Response to Request for Information - Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

Introduction

We welcome the NIH proposal to develop and implement a new policy to promote access to products arising from publicly funded inventions. Our comments below build on previous input that we have provided to NIH, and seek to provide NIH with further insights on approaches for facilitating access from a global perspective.

We understand the challenges faced by NIH in identifying and attracting suitable licensees to undertake development of NIH inventions in ways that the benefits are made accessible to the global public. We believe that including requirements to develop and implement access plans for licensed products under license agreements for early-stage medical technologies can facilitate the achievement of this goal. Planning for access early in the innovation timeline supports the timely consideration of ways to address potential access barriers for an end product, and the development and implementation of solutions to those challenges.

Broader recent recognition of the importance of early access planning is evidenced through the increasing number of prominent research universities and institutions such as UCLA, University of California Berkeley, the Innovative Genomics Institute, and Columbia University including such considerations in their own license agreements and socially responsible licensing policies. In addition to the benefits for global public health, access-oriented licensing has also been demonstrated to provide benefits to industry partners, including additional revenue streams.

Scope of the access plan requirement

Attaching the obligation to the licensed product helps avoid the problems of focusing too narrowly on a single patent.

We support the attachment of the access plan to the "Licensed Product(s)", rather than only to the licensed patent rights. Developments across different types of health technologies are increasingly complex, and the patent rights under a license from NIH may be only one small part of the finished, commercialized product. The commercialized product may utilize other third party patents and/or, as is increasingly the case, depend upon the innovator's proprietary intellectual property, such as manufacturing know-how. A requirement to develop an access strategy for the "Licensed Product(s)" therefore helps to ensure that access is achieved no matter how the NIH patent rights are utilized in the invention at issue.

The Access Plan should address global public health needs.

We note that the proposed definition of "Access Plan" for model license agreements references a strategy to support access for: (i) the U.S. population including underserved communities; **and/or** (ii) populations in low- and middle-income countries (LMICs). We believe that the starting point for all access plans should be to consider **global** access needs, including underserved communities in the U.S. as well as underserved populations around the world.

As it currently stands, the "and/or" language opens a possibility for licensees to choose to address access needs only for the U.S. population even where there is demonstrable need in LMICs, or vice versa, without having to justify that choice. Such an outcome would threaten to undermine NIH's stated goal of "transforming knowledge into improved health **for all".**

If the intention of the "and/or" wording was to allow for scenarios where a particular technology may be important for a disease field that is only prevalent in one region (*e.g.* ebola), NIH could include clarifying language to this effect. For example, NIH could (1) eliminate the "or" of the "and/or", and (2) specify that a modification or waiver of the access plan obligation may be granted where there is no demonstrable public health need in one of the two referenced populations.

NIH should establish a set of criteria against which waiver requests will be assessed.

The current proposal for access plan obligations does not establish any parameters for the evaluation of access plan waiver and modification requests from licensees. We encourage NIH to specify a structured and transparent process through which licensees may present cases for waivers or modifications. Such requests should be reviewed against clear criteria including assessment of the quality of evidence demonstrating a limited public health need for a licensed product. NIH may wish to consider obtaining input from independent, external experts as a part of the review process.

The importance of a flexible approach to access requirements

We applaud the proposal's recognition of the need for a tiered approach to access requirements in NIH licenses that considers different approaches for different stages of development. For early-stage technologies, the open and non prescriptive nature of the access plan obligation is a logical baseline requirement that may facilitate access to downstream licensed products without limiting NIH's ability to attract suitable development partners.

However, there is a broad range of more prescriptive access-related provisions that NIH could consider for inclusion in license agreements for which NIH has leverage to include more prescriptive access conditions. In addition to later-stage inventions (*e.g.*, taken to Phase II or III clinical trials by NIH), additional leverage may exist where the licensed technology is itself a stand-alone product (*e.g.,* a molecule), is commercially attractive to potential developers, and is of significant public health value in LMICs. More stringent access obligations should be tailored to the context of a specific license, considering factors such as the technology and public health

needs. We have provided some examples of some of the types of clauses that may be relevant in the attached Appendix.

Enforcement of access requirements

We note that the proposal does not specify how the access plan language will be incorporated into NIH's current license agreement templates, including how it will interact with performance requirements. In particular, there is no statement regarding the consequences of a licensee's failure to submit a satisfactory access plan and/or to make reasonable progress against a plan.

For licenses of early-stage inventions, safeguards against a licensee's failure to meet its access obligations are likely to align with existing NIH policies and practices including the grant of non-exclusive licenses wherever possible, carve outs in an exclusive license for certain territories and/or fields, and an extension of the rights under exclusive license to require sublicensing to third parties "when the public health and safety so require." We recognize, however, that while these approaches allow alternative licensees to use the licensed patent rights, they would not provide access to the foreground intellectual property that may have been developed by the initial licensee to manufacture a licensed product, and that this could result in delayed access for underserved populations while an alternative licensee develops a new product.

However, as noted in the section above there are some scenarios that may provide NIH with greater leverage to introduce additional obligations to reduce the risk of patients being left without access in the event of a licensee's failure to implement its access plan. For example, some global health R&D funders include an "access license" in their agreements with product developers, which provide the funder with sufficient rights to continue development of a funded product with a new partner that is capable of fulfilling access requirements.

Implementation of the access plan requirement

NIH should select licensees that demonstrate willingness and capacity to follow through on access commitments

As part of its due diligence process for prospective licensees, NIH should ask potential licensees to submit information demonstrating a commitment to access, including an initial outline of strategies that the licensee might use to facilitate access to licensed products and overcome potential barriers. This approach would support the NIH in the selection of licensees that are most likely to achieve the NIH's access goals both within the U.S. and for LMIC populations.

NIH should publish a comprehensive access plan guidance document

NIH can support aligned expectations on the goal and underlying concepts of access through the publication of a comprehensive guidance document that can be easily accessed on the NIH website (as NIH similarly does with its resources for the public access policy), and is prominently referenced in all license opportunities advertised by NIH and applications for NIH licenses. The guidance document should provide clear definitions of what is meant by "access" and the factors that can affect access in different contexts (*e.g.*, product type or therapeutic area), as well as examples of successful access interventions across a range of contexts.The more detailed the guidance document, the less daunting the process should be for a licensee. Examples of guidance documents published by other major R&D organizations are available on GHIAA's MAPGuide Platform.

NIH should harness the expertise of implementing partners and expert advisors to achieve NIH's access objectives

In addition to a guidance document, NIH should take an intentional role in connecting licensees to stakeholders with expertise in access to health technologies. Such support could begin with a pool of expert advisors that can be contacted for guidance on the development, implementation and periodic update of an access plan, starting from the grant of or even application for an NIH license. This expert advice is likely to be particularly valuable to smaller organizations that may have limited in-house capacity for, and prior experience with, access planning.

Expert advice for access planning could be supplemented by introductions to potential implementing partners with relevant global health expertise as a licensed product approaches pivotal clinical trial stage. This is similar to an approach already being applied in UC Berkeley's license agreements through a right to include a "designated entity" in discussions related to Affordable Access Plans. For early-stage technologies, the non-prescriptive nature of the NIH policy can potentially be counterbalanced by specific, concrete, and binding plans entered into between licensees and such designated entities or implementing partners that can be introduced by NIH.
NIH should therefore build and leverage existing relationships with a range of implementing partners including voluntary licensing partners such as MPP, as well as product development partnerships, funders, procurement agencies, governments and regional intergovernmental bodies. Timely introductions to such stakeholders and encouraging collaborations between the broad range of organizations involved in facilitating access could prove to be a critical enabler for successful outcomes.

Ongoing review and good faith discussion of access plans

We note that the proposal limits NIH's role in monitoring progress on the implementation of the access plan to no more than once per year. We believe that more active and frequent access

plan review and progress monitoring, beginning with a good faith discussion upon initial submission of the plan, would better facilitate timely identification of potential gaps in an access plan and/or challenges to effective implementation. This approach would also provide NIH with the opportunity to offer additional assistance or advice to licensees if necessary, for example through introductions to implementing partners as discussed above. We therefore recommend that NIH: (1) remove the cap on once yearly meetings; and (2) make reporting on access plan progress a standard component of licensee progress reporting.

We recognize the resource burden and expertise requirements associated with more frequent progress review, and propose that NIH establish a panel of independent external experts to support access plan review and monitoring activities. This approach would be similar to the "access committees" established by other major global health R&D organizations such as CEPI and DNDi to monitor and advise on access objectives.

Transparency

Given the role of public funds in supporting intramural research, the variety of stakeholders both in the U.S. and around the world that would be deeply impacted by the implementation of the access plans, and the potential benefits of public feedback on access plans, transparency of access plans and progress on their implementation should be a matter of standard practice. A transparent approach would be consistent with, and could potentially be integrated into, the resources that NIH already maintains to share information with the public such as RePORT.

We note that the proposal does specify that licensees must provide a non-confidential version of its Access Plan that NIH can "publish or otherwise share with third parties". We encourage NIH to establish criteria for assessing information that may be considered proprietary and confidential and that which should be made available to the public to support transparency and accountability. These criteria could be included in the access plan guidance document discussed above.

To the extent it is helpful to consider, MPP's approach to transparency is documented in its Transparency Policy, which commits the organization to the "broadest possible disclosure of records possible" while acknowledging legitimate rights to "privacy, property rights of persons to trade secrets and confidential or commercial business information, and the need for MPP to promote frank internal deliberations." The broad commitment to transparency is grounded in MPP's mandate as a public-health organization, as well as the "public health issues at stake and the widespread public interest in its work," while providing narrow exceptions including the "legitimate interests" of MPP's partners. Even where there is legitimately confidential information, the Transparency Policy commits MPP to redacting such information in such a way that the disclosable information can be released.

Taking a minimalist approach to determining what is truly confidential has supported MPP in publishing all of its agreements with minimal redactions, furthering the impact of the

organization's work with a broad array of stakeholders around the world while remaining amenable to its industry partners. We encourage NIH to take a similar approach.

Next Steps

We congratulate NIH on the development of the proposed policy on "Promoting Equity Through Access Planning" which represents a significant step towards expanded access to healthcare technologies arising from NIH research. We encourage consideration of the opportunities to maximize global impact outlined above, as well as expansion of access-oriented objectives to other NIH policies, including those pertaining to extramural research. GHIAA and MPP remain available to provide practical and pragmatic perspectives to NIH as it moves forward with this important policy.

About the Authors

The Global Healthcare Innovation Alliance Accelerator (GHIAA) is a 501c3 non-profit organization that creates resources, curates information, collaborates with stakeholders and provides consulting support related to policies and agreement provisions that aim to achieve equitable, global access to medical products.
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The Medicines Patent Pool (MPP) is a Geneva-based, United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries (LMICs). Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.
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Appendix - examples of clauses supporting aspects of access

- **Affordability**
  - A maximum profit margin on a cost of goods that is subject to audit (see GARDP – Orchid, Cefiderocol Manufacturing Sublicense and Technology Transfer Agreement)
  - Implementing actions to reduce cost of goods without negatively impacting quality (also see GARDP-Orchid agreement)
  - A commitment to achieving the lowest, sustainable competitive price for the Licensed Product (see Pfizer – MPP, TB Therapeutic (Sutezolid) Non-Exclusive License Agreement)
- **Availability**
  - Commercially reasonable efforts to make timely and sufficient supplies of the licensed product to public sector purchasers (see PATH – Aridis, Rotavirus Vaccine Development Agreement)
  - A commitment to obtain relevant regulatory approvals, including WHO Prequalification, and to register the licensed product in the relevant markets in a timely manner (see Gates Foundation - Novavax, RSV Vaccine Global Access Commitments Agreement)
- **Appropriateness & adoption**
  - Agreement to develop the licensed product in accordance with a Target Product Profile (TPP) (see Entasis – DNDi/GARDP, Gonorrhoea Medication, Collaboration Agreement)
  - Commitment to undertake educational activities to encourage appropriate uptake of the product (see AXA Prime Impact Master Fund – Revelation Biosciences, Diagnostics & Therapeutics for Viral Infections, Global Health Agreement).
- **Management of intellectual property rights**
  - Commitments for sublicensing and technology transfer to alternative manufacturers to address affordability and availability requirements for all populations that have a need for the licensed product (see PHS – Aridis, Rotavirus Vaccine Exclusive and Non-Exclusive License Agreement)
  - Grantbacks of improvements on the licensed technology to the NIH (see Merck – MPP, Molnupiravir License Agreement)

Further details on the above commitments as well as other access-related agreement provisions including access to data and results, quality management and conduct of clinical trials are available from the issue summaries in the GHIAA MAPGuide.