole’s preference for licensees to be a small business.\(^10\)
- U.S. Manufacturing Preference: If the agreement acknowledges the requirement for the licensee to make reasonable efforts to manufacture the medical technology to be substantially in the United States.\(^11\)

**Socially Responsible Licensing Provisions**

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\(^7\) The private status of a university impacts its obligations under FOIA and state FOI laws, as discussed in Section 3.

\(^8\) 35 U.S.C § 200.


\(^10\) Id.

\(^11\) 35 U.S.C § 204.
- Affordable Access Plan: If the agreement incorporates any type of plan for the equitable distribution of the licensed technology in Low-and-Middle-Income Countries ("LMICs"), as identified by the World Bank.
- Non-Suit Provision: Whether the PFRI maintains a right to decline pursuing a patent infringement action against any third party engaged in the manufacture, sale, or importation of the licensed technology in LMICs.
Table A2. Comparison of University Model Licenses

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<td>Yes (General Terms)</td>
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12 UCLA has not published a model license, but has released its Affordable Access Provision, which states in relevant part: "As part of its public mission to bring products to the marketplace, UCLA strives to enable underserved populations, which have limited access to adequate quantities of medical innovations arising from UCLA’s laboratories, to have access to these innovative products. Licensees are encouraged to consider these populations’ interests when marketing and selling Licensed Products." “UCLA Considers Underserved Populations When Licensing Medical Research Discoveries,” UCLA Technology Development Group (Link).
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We further recommend the agency consider direct support that can be offered to licensees in the form of grants, partnerships with trusted organizations, or just staff support from the agency to assist in licensing goals. By offering these forms of support, the policy can empower licensees to develop and execute more robust and effective access strategies, ultimately enhancing the accessibility of their innovations.

We further recommend setting clear metrics and benchmarks for assessing the success of access plans, making it difficult for licensees to gauge their progress and identify areas for improvement. Without measurable standards, it is challenging to ensure that access plans are effective and aligned with policy goals. To address this, the NIH should launch an additional Request for Proposals (RFP) to determine appropriate benchmarks for success. This RFP could invite experts and stakeholders to propose metrics and evaluation frameworks, ensuring a comprehensive and informed approach. Clear benchmarks would enable licensees to monitor their progress, identify shortcomings, and make necessary adjustments, fostering continuous improvement in access planning and implementation.

To support licensees in overcoming access challenges, we propose:

1. **Support Mechanisms**: Provide detailed guidelines, best practices, and case studies to help licensees develop comprehensive access strategies.
2. **Early Stage Licensing Examples and materials**: Provide guidance for early stage technologies that are as robust as late-stage.
3. **Direct Assistance Programs and Incentives**: Establish funding, partnerships, and resources to assist licensees in implementing effective access strategies.
4. **Clear Metrics and Benchmarks**: Launch an additional Request for Proposals (RFP) to determine appropriate benchmarks for success.

**Proposal 5: Establishing Licensee Obligations Depending on the Stage of Technology Development**

Despite efforts by the agency to establish clear licensee obligations tailored to different stages of technology development in the biomedical sector within the access policy, significant ambiguities persist, especially concerning obligations after Phase III clinical trials. The agency should define requirements for "tailored" access provisions for products in advanced development stages. The policy should outline mechanisms to adapt these provisions to
dynamic market changes, potentially compromising long-term product accessibility. For example, in the case that an access plan is viable when submitted, but then a major change in supply chain renders the price unsustainable, or other aspects of the plan unworkable, there should be guidance published on how to make a clear modification.

We suggest the agency should develop comprehensive, stage-specific guidelines outlining mandatory obligations for licensees at each phase of technology development, from preclinical stages through to market entry. These guidelines would serve to clarify and enforce licensee responsibilities, ensuring consistent and equitable access to biomedical innovations throughout their lifecycle. While concerns about potential bureaucratic delays due to stage-specific requirements may arise, an alternative approach could be to frame per-stage access mandates as a leverage point in the NIH review process rather than as strict obligations.

Establishing a chain obligation framework that mandates the transfer of access commitments across licensees is crucial to maintaining continuity in accessibility as technologies progress through regulatory approval and beyond. This framework would promote sustainability and fairness in access provisions, aligning with evolving legal standards and industry practices in the United States. An important addition that must be included is “Reach Through” clauses, which guarantee that any future uses of transferred technologies are bound by the same access protections stipulated in the initial transfer agreements. By integrating these recommendations, the NIH can ensure transparency across the biomedical sector, while enhancing accountability and public trust in the licensing process, and maximizing the societal benefits derived from NIH-funded biomedical research and innovation.

To ensure clarity and consistency, we recommend:

1. **Stage-Specific Obligations**: Develop clear, mandatory obligations for licensees at each development stage, ensuring continuous and equitable access.
2. **Chain Obligations**: Implement "Reach Through" clauses to ensure access commitments are transferred across licensees, maintaining continuity in accessibility.
Proposal 6: Assessing Policy Impact

It is essential to delineate clear categories for "standards" to provide a baseline for evaluating compliance with the new policy. The agency must develop detailed guidelines and procedures for compliance, ensuring clarity and uniformity in implementation of access policies is fundamental. We recommend regular reviews to monitor compliance with access plans and identify areas for improvement as well as a reporting mechanism to indicate when a licensee does not appear to be compliant with their plan. Further, enforcement mechanisms to address non-compliance should include penalties and corrective actions, including some that have been previously discussed in this comment letter.

In terms of compliance, the agency's licensing template could include a recurrent mandatory survey for a broad range of licensees about their access plan and process, and the agency could use the results to assess the need for further action.

It is essential that the agency establish a comprehensive and detailed system to ensure that outputs genuinely benefit the public interest. Without mechanisms for feedback, reporting, and compliance with access plans, licensees may be incentivized to de-prioritize following their access plans as submitted.

Effective assessment of the policy's impact requires clear standards and compliance strategies. We suggest:

1. **Categorization of Standards:** Establish clear categories for standards to provide a baseline for evaluating compliance.
2. **Enforcement Mechanisms:** Implement penalties and corrective actions for non-compliance. Allow for reporting of potentially non-compliant licensees.
3. **Impact Metrics and Reporting:** Use a mandatory reporting requirement to assess compliance with access plans, and ask for input where needed from experts.

**Conclusion**

We commend the NIH for its efforts to enhance access to NIH-owned innovations and welcome the opportunity to contribute feedback on this critical initiative. By incorporating specific guidelines for access planning, enforcing affordability measures, providing clear criteria for
flexibility, and establishing robust support mechanisms for licensees, the policy can ensure that NIH-funded inventions truly benefit the public. Additionally, the inclusion of transparent processes for waiver requests, detailed metrics for success, and mechanisms for regular feedback and compliance monitoring will strengthen the policy’s effectiveness and ensure continuous improvement. UAEM is eager to collaborate with the NIH and other stakeholders to refine these proposals and build a more equitable and accessible biomedical innovation ecosystem.

Thank you for considering our comments.

Sincerely,

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