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

Dear Dr. Tabak and Ms. Rives:

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a 50-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

We write this submission in response to the Request for Information (RFI) by the National Institutes of Health (NIH) regarding NIH's proposal to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer-funded inventions.

We commend this significant step to advance global access to medicines developed with the technologies owned by NIH and the public. Access provisions can advance global health equity while balancing commercial concerns; NIH can preserve reasonable income streams in high-income markets while ensuring companies do not unjustly deprive communities in low- and middle-income countries (LMICs) of medicines developed using publicly owned technology.

Recommendations for All NIH-Licensed Technologies (*see RFI Issue 1 and 3*)

First, we recommend changes to NIH's proposed policy that should apply to all licensed technologies. Most critically, we recommend that all licensing agreements include conditions for advancing equitable access, which are appropriate regardless of a licensed technology's stage. However, if NIH adopts the access planning approach, which has been drafted as an obligation

to formulate an “Access Plan” when licensed products are within three months of the first pivotal clinical trial, we provide specific modifications that are key to ensuring efficacy of the draft policy.

We then recommend critical practices for ensuring oversight, accountability, and transparency of access obligations in all NIH licensing agreements. Next, we strongly urge NIH to include provisions to ensure access obligations survive the transfer of NIH technology to new parties. Finally, we request that NIH clarify the scope of the policy with respect to third-party intellectual property (IP) rights, which are often vital to ensuring global access to medicines and urge NIH to prioritize nonexclusive licensing in all agreements.

Our recommendations are summarized below:

1. A fair pricing standard for U.S. residents and conditions for global access in all licensing agreements are preferable to Access Plans, which should, at the very least, have specific milestones for achieving access objectives.
2. If NIH adopts the use of Access Plans, which are less desirable, the agency should:
 - a. ensure that Access Plans address the needs of both underserved communities in the United States and populations in LMICs;
 - b. review Access Plans to confirm they meaningfully advance access objectives;
 - c. limit waivers and modifications of Access Plans to preserve the policy’s efficacy; and
 - d. require licensees to formulate Access Plans concurrently with the licensing of technology, as delayed consideration of access objectives has been ineffective.
3. All licensing agreements should proactively define affordability (for access in LMICs) as the sustainable cost of production plus a reasonable profit margin.
4. Licensing of all NIH technologies should include substantive oversight and accountability provisions to ensure licensees fulfill access obligations.
5. To maintain stakeholder support, NIH must provide transparency of licensing agreements, associated access conditions or Access Plans, and licensing opportunities to supply LMICs.
6. NIH should ensure that access obligations survive the transfer of licensed technology to new parties, which will be important as early-stage NIH inventions change ownership as they advance to later stages of development.
7. The scope of the policy with respect to third-party IP rights should be clarified, as these rights are implicated in key access strategies, such as technology transfer activities.
8. Nonexclusive licensing is preferred for the development and commercialization of all NIH technologies.

Recommendations for Licensing of Later-Stage Inventions (*see* RFI Issue 1 and 5)

Second, we draw on the practices of universities and funders to recommend specific obligations for licensees of later-stage NIH technologies to promote effective access, which should be integrated as specific terms in licenses (RFI Issue 5). If NIH is unwilling or unable to adopt these as specific licensing conditions, they should be included in future guidance by NIH as examples of acceptable, commercially reasonable strategies to promote access (RFI Issue 1). We note that, while we urge NIH to grant nonexclusive licenses where possible, several recommendations in Section 2 presume that NIH will continue to grant exclusive licenses in certain circumstances.

1. Obligations to partner with public health organizations to advance global access to licensed technology.
2. Timely registration and supply of licensed products in LMICs.
3. Reserved rights for NIH to issue a humanitarian license to permit affordable supply of products relying on publicly owned technologies in LMICs.
4. Agreements not to assert IP rights in LMICs that, if enforced, would deprive those countries of affordable supply of licensed products.
5. Sublicensing and technology transfer commitments, particularly with respect to LMIC manufacturers.
6. Waiving marketing and data exclusivities in LMICs, which further delay access in countries that are rarely prioritized in global supply.

Recommendation to Extend the Scope of the Policy

Third, although the proposed policy is limited to NIH's intramural research program, NIH has the opportunity and ability to ensure that its policies have a more significant impact on promoting access to medicines by extending the proposed policy to include NIH's **extramural** research program, which accounts for nearly 83% of NIH's budget.¹

¹ *What We Do: Budget*, NAT. INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> (last visited July 19, 2024).

Introduction

NIH's mission involves the application of its research "to enhance health, lengthen life, and reduce illness and disability."² In doing so, the agency aspires to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."³ The scientific community and the broader public expect the same.

In order to fulfill its mission, the agency recognizes that the results of its work "need to reach people in ways that can improve their lives" and that "[p]eople only realize such benefits if they have access to the products and services that are built on NIH's work."⁴ As the agency observes, it "is in a unique position to prioritize R&D, licensing, exclusivity, and partnerships in areas that would not otherwise receive sufficient support in the commercial market, such as neglected tropical diseases and rare diseases."⁵

Licensing and technology transfer are important tools for NIH, which it undertakes "with the goal of moving scientific research and discovery forward for the benefit of public health."⁶ In doing so, however, the agency recognizes that the terms of its licensing agreements "should not hinder public benefit or the ability of new biomedical technology to reach the market."⁷

NIH's goal of exemplifying the highest standards of public accountability and social responsibility is linked to the licensing of NIH-owned technologies. For example, NIH would not advise wide swathes of the globe to use treatments that are clinically inferior compared to other treatments. But through its licensing practices, NIH has entrusted publicly owned technologies to private companies, which then price medicines so exorbitantly that experts recommend treatments scientifically proven to be less effective for many parts of the world.⁸

Private control over decisions relating to the production, pricing, and distribution of medicines developed through taxpayer-funded research has broad implications for global health and must remain accountable to the public. Justice and fairness are key considerations for NIH licensing practices, as they will determine when licensees can deprive LMICs of medicines

² *Mission and Goals*, NAT. INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/mission-goals> (last visited July 19, 2024). Relevantly, NIH has proposed amending its mission to read ". . . to reduce illness **for all people**;" Lawrence Tabak, *Words Matter, Actions Have Impact: Updating the NIH Mission Statement*, NIH DIR.'S BLOG (Sept. 28, 2023), <https://directorsblog.nih.gov/2023/09/28/words-matter-actions-have-impact-updating-the-nih-mission-statement/>.

³ *Mission and Goals*, NAT. INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/mission-goals> (last visited July 19, 2024).

⁴ NAT. INSTS. HEALTH, TRANSFORMING DISCOVERIES INTO PRODUCTS: MAXIMIZING LEVERS TO CATALYZE TECHNOLOGY TRANSFER—SUMMARY OF NIH WORKSHOP PROCEEDINGS 2 (July 31, 2023) [hereinafter "Workshop Report"].

⁵ Workshop Report, at 10.

⁶ NAT. INSTS. HEALTH, NIH TECHNOLOGY TRANSFER: ANNUAL REPORT 5 (2022).

⁷ Workshop Report, at 7.

⁸ See Appendix: case study on darunavir.

developed with publicly owned technology and whether knowledge about such technologies is shared with LMICs – or whether it remains sequestered in the hands of pharmaceutical firms predominantly situated in high-income countries.

NIH's proposal to include access provisions in future licensing agreements demonstrates its commitment to addressing these critical questions and will have profound global implications. We commend NIH for taking this important step. Under the proposed policy, where NIH grants a license authorizing the use of technologies developed from NIH's internal research program (the intramural research program) to commercialize human drugs, biologics, vaccines, or medical devices, licensees will be required to submit an "Access Plan" within three months of entering Phase III trials (or the equivalent). The Access Plan must describe, among other things, "one or more strategies to mitigate access challenges across affordability, availability, acceptability, and sustainability," with a view to supporting broad access across the entire U.S. population and, additionally, underserved communities, and/or people living in LMICs.

We hope to assist NIH in embracing the bold and effective policies required to fulfill its objectives. To aid NIH, we have proposed a set of recommendations that should apply across all licensing agreements to improve the effectiveness, clarity, and impact of the draft policy (Section 1), as well as examples of key licensee obligations to include in NIH's later-stage licensing agreements (Section 2) and additional steps that NIH should take to promote equitable access (Section 3).

As NIH helps expand access to medical products relying on publicly owned technologies, we encourage the agency to take a leadership role in helping prospective licensees craft substantive access strategies to reach historically underserved communities within the United States and abroad. This can include fostering collaborations and partnerships among prospective licensees and domestic and international organizations that have a wealth of expertise in advancing access to lifesaving medical products.

1. Recommendations for All NIH-Licensed Technologies

This section focuses on our recommended changes to NIH's proposed policy that should apply across all licensed technologies, regardless of stage. **First**, we advocate that all NIH-licensed technologies should integrate meaningful conditions for advancing access objectives or, at the very least, licensees must include milestones for achieving access objectives in the formulation of Access Plans. We include suggestions to accommodate uncertainty in product development. **Second**, if NIH adopts the approach of using Access Plans rather than conditions, which we do not prefer, we recommend specific modifications that are key to ensuring the policy's success. **Third**, we advocate that NIH include strong oversight and accountability mechanisms in the licensing of all NIH technologies to ensure compliance with access obligations. **Fourth**, we recommend transparency measures for the licensing of NIH technologies. **Fifth**, we recommend provisions in all NIH licensing agreements to ensure the survival of access obligations when the technology is transferred to new parties. **Sixth**, we request that NIH clarify the draft policy with

respect to third-party IP rights for all NIH-licensed technologies, which can and should be implicated by access strategies to support affordable supply in LMICs (such as technology transfer activities). **Finally**, we recommend that NIH prioritize nonexclusive licensing where possible in the commercialization of all NIH-owned technologies.

1.1. NIH should prioritize conditions or milestones over vaguer access commitments

NIH's proposed policy primarily relies on the submission of non-binding affordable access plans, triggered upon clinical development of an NIH technology, in lieu of specific licensing conditions or milestones for achieving equitable access (although we acknowledge that NIH has sought input on potential access-oriented provisions for licenses covering products that the agency has advanced to Phase III trials in RFI Issue 5).

We strongly urge NIH to adopt equitable access conditions in licensing agreements, rather than vaguer access plans. First, we discuss how this aligns with the approach of other agencies within the U.S. Department of Health and Human Services (HHS) and suggest that NIH include a fair pricing standard in all licensing agreements. Second, we propose high-level conditions for advancing global access in all licensing agreements which are commercially reasonable for NIH inventions, regardless of their stage. Third, we discuss the use of milestones to achieve access objectives if NIH adopts Access Plans instead of conditions, even though the Access Plan approach is not preferred.

Fair pricing

First, it is commercially reasonable to attach baseline conditions to all licensing agreements for NIH technology, as shown by the practices of the Administration for Strategic Preparedness and Response (ASPR). ASPR has made “fair pricing a standard part of contract negotiations for medical products developed or purchased as part of its commitment to obtain best value for the U.S. taxpayer.”⁹ It has entered agreements for the development of vaccines or treatments with four manufacturers with similar language barring the list price of products in the United States from being higher than the retail price in comparable global markets.¹⁰ As ASPR notes, “[t]hese actions are the result of a successful and collaborative approach by ASPR and its industry partners and show HHS's commitment to keep Americans from paying unfair prices for the care they

⁹ Press Release, U.S. Dep't Health & Hum. Servs., New HHS Actions and Research Highlight How President Biden's Administration is Lowering Prescription Drug Costs (Dec. 14, 2023), <https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html>; FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates, THE WHITE HOUSE (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/#:~:text=Building%20off%20last%20week's%20announcement,value%20for%20the%20US%20taxpayer.>

¹⁰ *Id.*

need.”¹¹ This demonstrates that the inclusion of a fair pricing standard in taxpayer supported development agreements is commercially reasonable.

President Biden himself has stated, “It’s a simple principle. You shouldn’t pay the highest price in the world for drugs that your tax dollars have already helped create.”¹² We believe this is an uncontroversial principle that should extend to all medicines relying on U.S. taxpayer support, including all products developed using licensed NIH technologies. Notably, NIH’s policy as currently formulated would allow licensees to charge U.S. taxpayers higher prices for licensed products than residents in other countries, particularly where the licensee does not adopt any pricing constraints in its Access Plan. Therefore, we recommend that NIH model its licensing agreements on ASPR’s policy and ensure that all agreements include a commonsense provision barring licensees from charging a list price for licensed products in the U.S. that exceeds the retail price in comparable global markets.

Conditions for global access

Second, in addition to this fair pricing provision, we advocate for high-level conditions on global access that are appropriate for NIH licensing agreements, regardless of stage. For example, the RIGHT Foundation, which is a partnership between the Government of South Korea, the Bill & Melinda Gates Foundation (the Gates Foundation), and life science companies, uses a Global Access Policy that applies to **all** funded projects. That policy is implemented through a specific Product Access Policy, which requires that:

- a. “When awardees and Project participants are successfully granted a patent deriving from Projects, awardees and Project participants will grant royalty-free, irrevocable, and worldwide licenses to users operating for the benefit of the public market in Least-Developed Countries (LDCs) . . . and Low-Income Countries (LICs);”
- b. “. . . awardees and Project participants will set affordable prices in public market [sic] for products that enable access to the product for patients and citizens of LDCs and LICs. Awardees and Project participants may implement tiered pricing for middle income countries where it is mutually deemed beneficial or necessary in furtherance of the charitable objectives of Projects;” and
- c. “The RIGHT Foundation, and awardees and project participants may have a good faith negotiation with a relevant 3rd party to ensure sufficient supply of the funded products to LDCs, LICs and where otherwise applicable.”¹³

¹¹ *Id.*

¹² *Remarks by President Biden on Progress to Lower Prescription Drug Costs*, THE WHITE HOUSE (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/12/14/remarks-by-president-biden-on-progress-to-lower-prescription-drug-costs/>.

¹³ *Global Access Policy*, RIGHT FOUND., <https://rightfoundation.kr/en/access-policy/> (last visited July 19, 2024).

We support similar baseline obligations in all licensing agreements with NIH that can impact global access for licensed technologies while balancing concerns about flexibility and appropriateness for early-stage inventions. We recommend the inclusion of the following provision in all licensing agreements to foster global access to medicines relying on NIH technology.

To the extent that Licensee cannot or chooses not to provide timely supply of licensed products in LMICs, licensee will grant sublicenses and share all necessary intellectual property, technology, know-how, and other information or data relating to the licensed product on reasonable terms and conditions to qualified third parties seeking to supply the licensed product to LMICs on an affordable basis.

This provision aligns with the practice of universities. The Massachusetts Institute of Technology (MIT) and the University of Vermont both employ a provision that defines “a ‘Charitable Objective’ as being the availability of the product in developing countries at low cost,” allows the universities to identify third parties that can commercialize the licensed products for the charitable objective, and refer them to the licensee for a sublicense.¹⁴ If the licensee refuses to grant the sublicense, it must provide a written report with justification for refusing the sublicense, but the university reserves “sole discretion” to issue the sublicense if it determines the refusal was unreasonable.¹⁵ We believe it is vital that qualified third parties be allowed to address unmet need in LMICs when products rely on publicly owned technologies and strongly urge NIH to adopt provisions that enable such sublicensing. Moreover, the condition we recommend is sufficiently general and aligns with current practices, such that it accommodates uncertainty in product development and is commercially reasonable.

Additionally, when licensees fail to address whether publicly owned technologies can practically be used by patients, providers, and facilities in LMICs, this should satisfy the condition that the licensee is unable to supply the licensed product in those countries. This would require the licensee to grant sublicenses to qualified entities, which may resolve concerns about adapting the licensed product to conditions in LMICs where the licensee is unwilling or unable to do so. For example, a potential sublicensee may be able to innovate a heat-stable formulation of a licensed product that can be used in LMICs with hot climates, where the licensee fails to do so. As such, licensees would not be able to withhold the knowledge for producing licensed technologies from developers who can adapt these technologies in LMICs, if the licensee chooses to prioritize addressing conditions in high-income markets.

We strongly believe this knowledge sharing with LMICs is critical, as knowledge for producing efficacious publicly owned medical technologies should not be concentrated in the hands of

¹⁴ MOHAMMAD SHAHZAD, PROMOTING GLOBAL ACCESS TO HEALTH TECHNOLOGIES: A LICENSING TOOLKIT FOR PUBLIC SECTOR INSTITUTIONS 19 (Aug. 2022), https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf.

¹⁵ *Id.*

pharmaceutical firms predominantly situated in high-income nations, wielded to the exclusion of wide swathes of the globe. We commend NIH for taking steps to advance knowledge sharing of publicly owned technologies with the world, including licensing key COVID-19 technologies to the World Health Organization (WHO) and the National Institutes of Allergy and Infectious Diseases' (NIAID) collaborative research agreement with Afrigen in South Africa to support WHO's mRNA Vaccine Technology Transfer Hub program.¹⁶ Recognizing the importance of knowledge sharing for access to publicly owned technologies in LMICs, NIH should include the recommended global access provision that enables knowledge sharing where licensees cannot or will not supply licensed products in LMICs. Diversifying the producers that can support medical needs in LMICs through these knowledge sharing provisions also advances sustainable and resilient global health manufacturing and supply chain capacity, which aligns with the White House's commitments to expanding access to medicines around the world.¹⁷

Industry resistance to knowledge sharing provisions, even in situations as dire as a global health pandemic,¹⁸ should not dissuade NIH from leveraging its licensing authority and securing just access for LMICs. That is, industry will always resist measures that could constrain profit-maximization, but such resistance should not deter NIH from upholding public interest principles and ensuring equitable access through knowledge sharing provisions on publicly owned inventions that taxpayers have derisked. As such, we urge the agency to exercise discretion in considering tailored provisions on a case-by-case basis to overcome industry resistance and advance knowledge sharing with LMICs.¹⁹

For example, NIH could additionally require that sublicensees and technology transfer recipients supplying LMICs make additional payments/ pay higher royalties to the original licensee if they are supplying licensed technologies in new therapeutic areas and for new indications. With this limitation, manufacturers would not be barred from innovating new uses of, say, a platform technology for meeting unmet needs in LMICs or addressing endemic diseases in those countries,

¹⁶ *NIH Contributions to WHO COVID-19 Technology Access Pool and Q&As*, NAT. INSTS. HEALTH (May 12, 2022), <https://www.techtransfer.nih.gov/policy/ctap>; Press Release, Public Citizen, NIH-Afrigen Agreement Will Help WHO's Fight Against Pandemics (July 8, 2022), <https://www.citizen.org/news/nih-afrigen-agreement-will-help-whos-fight-against-pandemics/>.

¹⁷ *FACT SHEET: Update on the United States Commitment to Expanding Access to Medicines Around the World*, THE WHITE HOUSE (Mar. 29, 2024), <https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/29/fact-sheet-update-on-the-united-states-commitment-to-expanding-access-to-medicines-around-the-world-2/>.

¹⁸ *WHO Pandemic Agreement: Pros and Cons for U.S. Innovation*, PHRMA (Jan. 23, 2024), <https://phrma.org/en/resource-center/Topics/International/WHO-Pandemic-Agreement-Pros-and-Cons-for-US-Innovation>.

¹⁹ Public Citizen, Comment Letter on Notice and Request for Comments on Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement, at 12 (Jan. 31, 2024), https://www.citizen.org/wp-content/uploads/Public_Citizen_Comment-Re_WHO_Pandemic_Instrument.pdf.

if the original licensee is unable or unwilling to do so. And in turn, the original licensee benefits from additional payments or higher royalties in new fields of use beyond those envisioned in NIH's original licensing agreement.

If necessary, NIH can also consider limitations in sublicensing on the release of know-how to other parties, besides the sublicensee, which can guard against disseminating information that could give competitors an advantage. Again, these provisions should be considered on a case-by-case basis; for example, such limitations on the release of know-how to other parties would be inappropriate for platform technologies that may be subject to collaborative R&D partnerships to meet need in LMICs. Take, for example, the mRNA technology transfer hub which has multiple entities collaborating to adapt the mRNA technology platform for endemic diseases in LMICs.²⁰ If NIH unduly limits the sharing of know-how in sublicensing to entities seeking to affordably supply LMICs, the agency can unintentionally hamper these collaborative efforts.

In sum, we urge NIH to include a global access provision in all licensing agreements that requires the licensee to grant sublicenses and share all necessary information relating to the licensed product to a qualified third party seeking to affordably supply LMICs, where the licensee itself is unwilling or unable to do so. The condition should also be interpreted to allow sublicensees to adapt licensed technologies in LMICs where the licensee is unable or unwilling to do so. Finally, industry resistance to these vital knowledge sharing conditions should not dissuade NIH from upholding public interest principles and securing access in LMICs via these terms.

Global access milestones

If NIH does not adopt conditions for global access in licensing agreements, it should, at the very least, require licensees to include specific milestones that must be met in order to achieve equitable access within Access Plans. These milestones must address affordable supply to LMICs. In early-stage licensing agreements, target price and price ceilings in LMICs may be appropriate, which can be modified as the licensed technologies advance in the development pipeline. Similarly, in early-stage licensing agreements, we advocate that licensees define their high-level regulatory and supply strategy, such as where first registration will occur.

We recommend that a specific mechanism be included to ensure that a third party could be sublicensed to ensure registration and affordable supply in LMICs. Specifically, a milestone could be that “upon the first clinical phase trial for a licensed product, the licensee will identify a generic manufacturer in a middle-income country to produce the licensed technology at a reasonable

²⁰ *The mRNA Vaccine Technology Transfer Hub*, WORLD HEALTH ORG., <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub> (last visited July 19, 2024).

price for developing countries.”²¹ If the licensee is unwilling or unable to appoint this manufacturer, it could, at the very least, be required to issue a sublicense on reasonable terms and conditions to a qualified third party seeking to supply LMICs on an affordable basis.

Concerns about the feasibility of equitable access milestones in Access Plans militate in favor of tailoring appropriate triggers for milestones requirements, as opposed to deferring to industry in the formulation of abstract access plans. For example, the requirement to designate a generic manufacturer in an LMIC to supply other LMICs at a reasonable price can be triggered upon the later-stage clinical development of a candidate using NIH technologies.

Summary

In summary, we advise (1) NIH to adopt a fair pricing standard for U.S. residents in all licensing agreements with the agency, (2) a condition to support affordability and supply in LMICs in all licensing agreements, and (3) milestones for achieving global access in Access Plans, should NIH adopt that approach (which is not preferred). Licensees and NIH can draw on our recommendations discussed in greater detail in Section 2 (Recommended Obligations in Later-Stage Licensing Agreements) for examples of other kinds of milestones for advancing global access in LMICs.

1.2. Proposed modifications to the Access Plan policy

We strongly urge NIH not to adopt the Access Plan approach for achieving equitable access, as conditions applied across licensing agreements can better meet access objectives while addressing uncertainty in product development and commercial concerns.

However, if NIH adopts the requirement that licensees adopt non-binding Access Plans upon the first pivotal clinical trial, we recommend the below modifications, at a bare minimum, to effectuate the goals of the draft policy, in addition to our earlier recommendation that Access Plans include meaningful milestones for addressing global access.

Access Plans must:

- a. meet needs for both (1) underserved communities in the United States, and (2) Low- and Middle-Income Countries (LMICs);
- b. be subject to meaningful review by NIH;
- c. not be waived or modified, except in limited circumstances; and
- d. be formulated earlier than when technologies enter Phase III trials.

²¹ Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC’Y 14, 17-18 (Mar. 2023).

Access should be for all in the U.S. and globally

First, we advocate that Access Plans must account for LMICs, in addition to underserved communities in the United States. The proposed amendments to the NIH IRP model license agreements require access plans to disclose a “strategy to support broad access to Licensed Product(s) for the U.S. population, as well as (a) through the lens of promoting equity for underserved communities . . . and/or (b) populations in low- and middle-income countries, as defined using the World Bank classification system” (Appendix, Section II).

We commend the inclusion of underserved communities in the U.S. and LMICs. However, we do not support the proposed policy to the extent that it allows licensees to select between these two groups, as this undermines equitable access. We strongly encourage NIH to delete “/or” from the draft policy. The University of California, Berkeley (UC Berkeley), for example, requires licensees to provide access plans addressing both LMICs and underserved or vulnerable U.S. populations.²²

The NIH IRP model license agreement already permits licensees to seek a waiver or modification of the equitable access plan, which NIH shall consider in good faith. NIH can account for geographic considerations in this process, within its reasonable discretion. Thus, there is already a mechanism by which a licensee can limit its access planning to the U.S., if necessary, through these waiver and modification provisions. Importantly, NIH must approve those waivers or modifications in good faith, which serves as a check against a licensee inappropriately omitting global communities from its access planning. For example, if a licensee believes a technology cannot be adapted for LMICs, NIH should still require an Access Plan allowing for sublicensing if other qualified entities can adapt the licensed technologies for conditions in LMICs. Also, NIH could require an Access Plan to include consultation with domestic and international organizations to explore possible avenues for adapting licensed technologies in LMICs.

The draft policy, however, currently allows licensees to choose whether to prioritize domestic or global populations in Access Plans, and the licensee need only consider NIH’s proposed modifications or revisions to the plan in good faith. Thus, the licensee has the power to determine whether its Access Plan will reach global communities, and it only has a minor obligation to consider in good faith a proposed modification by NIH to extend the Access Plan to the rest of the world. We are concerned that this consolidates too much discretion over the global health implications of publicly owned technologies in the hands of private entities, as opposed to NIH which is bound by mandates of public accountability. More fundamentally, justice requires that both LMICs and underserved communities in the U.S. are accounted for in licensees’ Access Plans.

²² U. C. BERKELEY, *Sample Exclusive Licensing Agreement*, at 10, <https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf>.

Meaningful review of proposed Access Plans by NIH

We strongly urge NIH to amend the draft policy to provide for meaningful review of the adequacy of Access Plans. At present, the draft policy and model license language contain no requirement for NIH to review, accept, or approve a licensee's Access Plan once submitted. The policy merely requires that the licensee submit an Access Plan, as defined therein. Later, NIH can request that the licensee confer with it—no more than once a year—to “review Licensee's progress” and the licensee must agree to “consider in good faith any reasonable modifications suggested by NIH with respect to the Access Plan” (Appendix, Section II). However, there is no procedure under which NIH assesses or makes any determination as to the adequacy of the Access Plan, and it lacks any capacity to formally request or require changes.

To meet the current proposed definition of the “Access Plan,” the licensee need only identify “one or more strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability” (emphasis added). The combined effect of this definition and the lack of meaningful review is that a licensee could submit a document stating merely—to use one of the strategy examples given in the policy—that it intends to prepare culturally-sensitive patient education materials (*see* Appendix, Section III). Although this is an important part of any multifaceted access strategy, alone, it is unlikely to meaningfully improve access for vulnerable U.S. populations or for LMICs. Nonetheless, the licensee will have discharged their duty under the policy, there being no requirement for the licensee to adopt a more detailed and satisfactory plan subject to NIH's review.

If NIH does retain a policy of Access Plans instead of more concrete conditions, then we strongly recommend that NIH, at a minimum, amend the current language in the draft policy to more closely resemble the wording used by UC Berkeley; namely, that access plans must include licensee's “plans (including strategies and timelines)” to improve access,²³ instead of “one or more strategies” to improve access.

Critically, we advocate that the policy give NIH the capacity to meaningfully supervise the adequacy of Access Plans, like other entities. The Gates Foundation, for example, has required Foundation approval of global access strategies or the collaborative development of supply plans by the Foundation and the partner in certain agreements.²⁴ We recommend that:

- a. licensees should be required to submit a proposed Access Plan to NIH for review and feedback before it is finalized, preferably in conjunction with a public health organization such as WHO, Unitaaid, the Medicines Patent Pool (MPP), or civil society organizations

²³ *Id.*

²⁴ GATES FOUND. & ARSANIS, INC., *Amended & Restated Agreement*, at 6 (Aug. 1, 2018), https://ghiaa.org/wp-content/uploads/2022/04/BMGF_Arsanis-Grant-Agreement.pdf; GATES FOUND. & ARSANIS, INC., *Letter Agreement*, at 10 (Apr. 24, 2017), https://ghiaa.org/wp-content/uploads/2022/04/BMGF_Arsanis-Strategic-Relationship-Letter.pdf.

specializing in access to medicines (similar to how UC Berkeley allows third parties to attend meetings related to licensees' Affordable Access Plans);²⁵

- b. the proposed changes to NIH IRP model agreements should include an express duty of good faith on licensees in the preparation of Access Plans; and
- c. NIH should retain discretion to formally request changes to Access Plans at least once a year, which should be directly negotiated by NIH and the licensee (rather than NIH merely submitting changes to the licensee for good faith consideration). An exception should be included, however, such that NIH can request changes in response to outbreaks,²⁶ or Licensees' inability to comply with their own Access Plan, even if they have formally requested changes within the last year.

Limitations on waivers and modifications of Access Plan requirements

We strongly urge NIH to limit the circumstances in which waivers and modifications of the Access Plan requirement will be granted. In the draft policy, NIH proposes to include a process by which licensees can seek a waiver or modification of the Access Plan obligation, in whole or in part, which NIH will consider "on a case-by-case basis" and with reference to criteria to be identified in proposed additional guidance (*see* Appendix, Section III). We strongly recommend that NIH grant waivers and modifications in exceedingly narrow circumstances that are articulated in advance of the policy and the release of a new NIH IRP model license agreement. For example, licensee's lack of capacity to fulfill access objectives in LMICs or for underserved communities in the U.S., by itself, should not be a basis for waiving the Access Plan obligation, as Access Plans could include a commitment to grant sublicenses to entities who can adapt licensed products for these unmet needs.

Waivers or modifications should only be granted to the extent of the justification and no further. Further, we strongly recommend that the draft policy be amended to require NIH to publish a notice whenever it has waived or modified the requirement to formulate an Access Plan, together with its justification.

Unrestricted agency discretion to waive or modify the minimal requirement to file an Access Plan risks rendering the entire draft policy ineffective. Waiving the Access Plan requirement entirely, for example, would allow private entities to commercialize publicly owned technology with no consideration for underserved communities in the United States or LMICs. Further, there is a wealth of expertise among domestic and international organizations that NIH can draw on for

²⁵ U. C. BERKELEY, *Sample Exclusive Licensing Agreement*, at 10, <https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf>.

²⁶ CEPI includes provisions requiring the partner to cooperate with its requests on adapting a project when an outbreak occurs. *See* CEPI & CUREVAC AG, *Framework Partnering Agreement*, at 23 (Feb. 15, 2019), https://ghiaa.org/wp-content/uploads/2021/06/CEPI_CureVac-partnering-agreement.pdf.

assistance in access planning, and such advice and technical assistance should be exhausted before the grant of any waiver or modification to the Access Plan requirement. As stated above, UC Berkeley has included provisions in licensing agreements allowing such third parties to attend meetings related to Access Plans.²⁷ Further, UC Berkeley allows these parties to attend an initial meeting where a licensee must explain why it believes an Access Plan is not needed or infeasible, and the university retains the right to require an Access Plan if it concludes the plan is reasonable and desirable.²⁸ We recommend NIH include similar provisions to ensure this technical assistance is available and exhausted before waivers or modifications of the Access Plan requirement are granted.

Planning for equitable access should commence earlier than Phase III trials

The draft policy proposes that licensees need only submit an Access Plan within three months of a licensed product entering its first pivotal clinical trial (i.e., Phase III trial or equivalent), unless waived or modified in advance. We do not recommend deferring the creation of binding equitable access commitments to later stages of development, as flaws have emerged in practice in attempting to retain this flexibility. Take, for example, the funding agreement between the Coalition for Epidemic Preparedness Innovations (CEPI) and Moderna for the development of a COVID-19 vaccine candidate. Moderna agreed to abide by CEPI's equitable access policy and agreed in good faith to develop an equitable access plan with CEPI in the event of a more complete funding agreement.²⁹ However, a more complete agreement does not appear to have been signed, and equitable access was not achieved with respect to the vaccine.³⁰

Instead, we advocate that Access Plans be formulated concurrently with the execution of all NIH licensing agreements, just as the inclusion of access conditions would require NIH and licensees to think collaboratively about access ramifications of NIH technology from the outset of negotiating the agreement. To account for changes and uncertainty in the development process, NIH can meet with licensees to monitor progress on Access Plans and formally request changes responsive to unfolding circumstances at least once a year, which NIH and the licensee will negotiate and finalize together.

²⁷ U. C. BERKELEY, *Sample Exclusive Licensing Agreement*, at 10, <https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf>.

²⁸ *Id.*

²⁹ ZAIN RIZVI, PUBLIC CITIZEN COVAX'S CHOICES 19-20 (2020); Letter from Public Citizen, Health GAP, Médecins Sans Frontières Access Campaign, & People's Vaccine Alliance to CEPI, Greater Disclosure of Equity Terms Needed (Dec. 11, 2023), <https://www.citizen.org/article/letter-to-cepi-ceo-greater-disclosure-of-equity-terms-is-needed/>; CEPI & MODERNATX, INC., *Outbreak Response Funding Agreement*, at 3 (Jan. 23, 2020) (obtained from a FOIA request and on file with Public Citizen).

³⁰ Letter from Public Citizen, Health GAP, Médecins Sans Frontières Access Campaign, & People's Vaccine Alliance to CEPI, Greater Disclosure of Equity Terms Needed (Dec. 11, 2023), <https://www.citizen.org/article/letter-to-cepi-ceo-greater-disclosure-of-equity-terms-is-needed/>.

Summary

In summary, we recommend that Access Plans include specific milestones for advancing global access if NIH does not adopt access conditions in all licensing agreements. In addition, we recommend that (1) Access Plans address both LMICs and underserved communities in the U.S.; (2) Access Plans be subject to meaningful review by NIH to ensure, for example, that licensees cannot simply rely on strategies unlikely to impact global access in order to comply with the policy; (3) NIH only grant waivers or modifications of the requirement to formulate an Access Plan in very narrow circumstances, to be disclosed before the policy is finalized; and (4) licensees should formulate Access Plans concurrently with the execution of licensing agreements, with procedures in place to allow for annual modifications to account for unfolding developments.

1.3. Defining affordability for equitable access in LMICs

All NIH licensing agreements should proactively define affordability for the purposes of delivering equitable access in LMICs, whether through conditions or Access Plans with milestones. The definition should be concrete and enforceable. Without strong definitions, NIH could risk rendering all other access provisions for LMICs meaningless. We advocate for a definition of affordability that accounts for the lowest sustainable cost of producing the licensed product, plus a reasonable margin, which is a metric used by the Drugs for Neglected Diseases initiative (DNDi).

DNDi defines affordability as the “pricing of a Product at the lowest sustainable level which may include only: (a) the full production costs, as optimized without compromising the quality of the Product; (b) direct distribution costs; and (c) a reasonable margin to ensure manufacturing and distribution of the Product on a sustainable basis.”³¹ DNDi recognizes, though, that this definition may not deliver locally affordable prices in some circumstances where the lowest sustainable level for pricing exceeds the budgets of purchasers for low-resourced settings.³² This definition of affordability prevents the partner from incurring a loss and guarantees a reasonable profit margin on the developed technologies. In some agreements, DNDi further defines affordability by establishing a ceiling price, defining a percentage for the reasonable margin on the product, and/or identifying the cost items that can be included in the calculation of price.³³ Other institutions have also used a similar cost-plus framework that defines affordability based on costs of goods plus a defined or reasonable margin, such as University College London.³⁴

³¹ Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécol, *Striking fair deals for equitable access to medicines*, 18 J. INTELL. PROP. L. & PRAC. 323, 331 (2023).

³² *Id.*

³³ *Id.*

³⁴ Thi-Yen Nguyen, Mohammad Shahzad, & Juliana Veras, *Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America: Identifying Key Provisions To Promote Global Access To Health Technologies*, 53 LES NOUVELLES – J. LICENSING EXECS. SOC’Y

A weaker approach is using a soft pricing obligation that requires a developer to achieve affordable prices without greater specificity.³⁵ The Global Health Innovation Alliance Accelerator's (GHIAA) commentary indicates that these soft pricing obligations are easier to pass through from the original licensee to downstream entities involved in later-stage development of the product but, due to their vagueness, are difficult to enforce.³⁶

We believe the soft pricing obligation is too weak to ensure affordability of downstream products in LMICs due to the difficulty in enforcing a vaguer obligation. We strongly urge NIH to adopt an affordability metric that accounts for the lowest sustainable cost of production with a reasonable margin. Using this approach, licensees would be required to report the costs of producing the licensed product to NIH for the purposes of verifying affordable prices. A benefit of this approach is that academic experts and civil society have pioneered empirical methods for calculating the costs of producing medicines with publicly available information,³⁷ which can serve as a check against inaccurate reporting to NIH.

1.4. NIH must provide for meaningful oversight and accountability to ensure that licensees comply with their access obligations.

Oversight and accountability are needed for any approach seeking to integrate equitable access commitments into NIH licensing agreements, regardless of whether NIH uses access conditions or Access Plans with milestones. The current proposal for licensees to “confer with NIH to review Licensee’s progress” on Access Plans no more than once a year, and to “consider” NIH’s suggestions in good faith, is insufficient (*see* Appendix, Section II).

In this section, we first urge NIH to include affirmative reporting obligations on an annual basis, the right to have third parties present for reviewing reported progress, and audit rights to effectively monitor the transfer of NIH technologies to the private sector. Second, we advocate for accountability terms in licensing agreements, including step-in rights and reversion or termination clauses where a licensee breaches its access obligations.

Monitoring

A well-constructed monitoring provision requires the partner to specifically report on progress towards access obligations, as the Gates Foundation has done in its funding agreement with

189, 196 (2018); Global Healthcare Innovation Alliance Accelerator, *Strategies for Affordable Pricing Provisions*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/affordability/> (last visited July 19, 2024).

³⁵ *Id.*

³⁶ *Id.*

³⁷ E.g., Melissa Barber, Dzintars Gotham, Helen Bygrave, & Christa Cepuch, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, 7 JAMA NETWORK OPEN e243474 (2024).

Arsanis for a *Staphylococcus aureus* antibody development program.³⁸ The monitoring provision required Arsanis to produce a report within a redacted amount of time after each fiscal year that describes the use of funding and evaluates Arsanis' progress towards achieving the global access commitments, including a cost-plus pricing obligation for developing countries.³⁹ That agreement also provides for a Progressive Review Group that periodically meets and allows third parties to be invited from time to time while subjecting them to confidentiality agreements.⁴⁰ The Gates Foundation included a similar monitoring provision in its funding agreement with CureVac, which required a quarterly report and consultation with the Foundation "regarding progress with respect to the Projects including information regarding progress against the Global Access Commitments."⁴¹

By contrast, UC Berkeley can request once annually to meet with the licensee to review its progress on the affordable access plan and the licensee must consider any modifications in good faith with respect to the plan.⁴² Under the terms, the licensee must meet with the university within 30 days of the request for this purpose.⁴³ While NIH's draft policy closely resembles this mechanism, UC Berkeley retains an important right to invite a designated third party to these discussions reviewing the Access Plan, although the discussion is subject to confidentiality obligations.⁴⁴

DNDi, the Gates Foundation, and CEPI also include audit rights in their agreements to verify the accuracy of information received from a partner. DNDi has included a right to audit cost factors that are used in determining the affordable pricing of products in all development agreements with partners.⁴⁵ CEPI included a right to audit Novavax's records once annually in its COVID-19

³⁸ GHIAA, *How Do Reporting Obligations and Audit Rights Support the Achievement of Equitable Access Objectives?*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/reporting-audit-rights/> (last visited July 19, 2024); GATES FOUND. & ARSANIS, INC., *Letter Agreement*, at 16 (Apr. 24, 2017), https://ghiaa.org/wp-content/uploads/2022/04/BMGF_Arsanis-Strategic-Relationship-Letter.pdf.

³⁹ GATES FOUND. & ARSANIS, INC., *Letter Agreement*, at 16 (Apr. 24, 2017), https://ghiaa.org/wp-content/uploads/2022/04/BMGF_Arsanis-Strategic-Relationship-Letter.pdf.

⁴⁰ *Id.* at 10.

⁴¹ GHIAA, *How Do Reporting Obligations and Audit Rights Support the Achievement of Equitable Access Objectives?*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/reporting-audit-rights/> (last visited July 19, 2024); GATES FOUND. & CUREVAC GMBH, *Global Access Commitments Agreement*, at 13 (Feb. 13, 2015), https://ghiaa.org/wp-content/uploads/2021/06/BMGF_CureVac-Global-Access-Commitments-Agreement.pdf.

⁴² U. C. BERKELEY, *Sample Exclusive Licensing Agreement*, at 10, <https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf>.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Dominique Junod Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécol, *Striking fair deals for equitable access to medicines*, 18 J. INTELL. PROP. L. & PRAC. 323, 332 (2023).

vaccine development contract, which provided CEPI on-site access and information related to cost of goods.⁴⁶ The Gates Foundation has included audit rights to scientific data and on-site inspection provisions in its agreements, with confidentiality obligations in some instances.⁴⁷

We recommend that NIH require affirmative annual reporting on licensees' progress on access obligations (either conditions or Access Plans with milestones), like the Gates Foundation has employed with Arsanis, but integrate the flexibility in agreements with UC Berkeley and the Gates Foundation that allows third parties to be invited to consultations on progress. Civil society and WHO representatives are participants that can assist in these discussions to achieve equitable access. Progress reports should be made publicly available on NIH's website. We also urge NIH to adopt provisions for auditing records to verify the accuracy of information received from licensees or downstream entities.

Accountability

Agreements generally use three approaches for breaches of access obligations: (1) step-in rights, (2) converting a license from exclusive to nonexclusive, and/or (3) terminating the license. We believe that all three approaches may be instructive for NIH in licensing agreements for all technologies.

First, agreements by the Gates Foundation and CEPI provide examples of step-in provisions that NIH can include in its licensing agreements. They provide for Global Access Licenses & Public Health Licenses in the event of breach of equitable access obligations, which allows the funders to step-in, issue licenses to new entities to achieve supply in LMICs, and compel the partner to work with the new entity, including stringent technology transfer obligations, to ensure the license is practicable.

The Gates Foundation employed a detailed step-in rights approach in an agreement with Novavax for an RSV vaccine used in maternal immunization.⁴⁸ The Global Access License in that agreement is triggered upon the uncured breach of the grant agreement or the global access commitment agreement. The license provides the Foundation with a "non-exclusive, irrevocable, perpetual, sublicensable, royalty-free and fully-paid up, worldwide [] license to the Foundation

⁴⁶ GHIAA, *How Do Reporting Obligations and Audit Rights Support the Achievement of Equitable Access Objectives?*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/reporting-audit-rights/> (last visited July 19, 2024); GHIAA, *CEPI – Novavax, COVID-19 Vaccine Funding Agreement: Protecting & sharing information | Information sharing*, MASTER ALLIANCE PROVISION GUIDE (MAPGUIDE), https://ghiaa.org/provision_document/cepi-novavax-covid-19-vaccine-funding-agreement-3/.

⁴⁷ GHIAA, *How Do Reporting Obligations and Audit Rights Support the Achievement of Equitable Access Objectives?*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/reporting-audit-rights/> (last visited July 19, 2024).

⁴⁸ GATES FOUND. & NOVAVAX, INC., *Global Access Commitments Agreement*, at 13-14 (Sept. 25, 2015), https://ghiaa.org/wp-content/uploads/2022/11/Gates_Novavax-Global-Access-Commitments-Agreement.pdf.

to all intellectual property, technology, know-how, and information owned, controlled or used (subject to reasonably [sic] sublicensability by third party licensor(s)) by the Company,” that are necessary or useful for providing the product for maternal immunization intended to benefit developing countries.⁴⁹

With respect to technology transfer for the exercise of this Global Access License, the Gates Foundation provides for the execution of instruments between Novavax and the technology transfer recipient, including a “quality agreement, safety data exchange agreement, and other customary agreements related to technology transfer of the Product.”⁵⁰ That provision bars the recipient from being required to pay any royalties, milestones, or fees associated with such agreements.⁵¹ Novavax is required to “cooperate with the Foundation in good faith to make available . . . all necessary intellectual property, technology, know-how and other information relating to the Product (including but not limited to master batch records, SOPs, QA/QC information, detailed bill of materials for the Product and other manufacturing documentation)” to exercise the Global Access License.⁵² The step-in rights include other beneficial provisions, including the right to applicable records (e.g., manufacturing records), the right to access regulatory filings, and a requirement to “take all reasonable and diligent steps” to eliminate third party costs or royalties.⁵³ Other examples of step-in provisions can be found in the Gates Foundation’s agreements with CureVac⁵⁴ and Arsanis⁵⁵ and CEPI’s agreement with CureVac.⁵⁶

We recommend that NIH include step-in rights in all licensing agreements, which should provide the agency with a nonexclusive, irrevocable, perpetual, sublicensable, royalty-free and fully-paid up, worldwide license to all intellectual property, know-how, and rights necessary or useful for providing a product developed with NIH technology in LMICs. Federal law already requires federal agencies to retain step-in rights on exclusive or partially exclusive licenses: any exclusive or partially exclusive license on a federally owned invention shall include a provision “retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States.”⁵⁷ The step-in rights we recommend here align with what is already required of

⁴⁹ *Id.*

⁵⁰ *Id.* at 14.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ GATES FOUND. & CUREVAC GMBH, *Global Access Commitments Agreement*, at 7 (Feb. 13, 2015), https://ghiaa.org/wp-content/uploads/2021/06/BMGF_CureVac-Global-Access-Commitments-Agreement.pdf.

⁵⁵ GATES FOUND. & ARSANIS, INC., *Letter Agreement*, at 11–12 (Apr. 24, 2017), https://ghiaa.org/wp-content/uploads/2022/04/BMGF_Arsanis-Strategic-Relationship-Letter.pdf.

⁵⁶ CEPI & CUREVAC AG, *Framework Partnering Agreement*, at 27–30 (Feb. 15, 2019), https://ghiaa.org/wp-content/uploads/2021/06/CEPI_CureVac-partnering-agreement.pdf.

⁵⁷ 35 U.S.C § 209.

NIH and ensures that, where licensees fail to comply with access obligations, NIH retains rights to allow other manufacturers the freedom to operate for supplying medical products in LMICs. Such provisions should enumerate (1) specific obligations for technology transfer that are necessary or useful for exercising the step-in rights; (2) the kinds of information that will be transferred to the recipient, such as regulatory submissions and clinical data; and (3) requirements to minimize costs to third parties in the exercise of those step-in rights.

Second, some institutions revert exclusive licenses on their technology to nonexclusive licenses upon breach of equitable access commitments. The University of British Columbia (UBC) reverts to nonexclusive licensing for drugs and medical devices if it finds that the needs of vulnerable communities are not being met by the exclusive license.⁵⁸ Similarly, Harvard provides for reverting exclusive licenses to nonexclusive if they fail to meet milestones, such as access in certain territories. Harvard will inform the licensee that a third party will be recruited to meet need, however, the university will give the licensee an opportunity to address the issue first.⁵⁹

Third, some institutions provide for the termination of a license upon breach of equitable access obligations. Emory retains the right to terminate licenses where the licensee is not adequately developing relevant technology or failing to comply with the global access clause. Yale appears to have a similar policy, by virtue of including global access terms in its due diligence provisions.⁶⁰

We advocate for similar provisions reverting exclusive licenses to nonexclusive licenses and, in certain cases, allowing NIH to terminate licenses upon the breach of equitable access obligations. The threat of other competitors who may commercialize products in high-income markets or, even worse, the termination of entities' ability to use licensed technology can promote adherence to equitable access obligations.

Summary

In conclusion, we recommend strong oversight and accountability provisions to ensure that licensees comply with access obligations, regardless of whether those obligations derive from access conditions or Access Plans with specific milestones. In terms of oversight, we advocate for an annual affirmative reporting requirement on progress for equitable access, the right to have expert third parties at progress consultations, and the right to audit records to ensure accurate

⁵⁸ Nancy Gallini et al., *Implementation and Impact of the Global Access Principles at the University of British Columbia: Current Successes and Future Challenges*, 14 FRONT. PHARMACOL. 1, 5 (2023).

⁵⁹ Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC'Y 14, 26 (Mar. 2023).

⁶⁰ Thi-Yen Nguyen, Mohammad Shahzad, & Juliana Veras, *Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America: Identifying Key Provisions to Promote Global Access to Health Technologies*, 53 LES NOUVELLES – J. LICENSING EXECS. SOC'Y 189, 196 (Sept. 2018).

progress reporting. For accountability provisions, we recommend that NIH include step-in rights or the termination/reversion of licenses when licensees breach equitable access commitments.

1.5. Equitable access across the licensing of NIH technologies must be transparent

To maintain stakeholder support for NIH's access policy and increase faith in the agency's ability to safeguard public interest objectives when out-licensing its technologies, NIH can pair monitoring and accountability provisions with transparency obligations. For all NIH licensing agreements, regardless of the stage of development, we recommend that NIH model its transparency practices after the Medicines Patent Pool (MPP) and publish unredacted terms on supply and affordability in a timely manner. Should NIH adopt the Access Plan approach, we recommend that NIH publish Access Plans, any waivers or modifications of Access Plan requirements, progress reports on Plans, and feedback from NIH to licensees on Plan compliance. NIH can also consider maintaining an active public database of licensing opportunities to supply LMICs.

Transparency is already a norm in NIH licensing practices, as federal law and regulation require NIH to publish notice of prospective exclusive licenses and consider public comments before granting such licenses.⁶¹ These laws and regulations recognize the need for public accountability as private entities gain control over federal technologies. Similarly, NIH can recognize the need for public accountability with respect to equitable access licensing practices to show that public interest objectives are being preserved in these transfers of publicly owned technologies to private actors. Transparency in these licensing practices can also aid the measurement of outcomes and impact.⁶² An ancillary benefit to transparent equitable licensing practices is that others can draw on such provisions, which can help establish norms across the research and development landscape and aid other funders' and governments' negotiations with potential partners.⁶³

First, we recommend that NIH model its transparency practices after MPP, which publishes its licensing agreements, including with commercial entities, on its website.⁶⁴ At a minimum, any terms on access and affordability should remain unredacted and published in a timely manner.⁶⁵

⁶¹ 35 U.S.C. § 209(e); 37 C.F.R. § 404.7.

⁶² Public Citizen, Comment Letter on Notice and Request for Comments on Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement, at 12 (Jan. 31, 2024), https://www.citizen.org/wp-content/uploads/Public_Citizen_Comment-Re_WHO_Pandemic_Instrument.pdf.

⁶³ GHIAA, *Equitable Access Obligations in Funding Agreements: Best Practice Considerations*, MAPGUIDE: EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/equitable-access-pyramid/> (last visited July 21, 2024).

⁶⁴ *Agreements with Innovators*, MEDS. PAT. POOL, <https://medicinespatentpool.org/progress-achievements/licences> (last visited Jan. 22, 2024).

⁶⁵ UNIVS. ALLIED FOR ESSENTIAL MED., EQUITABLE TECHNOLOGY ACCESS FRAMEWORK 9 (July 2020).

If NIH chooses not to make agreements available, it should maintain a publicly accessible website reporting, at minimum, the following terms (as applicable):

- NIH patents licensed
- Primary Investigator involved in development of the NIH technology
- Summary of provisions on ownership of IP and background IP, licensing, and sublicensing
- Provisions on access, including pricing and supply terms, or full Access Plans
- Accountability provisions, such as step-in rights, termination of licenses, or conversion to nonexclusive licenses.

Second, we suggest modifications to the transparency obligations in the draft policy if NIH adopts Access Plans over conditions. In these circumstances, it is essential that Access Plans, waivers, modifications, and compliance reporting can be monitored by the public and by civil society. According to the draft policy, licensees must provide a non-confidential version of any Access Plans without “proprietary information,” to be defined by the agency, which “NIH may publish or otherwise make available to third parties.” If NIH adopts a view of “proprietary information” that aligns with the definition of trade secrets under federal law, we strongly urge NIH not to accede to *carte blanche* assertions of trade secret protections on information within Access Plans, particularly with respect to pricing and supply in LMICs. That is, information as basic as the pricing of products relying on publicly owned technologies should not be withheld from the public. More generally, it is flawed to claim that the pricing of any medical product is proprietary and commercially sensitive; price competition is a normal function of markets and arguments that concealing prices fosters innovation are dubious.⁶⁶ Disclosure of supply and pricing terms in Access Plans would also be consistent with the resolution approved by the World Health Assembly, and supported by the U.S., on “Improving the transparency of markets for medicines, vaccines, and other health products.”⁶⁷

Critically, we strongly urge NIH against assuring any secrecy with respect to Access Plans: these Plans concern public interest objectives on publicly owned technologies, and thus should be available to the *public*; additionally, government assurances of secrecy can result in liability for disclosure under the Takings Clause.⁶⁸ For this reason, we recommend that NIH avoid any assurances of secrecy for Access Plans.

Should NIH have other concerns about disclosing material terms publicly, which we believe lack merit, NIH can also aggregate information across Access Plans. Moreover, NIH can share even

⁶⁶ Robin C. Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Overreach*, 22 YALE J.L. & TECH. 61, 97 (2020).

⁶⁷ World Health Assembly, Res. 72.8, *Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products*, W.H.O. Doc. A72-R8 (May 28, 2019).

⁶⁸ Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 COLUM. L. REV. 493, 553–54 (2024).

information that is considered trade secret if it does so under a license for noncompetitive purposes, or limits disclosure to a subset of recipients who are not competitors.⁶⁹

Thus, in our view, the policy should expressly provide that NIH will (not “may”) publish all Access Plans (or, at the very least, non-confidential versions with all material terms as to supply and pricing), as well as: notice of any waivers or modifications (with justifications); progress reports; and all suggestions or recommendations made by NIH regarding compliance with, or amendments to, Access Plans.

We briefly note that confidentiality requirements under 35 U.S. Code § 209(f) are inapplicable to the Access Plan: marketing and development plans under § 209(f) are formulated to show an agency why an entity deserves a license in the first place, i.e., to show they can actually practice the federal invention if licensed. Access Plans are formulated when NIH has already decided to grant a license relying on this protected information and cover public interest objectives that should be transparent with the public. The plans are distinct as a legal matter, and thus the confidentiality limitations of § 209(f) do not apply. Should NIH have further concerns about transparency with respect to Access Plans, we believe conditions, again, would be a more effective choice for advancing access objectives. There is no question that access conditions in licensing agreements would not be subject to the confidentiality limitations on marketing and development plans covered by 35 U.S. Code § 209(f); to the extent that industry may raise arguments that transparency for Access Plans may be limited under 35 U.S. Code § 209(f), which we believe is an erroneous reading of the statute, NIH should instead use access conditions.

Third, NIH can advance equitable access by maintaining a public database of licensing opportunities to supply in LMICs. NIH already promotes successful licensing by maintaining an active database of licensing opportunities.⁷⁰ To advance global access objectives, NIH could add to this database opportunities for licensing NIH technologies and follow-on improvements on reasonable terms and conditions, either from a licensee or from NIH, for supply in LMICs.

In sum, we recommend that NIH publish its licensing agreements and, at a minimum, any provisions on access and affordability should remain unredacted and published in a timely manner. If NIH adopts the Access Plan approach, which is not preferred, Access Plans should be published in full, along with notices of any waivers or modifications (with justifications); progress reports; and all suggestions or recommendations made by NIH on compliance with, or amendments to, Access Plans. NIH should not provide any assurances of secrecy on these Access Plans to avoid certain legal liabilities. Finally, NIH should include in its existing databases opportunities to license NIH technologies and follow-on improvements for supplying LMICs.

⁶⁹ Amy Kapczynski, *The Public History of Trade Secrets*, 55 U. C. DAVIS L. REV. 1367, 1438-1440 (2022).

⁷⁰ *Technology Transfer: Opportunities*, NAT. INSTS. HEALTH, www.techtransfer.nih.gov/search (last visited June 11, 2024).

1.6. Survival of equitable access obligations

As NIH licenses its intramural technology, the agency should consider the stage of development relevant to the license and include provisions to ensure that access obligations follow the technology into late-stage development. Given that NIH technologies are often in early stages of research and development, there is a high likelihood that NIH's initial licensee of an early-stage technology may sublicense or transfer this IP to another partner to advance late-stage development and commercialization of such technology. There is a danger, then, that the effect of any access conditions or Access Plan could be nullified if access obligations are not appropriately structured to follow the technology through subsequent sublicensing and IP transfer. Multiple institutions and funders have devised clauses to address these scenarios and ensure the survival of their access commitments.

For example, the Gates Foundation included a detailed survival clause in an agreement with Novavax to develop an affordable RSV vaccine for maternal immunization in low-income countries. That clause applied to Novavax's "assets necessary to perform" the obligations under the agreement and provided that, in the event that the assets are acquired by a third party, that Novavax "will ensure all such obligations are assumed by the licensee, purchaser, transferee, acquirer, or successor in a written agreement reasonably acceptable to" the Foundation.⁷¹ The clause also prohibited Novavax from granting any rights to a third party or entering into any agreements that would limit the ability of Novavax or the third party acquiring its assets to fulfill the obligations of the agreement.⁷²

The obligations that follow the transfer of Novavax's assets subject to this clause incorporate highly-specific global access commitments including, but not limited to, submitting a dossier for WHO prequalification, seeking registration in developing countries upon WHO prequalification using WHO's collaborative procedure, ensuring an aggregate minimum supply of the vaccines is available annually, a redacted price commitment based on costs and a mark-up that cannot exceed a maximum redacted price, and an obligation to use reasonable and diligent efforts to bid on the relevant public sector tenders.⁷³

Similarly, UBC has included a provision to ensure sublicensees and other entities involved in the commercialization of the university's technology abide by global access principles. That provision

⁷¹ GHIAA, *How Can Agreement Provisions Ensure Sustainable Access to Funded Products?*, MAPGUIDE EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/ensuring-sustainability/> (last visited July 21, 2024); GHIAA, *Gates Foundation – Novavax, RSV Vaccine Global Access Commitments Agreement: Equitable Access | Access plans & principles*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE), https://ghiaa.org/provision_document/gates-foundation-novavax-rsv-vaccine-global-access-commitments-agreement/ (last visited July 21, 2024).

⁷² GHIAA, *Gates Foundation – Novavax, RSV Vaccine Global Access Commitments Agreement* (2015), MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE), https://ghiaa.org/provision_document/gates-foundation-novavax-rsv-vaccine-global-access-commitments-agreement/.

⁷³ *Id.*

provides that “the Licensee agrees to require all sublicensees and other parties involved in any aspect of the commercialization of the Technology, Improvements and any Products to execute agreements that bind such sublicensees or other parties . . . to comply with the Global Access Principles.”⁷⁴

We recommend that access conditions, or Access Plans with specific milestones, follow the transfer or sublicensing of assets related to NIH’s licensing agreement, just as the Gates Foundation and UBC have done. If NIH proceeds with adopting Access Plans, at a minimum, downstream entities that receive NIH technology should either comply with the initial licensee’s Access Plan (and any review and reporting requirements) or formulate a new Access Plan with specific milestones.

Additionally, we recommend that NIH draw on three specific practices used by CEPI and the Gates Foundation to ensure the survival of access obligations. These include (1) barring third-party agreements and subsequent transfers of technology from limiting the fulfillment of access obligations, (2) NIH review of third-party agreements to ensure the survival of equitable access obligations, and (3) requiring partners to include provisions in third-party agreements allowing NIH to enforce access requirements against these third parties.⁷⁵ NIH is already required by law to approve assignments of the license to a distinct entity or any sublicensing agreements by the licensee, and thus NIH can ensure the survival of access obligations in these agreements.⁷⁶

Finally, NIH licensing agreements should expressly stipulate that these obligations are *conditions* of the patent license, such that their contravention will place the licensee’s (and their sublicensee’s or contractor’s) exploitation of the NIH patents outside the authorized scope of the license. In these circumstances, the partner would be infringing NIH’s patents if it violated the access obligations. This avoids the possibility of courts determining that these obligations are “independent covenants” under the contract, rather than conditions of the license, which would

⁷⁴ Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC’Y 14, 32 (Mar. 2023).

⁷⁵ CEPI & VARIATION BIOTECHNOLOGIES INC., *COVID-19 Outbreak Response Agreement (ver 3.1)*, at 27 (Mar. 9, 2021), https://ghiaa.org/wp-content/uploads/2022/12/CEPI_VBI-COVID19-outbreak-response-agreement.pdf; GATES FOUND. & CUREVAC GMBH, *Global Access Commitments Agreement*, at 11-12 (Feb. 13, 2015), https://ghiaa.org/wp-content/uploads/2021/06/BMGF_CureVac-Global-Access-Commitments-Agreement.pdf.

⁷⁶ 37 C.F.R § 404.5(b)(3) (“The license may extend to subsidiaries of the licensee or other parties if provided for in the license but shall be nonassignable without approval of the Federal agency, except to the successor of that part of the licensee’s business to which the invention pertains”); 37 C.F.R § 404.5(b)(4) (“The license may provide the licensee the right to grant sublicenses under the license, subject to the approval of the Federal agency. Each sublicense shall make reference to the license, including the rights retained by the Government, and a copy of such sublicense with any modifications thereto, shall be promptly furnished to the Federal agency”).

give rise to more limited contractual remedies rather than an action for infringing NIH's patents.⁷⁷ Additionally or alternatively, NIH may seek to stipulate that contraventions of access obligations are material breaches giving rise to contract termination or other remedial rights.

In summary, we recommend that NIH include a provision in its model licensing agreements to ensure access obligations survive the transfer of NIH technology to other parties, as such transfers are likely in the development of early-stage NIH technology. In particular, we advocate that access conditions, existing Access Plans with milestones for global access, or the obligation to devise a new Access Plan with milestones follow the transfer of assets related to NIH's licensing agreement. Finally, we suggest NIH include provisions that: bar third-party agreements and subsequent transfers of technology that conflict with pre-existing access obligations; allow NIH to review third-party agreements to ensure the survival of these obligations; and require licensees to include provisions allowing NIH to enforce access obligations against third parties acquiring NIH technology.

1.7. The scope of the policy should be expanded to include third-party IP rights

The proposed policy expressly excludes third-party IP rights from its scope (Appendix, Section I), which creates uncertainty and should be clarified to the extent that proposed access strategies can, and should, implicate the IP rights of licensees, as recognized by multiple prominent institutions.

For example, NIH proposes "committing to license all intellectual property and know-how needed to make a product if the licensee exits a market" as an example of a desirable access strategy, distinct from sublicensing NIH IP rights to manufacturers in other countries or regions (Appendix, Section II). We understand this to refer to the licensee's *own* IP rights and know-how, and thus the draft policy's scope with respect to third-party IP rights should be clarified.

As NIH IP is often restricted to the early-stage of technology development, end-stage products will often rely upon the licensee's IP, including background IP generated before entering an agreement with NIH and other IP that may be required to enable practice of the publicly supported invention, including follow-on patents. There is broad consensus that the licensing of background IP, know-how, and follow-on innovations is a critical component of effective access, as recognized by DNDi, the Gates Foundation, UBC, and CEPI.

DNDi secures a "non-exclusive, worldwide, perpetual, irrevocable, fully paid, royalty-free license, with the right to sublicense to Third Parties under Partner's rights to and interests in Partner Background Technology and Partner Collaboration Technology" when it is necessary or useful for earlier-stage research and later-stage development purposes, or for non-commercial

⁷⁷ Kenall Mfg. Co. v. Cooper Lighting, LLC, 338 F. Supp. 3d 841 (N.D. Ill. 2018); *cf.* Roche Diagnostics Corporation v. Meso Scale Diagnostics, LLC, 503 F. Supp. 3d 156 (D. Del. 2020).

uses.⁷⁸ Importantly, DNDi includes within its definition of background IP “technology developed by such party, after the signature of the agreement outside the scope of the collaboration, and which is necessary or useful to the collaboration or to exercise granted licensing rights.”⁷⁹

For their own humanitarian licenses designed to achieve global access, the Gates Foundation has required that grantees provide the Foundation with “a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license” to use a funded development and essential background IP, defined as “Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development.”⁸⁰

UBC has included a provision in their licensing agreement, which states that “the rights granted to the Licensee under this Agreement shall at all times be subject to a reservation by the University of a transferable, irrevocable, perpetual, non-exclusive right to use and sublicense the Technology, and any Improvements and to manufacture, have made, distribute, and sell the Products for the benefit of the Developing World.”⁸¹

CEPI has included similar licensing of background IP and enabling rights in its development agreements when exercising a public health license.⁸² The public health license is a worldwide, royalty-free license that is triggered upon certain events, such as when an awardee does not wish to continue with CEPI for an additional work package, where the awardee and CEPI agree that the awardee will not be able to accomplish a defined work package, or when the awardee is in breach of the agreement or Equitable Access Plan.⁸³ CEPI is entitled to sublicense project results, enabling IP and background IP under the agreements terms, and defines enabling rights as contractual rights, IP or project results that could be asserted by the Awardee against CEPI to

⁷⁸ Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, *Striking fair deals for equitable access to medicines*, 18 J. INTELL. PROP. L. & PRAC. 323, 328-29 (2023).

⁷⁹ *Id.* at 326.

⁸⁰ GHIAA, *How Can Agreement Provisions Ensure Sustainable Access to Funded Products?*, MAPGUIDE EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/ensuring-sustainability/> (last visited July 21, 2024).

⁸¹ Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC’Y 32 (Mar. 2023); see also Nancy Gallini et al., *Implementation and Impact of the Global Access Principles at the University of British Columbia: Current Successes and Future Challenges*, 14 FRONT. PHARMACOL. 1, 5 (2023) (highlighting UBC’s practice of gaining “. . . access to any improvements developed by a licensee of a UBC technology necessary to sublicense to another company that can meet our GA principles”).

⁸² GHIAA, *CEPI – Novavax, COVID-19 Vaccine Funding Agreement: Equitable Access | Ensuring continuity*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE), https://ghiaa.org/provision_document/novavax-cepi-outbreak-response-to-novel-coronavirus-covid-19-funding-agreement-5/ (last visited July 21, 2024).

⁸³ *Id.*

prevent the exercise of its public health license.⁸⁴ CEPI also defines background IP to include licensed third-party background IP (that is, IP that CEPI's partner is licensing from another entity) and provides for payment to the third party to use their background IP.⁸⁵

We strongly recommend that the scope of the policy be clarified to cover background IP and that, to effectuate freedom to operate for manufacturers supplying LMICs, NIH should proactively include provisions for licensing third-party IP. We prefer the approach used by DNDi and UBC of including a provision that affirmatively licenses background IP and improvements in the initial licensing agreement, rather than conditioning a license to background IP on the formal exercise of step-in rights. NIH should also be aware of other parties' background IP rights (not just the licensee's) that could hamper access to products relying on NIH technology and seek the licensee's cooperation in obtaining these rights. Any license to background IP, enabling rights, or follow-on technology should be irrevocable, perpetual, transferable, and nonexclusive to ensure certainty for manufacturers supplying LMICs.

In sum, we strongly recommend that NIH clarify the scope of the draft policy as licensee's access strategies can, and should, address third-party IP rights that may be critical to ensuring downstream access to licensed products. Thus, we also believe it is necessary to remove the limitation in the draft policy that licensing IP and know-how needed to make a product is restricted to circumstances where a licensee exits a market (Appendix, Section III). Additionally, NIH should include provisions for licensing these background and follow-on rights, just as prominent funders and universities do.

1.8. Preference for nonexclusive licensing

We agree, as is currently proposed, that the policy should apply to all exclusive, partially exclusive, and nonexclusive licenses. Where possible, however, we advocate that NIH issue nonexclusive rather than exclusive licenses to its technologies, which multiple organizations support.⁸⁶ We understand that NIH makes this determination in accordance with the criteria specified under regulations, including prerequisite determinations that "the public will be served" by the granting of the exclusive license and that "the proposed scope of exclusivity is not greater than is reasonably necessary" to promote its practical application or utilization by the public.⁸⁷ Ensuring equitable access to health products developed using NIH technology is a critical consideration in determining whether "the public will be served".

As DNDi has written, nonexclusive licensing, in contrast to exclusive licensing, allows DNDi to share its knowledge with the larger research community, secure additional manufacturers of

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Public Citizen, Comment Letter on Maximizing NIH's Levers to Catalyze Technology Transfer (July 27, 2023), <https://www.citizen.org/wp-content/uploads/Public-Citizen-Comments-to-the-National-Institutes-of-Health-re-Maximizing-NIHs-Levers-to-Catalyze-Technology-Transfer.pdf>.

⁸⁷ 37 C.F.R. § 404(a)(2).

relevant technologies, and provide flexibility to build local capacity and improve security of supply and sustainable production.⁸⁸ Effectively, nonexclusive licensing brings in more collaborators in researching and developing technologies to advance global health principles and avoids the duplication of efforts particularly in resource-limited research areas. This is favored over the restrictiveness that attaches to exclusively licensing technologies to one entity. Examples include DNDi's 2012 agreement with AbbVie for researching new treatments for Chagas disease, helminth infections, leishmaniasis, and sleeping sickness, which subjected IP from the collaboration and background IP to nonexclusive licensing conditions.⁸⁹

DNDi has agreed to only a handful of exceptions to the principle of nonexclusive licensing, such as when the licensee would need to make large investments in infrastructure and the field is competitive, which is rare in its research area of neglected tropical diseases.⁹⁰ In other situations, the partner insisted on limited periods of exclusivity for indications outside of the field of research in the DNDi collaboration.⁹¹ Where DNDi granted exclusivity to partners, the exclusivity was subject to significant limitations, including exclusivity only for 3–5 years after market authorization, exclusivity only for certain territories, equitable and affordable access obligations attaching to the exclusive license to prevent abuse, and reversion of the exclusive license back to nonexclusive in certain cases, such as a lack of diligence by the partner.⁹²

Additionally, Knowledge Ecology International has advocated that exclusive licenses be limited to exclude countries with average incomes that are a third of the United States.⁹³ Similarly, Public Citizen has urged NIH to assess whether “a license should be nonexclusive or have its exclusivity limited, for example, by omitting [LMICs] from the geographic scope of exclusivity or by providing that a licensee will have its exclusivity curtailed or eliminated after certain revenue benchmarks have been achieved.”⁹⁴

It has been argued – and we agree – that continued license exclusivity should be tied to specific milestones, such as volume of sales in LMICs or latest product launch date in LMICs, to ensure that any grant of exclusivity (that is, to the licensee's commercial advantage) is justified by

⁸⁸ Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, *Striking fair deals for equitable access to medicines*, 18 J. INTELL. PROP. L. & PRAC. 323, 329 (2023).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Knowledge Ecol. Int'l, Comment Letter on Prospective Grant of an Exclusive Patent License: Vaccine Augmented Adoptive Cell Therapy for the Treatment of Cancer (89 FR 8438) (Feb. 22, 2024), <https://www.keionline.org/wp-content/uploads/KEI-Comments-NIH-License-Marble-Therapeutics-22Feb2024.pdf>.

⁹⁴ Public Citizen, Comment Letter on Maximizing NIH's Levers to Catalyze Technology Transfer (July 27, 2023), <https://www.citizen.org/wp-content/uploads/Public-Citizen-Comments-to-the-National-Institutes-of-Health-re-Maximizing-NIHs-Levers-to-Catalyze-Technology-Transfer.pdf>.

corresponding benefit to the public.⁹⁵ In other words, the licensing agreement may stipulate that if the licensee fails to meet certain targets for access in LMICs within a reasonable amount of time, the license becomes nonexclusive so that others can address unmet need in these countries; this may be particularly appropriate for late-stage licensing agreements. Similarly, NIH may also consider whether exclusivity could be limited in duration.

In sum, as federal law restricts the conditions under which NIH may issue exclusive or partially exclusive licenses,⁹⁶ and in accordance with federal policy, we advocate for nonexclusive licensing where practicable. To the extent that market conditions or lack of potential licensees require exclusive licensing, those licenses should be subject to equitable access obligations, bound in terms of time and geography, or tied to specific milestones.

2. Recommended Obligations in Later-Stage License Agreements

NIH seeks information on specific, access-oriented licensee obligations to be included in licensing agreements, particularly later-stage agreements (RFI Issue 5). We strongly recommend that such provisions are included in NIH license agreements as a matter of course, instead of sole reliance on non-binding and self-determined Access Plans. This section includes potential licensee obligations to promote access to health technologies developed and commercialized using NIH inventions. NIH should seek to include as many of these as possible in its licensing agreements, particularly for late-stage technologies that are closer to market launch.

2.1. Partnering with public health organizations

We support NIH's proposal of licensees partnering with public health, non-profit, or patient advocacy organizations as an example of an acceptable access strategy, especially the proposal to license IP to public health licensing bodies such as the Medicines Patent Pool (MPP) (*see* Appendix, Section III). NIH may consider explicitly advancing collaborations with qualified third parties in licensing agreements, including licensing bodies and WHO, to promote humanitarian access to medicines developed with the agency's technology and to facilitate registration in LMICs.

Collaborations with licensing bodies

The federal government recognizes the value of technology licensing bodies for global health, and NIH can integrate terms into licensing agreements providing for collaborations with these institutions. In May 2022, NIH licensed its COVID-19 technologies to MPP through WHO's COVID-19 Technology Access Pool (C-TAP) to advance global access to these lifesaving

⁹⁵ MOHAMMAD SHAHZAD, PROMOTING GLOBAL ACCESS TO HEALTH TECHNOLOGIES: A LICENSING TOOLKIT FOR PUBLIC SECTOR INSTITUTIONS 28 (Aug. 2022), https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf.

⁹⁶ 35 U.S.C. § 209.

technologies.⁹⁷ With respect to CARB-X, a partnership designed to address the threat of drug-resistant bacteria, HHS's Office of Global Affairs and the Biomedical Advanced Research and Development Authority (BARDA) endorsed collaborating with MPP in a Stewardship & Access Plan Development Guide for awardees to use in developing such plans pursuant to their award agreements.⁹⁸

Similarly, NIH can include obligations for licensees to license and transfer their intellectual property and know-how on reasonable terms and conditions to licensing bodies, such as MPP or WHO's Health Technology Access Pool (H-TAP), if they seek licensure. Licensing bodies can then sublicense to generic manufacturers that are willing to supply LMICs. Such arrangements may be attractive to licensees seeking to meet equitable access conditions in NIH agreements by allowing them to rely on the capacity and expertise of these multilateral entities to coordinate and support the manufacture of downstream products for LMICs, as opposed to coordinating these efforts alone. To the extent that licensing bodies do not seek a license, NIH may still advance equitable access in LMICs by including an obligation to make available nonexclusive licenses on reasonable terms and conditions for the tailored purpose of supply to LMICs.

Collaborations for accelerating registration in LMICs

Collaborations with WHO to achieve accelerated registration in LMICs can also address the fraught phenomenon where pharmaceutical firms fail to register medicines in LMICs at all, which thereby prevents generic manufacturers from relying on their data to obtain approval. In these circumstances, generic manufacturers must go beyond proving bioequivalence and repeat clinical trials, which "raises serious ethical questions, since it would imply withholding medicines that are already known to be effective from some patients (the control group), solely for commercial purposes."⁹⁹ To avoid these ethical issues, NIH can advance registration in LMICs in licensing agreements by promoting use of WHO's collaborative procedure for accelerated registration, when appropriate.

WHO created accelerated registration procedures with 60 participating countries for finished pharmaceutical products either (1) approved by a stringent regulatory authority (SRA) (including the FDA and EMA) or (2) has been prequalified by WHO's prequalification program.¹⁰⁰ The collaborative procedure allows confidential information sharing between WHO, the national medical registration authority (NMRA) and, where applicable, the SRA, to expedite the process

⁹⁷ NIH Contributions to WHO COVID-19 Technology Access Pool and Q&As, NAT. INSTS. HEALTH (May 12, 2022), <https://www.techtransfer.nih.gov/policy/ctap>.

⁹⁸ STEWARDSHIP & ACCESS PLAN (SAP) DEVELOPMENT GUIDE (2021), https://carb-x.org/wp-content/uploads/2021/03/Stewardship_Access_DevGuide_2021.pdf.

⁹⁹ Karin Timmermans, *Monopolizing Clinical Trial Data: Implications and Trends*, 4 PLOS MED 206, 207 (2007).

¹⁰⁰ *Collaborative Procedure for Accelerated Registration*, WORLD HEALTH ORG., <https://extranet.who.int/prequal/medicines/collaborative-procedure-accelerated-registration> (last visited July 21, 2024).

of registration in participating countries where the product has already undergone the intensive procedure of WHO prequalification or approval by the SRA.¹⁰¹ Through this procedure, the local registration authority commits to providing a decision within 90 days of receiving access to WHO's or the SRA's assessment and inspection information.¹⁰²

The accelerated registration procedure is restricted to SRA-approved finished pharmaceutical products "with public health relevance" according to WHO,¹⁰³ or finished pharmaceutical products that are prequalified by WHO, which is limited to a number of therapeutic areas.¹⁰⁴

NIH licensing agreements can promote use of WHO's accelerated collaborative registration procedure if the downstream product using NIH-technology falls into either category of eligible products and pursuing the accelerated registration procedure would be faster than other avenues available for registration and supply in LMICs. NIH can draw on the agreement between the Gates Foundation and Novavax for developing an RSV vaccine for maternal immunizations, which has provisions advancing use of WHO's collaborative procedure.¹⁰⁵ Thus, including such measures in licensing agreements can proactively facilitate wider registration in LMICs and address capacity concerns from licensees.

2.2. Timely registration and supply in LMICs

To more directly address the issue of delayed registration in LMICs,¹⁰⁶ NIH may consider more specific provisions detailing registration milestones in these countries. These provisions can also specify timelines for supply after registration to prevent scenarios in which downstream manufacturers register in LMICs but delay affordable supply. We note, for example, NIH's inclusion of "committing to supply product in a given market(s) for a designated duration" as an example of an access strategy (Appendix, Section III); in order to be effective, any such commitment should specifically address affordability, timelines, and the proportion or volume

¹⁰¹ *Accelerated Registration of Prequalified FPPs*, WORLD HEALTH ORG., <https://extranet.who.int/prequal/medicines/accelerated-registration-prequalified-fpps> (last visited July 21, 2024).

¹⁰² *Id.*

¹⁰³ *Accelerated Registration of FPPs Approved by SRAs*, WORLD HEALTH ORG., <https://extranet.who.int/prequal/medicines/accelerated-registration-fpps-approved-sras> (last visited July 21, 2024).

¹⁰⁴ *FPPs & APIs Eligible for Prequalification ("EOIs")*, WORLD HEALTH ORG., <https://extranet.who.int/prequal/medicines/fpps-apis-eligible-prequalification-eois>. (last visited July 21, 2024).

¹⁰⁵ GATES FOUND. & NOVAVAX, INC., *Global Access Commitments Agreement*, at 6 (Sept. 25, 2015), https://ghiaa.org/wp-content/uploads/2022/11/Gates_Novavax-Global-Access-Commitments-Agreement.pdf.

¹⁰⁶ Vincent Ahonkhai et al., *Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization*, 11 PLOS ONE e0166515 (2016).

of supply, to avoid a situation where licensees could comply strictly with the commitment by providing a *de minimis* supply that makes no meaningful impact on access.

At minimum, NIH should require licensees to commit to timely registration and supply of licensed products, on an affordable basis, in (1) any LMICs where **clinical trials** have been conducted for that product, or (2) any LMICs where the product can be used to prevent, diagnose, or treat an **endemic disease**. Where the licensee is unwilling or unable to supply in those countries, the licensee should be required to provide all necessary sublicenses, know-how, and data to allow other manufacturers to supply these countries.

First, it is well-documented that LMIC populations on whom clinical trials are conducted are often deprived of equitable access to new drugs once approved. A recent study of 70 countries contributing research participants to clinical trials supporting FDA new drug approvals reported that only 7% of those countries received market access to drugs tested on their populations within one year of U.S. approval, rising to only 31% within five years.¹⁰⁷ For low-income countries, those figures dropped to 0% within one year of U.S. approval and 22% within five years.¹⁰⁸ As a matter of equity and justice, NIH should require those countries to be prioritized. To prevent licensees from circumventing this requirement by failing to conduct clinical trials in LMICs at all, NIH should provide for conducting clinical trials in LMICs where a licensed product can be used to prevent, diagnose, or treat an endemic disease in licensing agreements.

More generally, LMICs where a licensed product can address endemic diseases should be prioritized for registration and supply. DNDi's licensing agreements with pharmaceutical manufacturers, developed by DNDi and its partners to reflect "'gold-standard' licensing principles," include provisions giving it distribution and sale rights of medical products in all countries in which relevant diseases are endemic, as reported by WHO.¹⁰⁹ DNDi also has template terms for registering and supplying licensed products in endemic countries that NIH may wish to draw upon.¹¹⁰

NIH licensing agreements should require licensees to consult with NIH in good faith regarding plans to register and supply in LMICs other than (1) where relevant clinical trials have been conducted and (2) where relevant diseases are endemic. Further, we briefly note that NIH should ensure licensees prioritize LMICs where clinical trials have been conducted or where diseases are

¹⁰⁷ Jennifer E. Miller et al., *Evaluation of Drug Trials in High-, Middle-, and Low-Income Countries and Local Commercial Availability of Newly Approved Drugs*, 4 JAMA NETWORK OPEN e217075 (2021).

¹⁰⁸ *Id.*

¹⁰⁹ Dominique Moser et al., *Striking Fair Deals for Equitable Access to Medicines*, 18(4) J. INTELL. PROP. L. & PRAC. 323 (2023).

¹¹⁰ GHIAA, *DNDi Template Development Collaboration and License Agreement*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE) (2023), https://ghiaa.org/provision_document/dndi-template-development-collaboration-and-license-agreement-4/.

endemic for registration and supply in Access Plans as specific milestones, while providing for good faith consultation on registration and supply in other LMICs.

We encourage NIH to negotiate timelines for affordable supply in LMICs following product registration (including, at least, the priority LMICs described in the above paragraphs). Provisions can be included to add flexibility if these timelines become infeasible, for example, due to delays in registration processes, where NIH and parties agree in good faith to negotiate modifications to the original timelines. As stated above, NIH can reference the WHO collaborative procedure for registration in various LMICs to facilitate achievement of these timelines.

Unreasonable failure to comply with these timelines and/or cooperate in the adjustment process could enliven remedial rights allowing the licensing of all relevant intellectual property and know-how to ensure unmet need in LMICs is addressed. For example, NIH may grant a license to another manufacturer (section 2.3) or require the licensee to grant a sublicense to a manufacturer (section 2.5) for production and supply in LMICs. Above, we described instances where an exclusive license may be terminated (section 1.4) or reverted to a nonexclusive license (sections 1.4 & 1.8). Any of these mechanisms may be used to remedy a failure to meet timely registration and supply obligations. Alternatively, NIH could rely on a covenant by the licensee not to sue developers providing products covered by the milestone in cases of unreasonable delay.

In sum, NIH may consider provisions in late-stage licensing agreements providing for timely registration and supply in (1) LMICs where **clinical trials** were conducted for a medical product's marketing authorization and (2) LMICs in which a licensed product can be used to prevent, diagnose, or treat an **endemic disease**. Further, we encourage NIH to include provisions requiring good faith consultation on the registration and supply of licensed products in other LMICs. Unreasonable failure to comply with these provisions on registration and supply requires NIH to exercise remedial rights to effectuate the access policy and meet health needs in LMICs.

2.3. Reserved rights for humanitarian licensing

Like other institutions, such as Harvard, UC Berkeley, and UBC, NIH can reserve for itself a right to license its technology for “humanitarian purposes” in licensing agreements, even in otherwise exclusive licensing agreements.¹¹¹ As discussed previously with respect to step-in rights, federal

¹¹¹ MOHAMMAD SHAHZAD, PROMOTING GLOBAL ACCESS TO HEALTH TECHNOLOGIES: A LICENSING TOOLKIT FOR PUBLIC SECTOR INSTITUTIONS 15–17 (Aug. 2022), https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf; see also U.C. Berkeley, Sample Exclusive Licensing Agreement ¶ 3.3, <https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf>; Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC'Y 32 (Mar. 2023) (discussing UBC's provision that “the rights granted to the Licensee under this Agreement shall at all times be subject to a reservation by the University of a

law already requires agencies to reserve for themselves licensing rights in exclusive or partially exclusive licenses. That is, any exclusive or partially exclusive license on a federally owned invention must include a provision “retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States.”¹¹²

Building on the rights NIH must already reserve for itself in exclusive or nonexclusive licenses, we advocate that NIH retain rights to issue a license that is perpetual, transferable, irrevocable, and nonexclusive for a non-profit or third party anywhere in the world to supply products using NIH technology in LMICs at affordable prices. Restrictions may be introduced to limit the sale or export of licensed products to high-income markets, but we advocate that the humanitarian license preserve the right to sell or export a product developed with NIH technology in other LMICs during any period of time in which an adequate affordable supply of the product is not available in those countries, as universities have included in the past.¹¹³

Licensing solely NIH’s technology for humanitarian purposes may be insufficient to make the license practicable in LMICs, particularly where products may infringe additional patents held by the licensee (e.g., “follow-on” patents) or requires their know-how. Achieving equity, thus, requires pairing this reservation with (1) covenants not to sue developers manufacturing products for LMICs that infringe the licensee’s subsequently obtained patents on commercialized NIH technology, (2) licensing additional IP and rights held by the licensee that could restrict access to developed NIH technology, and (3) executing technology transfer to manufacturers supplying LMICs to ensure that lack of know-how does not impede global access.

2.4. Non-assertion of rights in LMICs

We advocate for NIH to negotiate provisions barring licensees from asserting licensed patents or follow-on patents in infringement actions against third parties, non-profit or for-profit, supplying licensed products to LMICs on an affordable basis.¹¹⁴ Yale is successful in negotiating terms that would prevent the licensee from asserting its own patents, not just the university’s, against

transferable, irrevocable, perpetual, non-exclusive right to use and sublicense the Technology, and any Improvements and to manufacture, have made, distribute, and sell the Products for the benefit of the Developing World”).

¹¹² 35 U.S.C § 209.

¹¹³ For a similar provision, see a mandatory sublicensing provision included in ASS’N UNIV. TECH. MGRS. *Global Health Licensing Toolkit* at 9 (Mar. 17, 2012),

<https://www.autm.net/AUTMMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

¹¹⁴ Thi-Yen Nguyen, Mohammad Shahzad, & Juliana Veras, *Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America: Identifying Key Provisions To Promote Global Access To Health Technologies*, 53 LES NOUVELLES – J. LICENSING EXECS. SOC’Y 189, 196 (Sept. 2018), <https://www.lesi.org/publications/les-nouvelles/les-nouvelles-article-of-the-month/les-nouvelles-article-of-the-month-archives/les-nouvelles-article-of-the-month-february-2019>.

infringers in LMICs.¹¹⁵ This will be important for NIH licensing practices, as follow-on patents by a licensee can defeat a non-assert provision designed to allow generic manufacturing in LMICs if it is solely restricted to NIH patents.

We recommend that NIH use Yale’s approach, which requires that the licensee will not assert the patents licensed by NIH, nor its own patents claiming the licensed product, in connection with the supply of the licensed product in LMICs, provided the activity is not intended to export the products back to the U.S. or other major market countries.¹¹⁶ “Licensed product” in this context should be defined expansively, as in Section 2.13 of Yale’s standard start-up licensing agreement, to cover any product or component developed using NIH licensed technology, or where its manufacture, use, sale, import, export, or practice is claimed by a licensed NIH patent (as well as methods that use such products).¹¹⁷

2.5. Sublicensing and transfer technology commitments

NIH may include provisions for the licensee to designate sublicensees to supply LMICs to fulfill equitable access commitments. We support NIH’s inclusion of “sublicensing to manufacturers in additional countries or world regions” and “agreeing to sublicense relevant intellectual property and know-how on a low- or no-royalty basis” as examples of acceptable access strategies, although we strongly urge that these be further refined to ensure their efficacy (including backstops to ensure that technology can be made available in LMICs where “voluntary and mutually agreed terms” cannot be reached).

While licensing can secure freedom to operate in these jurisdictions and establish pathways to critical supply, NIH may consider pairing such sublicensing provisions with affirmative obligations to transfer technology to any such designee for humanitarian purposes.¹¹⁸ These provisions may be crucial to ensuring affordable supply to LMICs in certain circumstances, such as when simply providing the freedom to operate is insufficient for manufacturers without know-how to provide safe and affordable supply in a timely manner.

¹¹⁵ Mohammad Shahzad, *Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions* 23 (Aug. 2022), https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf.

¹¹⁶ Yale Univ., *Start-Up License (Other) Agreement*, §§ 2.13, 11.2(d), <https://ventures.yale.edu/sites/default/files/2023-05/Startup%20revised%2011-22%20patented.pdf> (last visited July 19, 2024).

¹¹⁷ *Id.*

¹¹⁸ GHIAA, *Approaches to Intellectual Property Rights Management in Funding Agreements*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, https://ghiaa.org/mapguide-home/mapguide-commentaries/ip-management/#licensing_techtransfer (last visited Apr. 16, 2023) (discussing the proactive appointment of a secondary manufacturer that can meet the affordable supply needs of lower-income countries).

Sublicensing

First, there are multiple practices and expert recommendations to draw on for the purposes of modeling an effective sublicensing provision. As discussed in Section 1.1, the Massachusetts Institute of Technology (MIT) and the University of Vermont both employ a provision that defines “a ‘Charitable Objective’ as being the availability of the product in developing countries at low cost” and allows the universities to identify third parties that can commercialize the licensed products for the charitable objective and refer them to the licensee for a sublicense.¹¹⁹ If the licensee refuses to grant the sublicense, it has to provide a written report with justification for refusing the sublicense, but the university reserves “sole discretion” to issue the sublicense if it determines the refusal was unreasonable.¹²⁰ The provision states that any such license granted by the university shall be on “substantially the same terms last proposed to Licensee by the third party providing that royalty rates are at least equal to those paid by Licensee.”

NIH is already required by law to reserve the right “to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health . . . needs.”¹²¹ We recommend that NIH supplement this provision by requiring any licensee to consider sublicensing requests from qualified third parties for the supply of LMICs, to report refusals of such grants of sublicenses, and to reserve for itself “sole discretion” on whether to issue the sublicense if it deems the licensee’s refusal unreasonable.

Experts also recommend that “upon the first clinical phase trial for a licensed product, the licensee will identify a generic manufacturer in a middle-income country to produce the licensed technology at a reasonable price for developing countries.”¹²² Similarly, the Global Health Innovation Alliance Accelerator’s commentary on this topic also suggests that a provision could require that the manufacturer be located in an LMIC, which can advance the development of local manufacturing capacity in these regions.¹²³

Drawing on these practices and guidance, we recommend a provision that would require licensees to designate sublicensees in LMICs to supply LMICs generally upon clinical development of a candidate, as it advances global health security by diversifying production and

¹¹⁹ Mohammad Shahzad, *Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions* 19 (Aug. 2022), https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf.

¹²⁰ *Id.*

¹²¹ 37 C.F.R. § 404.7(b)(2).

¹²² Mohammad Shahzad, *Global Access to Health Technologies—Part 2: Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions*, 58 LES NOUVELLES – J. LICENSING EXECS. SOC’Y 18 (Mar. 2023).

¹²³ GHIAA, *Approaches to Intellectual Property Rights Management in Funding Agreements*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, https://ghiaa.org/mapguide-home/mapguide-commentaries/ip-management/#licensing_techtransfer (last visited Apr. 16, 2023).

enhancing the resilience of supply to these countries.¹²⁴ Alternatively, as stated in Section 1.1 for all licensing agreements, NIH can include an obligation that licensees consider sublicensing requests from qualified third parties seeking to supply LMICs with safeguards against unreasonable refusal, when the licensee is unable or unwilling to do so.

Technology transfer commitments

Second, NIH can proactively include conditions requiring technology transfer to designated manufacturers that will supply LMICs at an affordable price.

Examples of technology transfer obligations

One example is CEPI's agreement with Valneva for the manufacturing and late-stage clinical development of a Chikungunya vaccine.¹²⁵ That vaccine was initially developed for travelers from high-income countries but, with CEPI's involvement, was expanded to target outbreak responses and use in lower-income nations.¹²⁶ CEPI included a proactive obligation requiring Valneva to engage in technology transfer to a manufacturer in an LMIC that would manufacture the product for regular supply to non-traveler markets, which included "all [LMICs] except for a redacted list of five countries which are included in the definition of Awardee's Traveler's Market."¹²⁷ That supply to non-traveler markets was further subject to redacted pricing obligations to advance affordability.¹²⁸

CEPI included the cost of the technology transfer in the Project Budget and required Valneva to "promptly and diligently provide all necessary guidance, information, materials and assistance reasonably required to transfer [Developer]'s technology to each such Sub-[Awardee] as outlined in the [product development plan]."¹²⁹ Significantly, CEPI also included clauses allowing it, in the case of an outbreak, to request the acceleration of technology transfer timelines to sublicensees

¹²⁴ See, e.g., Clauses 16.4ff and 17 of Annex A to the Chikungunya Vaccine Funding Agreement between CEPI and Valneva (dated July 24, 2019). Although this concerns different licensing arrangements, it provides a useful example of: types of scenarios in which such a provision may be triggered; designation of an alternative manufacturer; and associated enablement and technology transfer requirements: https://ghiaa.org/wp-content/uploads/2021/08/CEPI_Valneva-Chikungunya-Vaccine-Development-Agreement.pdf.

¹²⁵ GHIAA, *CEPI – Valneva, Chikungunya Vaccine Funding Agreement*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE) (2019), https://ghiaa.org/provision_document/cepi-valneva-chikungunya-vaccine-funding-agreement-3/

¹²⁶ Richard Hatchett, *Accelerating Access to the World's First Chikungunya Vaccine*, CEPI BLOG (Nov. 9, 2023), <https://cepi.net/accelerating-access-worlds-first-chikungunya-vaccine>.

¹²⁷ GHIAA, *CEPI – Valneva, Chikungunya Vaccine Funding Agreement*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE) (2019), https://ghiaa.org/provision_document/cepi-valneva-chikungunya-vaccine-funding-agreement-3/ (see the attached full agreement).

¹²⁸ *Id.*

¹²⁹ GHIAA, *Approaches to Intellectual Property Rights Management in Funding Agreements*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, https://ghiaa.org/mapguide-home/mapguide-commentaries/ip-management/#licensing_techtransfer (last visited Apr. 16, 2023).

and expansion of the technology transfer to another party (termed “Trusted Collaborator”).¹³⁰ Content would be transferred to the collaborator, subject to an agreement that would define use and non-disclosure of information received through the technology transfer.¹³¹ Valneva has signed an agreement with Brazilian manufacturer Instituto Butantan for the supply of this vaccine to LMICs to meet this technology transfer requirement.¹³²

Another example of a funding agreement in which CEPI included technology transfer obligations is CEPI’s agreement with CureVac for the development of an mRNA platform to rapidly manufacture vaccines against infectious disease outbreaks, which required CureVac to provide “all necessary commercially reasonable support” for technology transfer activities to other manufacturers.¹³³

The Gates Foundation was specific about the information subject to technology transfer obligations in its agreement with Novavax for the development of a maternal immunization for RSV. The relevant provision states Novavax will make available to the Foundation or entities of its choosing “all necessary intellectual property, technology, know-how and other information relating to the Product (including but not limited to master batch records, [Standard Operating Procedures], [Quality Assurance and Quality Control] information, detailed bill of materials for the Product and other manufacturing documentation) for the purpose of” exercising step-in rights (Section 1.4).¹³⁴

Operationalizing technology transfer obligations in NIH licensing agreements

We support promptness and diligence provisions for technology transfer obligations to LMIC manufacturers in late-stage licensing agreements, like in CEPI’s agreement with Valneva. We also urge NIH to specifically identify information subject to these obligations, as the Gates Foundation has done. This includes “all necessary intellectual property, technology, know-how and other information relating to the Product (including but not limited to master batch records, [Standard Operating Procedures], [Quality Assurance and Quality Control] information, detailed bill of materials for the Product and other manufacturing documentation).”¹³⁵

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² Press Release, Valneva, Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries (Jan. 25, 2021), <https://valneva.com/press-release/valneva-and-instituto-butantan-sign-final-agreement-on-single-shot-chikungunya-vaccine-for-low-and-middle-income-countries/>.

¹³³ GHIAA, *CEPI – CureVac, Framework Partnering Agreement*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE) (2019), https://ghiaa.org/provision_document/cepi-curevac-framework-partnering-agreement-3/.

¹³⁴ GHIAA, *Approaches to Intellectual Property Rights Management in Funding Agreements*, MAP GUIDE: EQUITABLE ACCESS TOOLKIT, https://ghiaa.org/mapguide-home/mapguide-commentaries/ip-management/#licensing_techtransfer (last visited Apr. 16, 2023).

¹³⁵ *Id.*

We note CEPI's agreement with CureVac presents the option of requiring "commercially reasonable support" for technology transfer activities, if necessary, to address industry resistance. In these circumstances, CureVac would still be required to provide technology transfer materials to enable a recipient to "adapt, develop and use the [mRNA] Platform for the Manufacture of Products for use in the Field and in the Affected Territories" and "develop, formulate, recreate and show equivalence (where relevant) to Products developed by" CureVac.¹³⁶ Further, CureVac remained obliged, at the request of CEPI, to enable the recipient "to establish a warm base for the further Development of the Platform, and Manufacturing of Products for use in the Field in the Affected Territory."¹³⁷ That is, even where technology transfer obligations are subject to the commercially reasonable support standard, licensees should still provide materials and support to enable the manufacture and adaptation of relevant technologies. For example, we envision that, even under the commercially reasonable support standard, a licensee must transfer all previously prepared documentation and data for market authorization of a licensed product to a technology transfer recipient.

As stated above with respect to enabling knowledge sharing in all licensing agreements where a licensee fails or refuses to affordably supply LMICs with a licensed product (Section 1.1), NIH can consider limitations in technology transfer obligations on the release of know-how to other parties, if necessary, to guard against disseminating information that could give competitors an advantage. To emphasize, these provisions should be considered on a case-by-case basis; for example, such limitations on the release of know-how to other parties could impede collaborative R&D partnerships across multiple entities to meet need in LMICs like the mRNA technology transfer hub.¹³⁸

Subject to careful consideration, NIH can also include other specific provisions on a case-by-case basis to overcome industry resistance to knowledge sharing with LMICs.¹³⁹ Again, NIH could require that technology transfer recipients supplying LMICs make additional payments or pay higher royalties to the original licensee if the supplied licensed technology has been adapted to new therapeutic areas and for new indications. Thus, recipients would not be barred from innovating and adapting novel applications of a technology for addressing unmet needs in LMICs where the original licensee is unable or unwilling to do so. In exchange, the original licensee

¹³⁶ GHIAA, *CEPI – CureVac, Framework Partnering Agreement*, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE) (2019), https://ghiaa.org/provision_document/cepi-curevac-framework-partnering-agreement-3/.

¹³⁷ *Id.*

¹³⁸ *The mRNA vaccine technology transfer hub*, WORLD HEALTH ORG., <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub> (last visited July 19, 2024).

¹³⁹ Public Citizen, Comment Letter on Notice and Request for Comments on Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement, at 12 (Jan. 31, 2024), https://www.citizen.org/wp-content/uploads/Public_Citizen_Comment-Re_WHO_Pandemic_Instrument.pdf.

receives additional payments or higher royalties in new fields of use beyond those envisioned in NIH's original licensing agreement.

To help licensees fulfill technology transfer obligations, NIH may consider encouraging licensees to transfer technology to competent U.S. federal agencies or international organizations (e.g., BARDA, WHO), which could assist in sharing information and providing support or training to multiple sublicensees.¹⁴⁰

Summary

In sum, upon licensed technologies entering clinical phases of development, NIH can proactively require the identification of LMIC sublicensees that will supply LMICs, or require any licensee to consider sublicensing requests from qualified third parties seeking to supply LMICs with safeguards against unreasonable refusal. To ensure that these manufacturers not only have the freedom to operate in these countries, but the know-how necessary for long-term supply, NIH can integrate proactive technology transfer obligations into licensing agreements. The agency has multiple options for effectuating these obligations, including relying on federal agencies or international institutions experienced in sharing know-how to help licensees transfer technology for these purposes. To the extent that these obligations can facilitate local manufacturing in LMICs, NIH practice can also advance global health security through diversified and resilient production.

2.6. Waivers of regulatory exclusivity in LMICs

A common phenomenon in LMICs is delayed registration by pharmaceutical firms,¹⁴¹ which tend to prioritize high-income markets. Data exclusivity periods that attach upon delayed registration in these countries further hamper the launch of generics and biosimilars because manufacturers cannot rely on the data of the originator for approval of more affordable alternatives. As stated above, there are serious ethical questions implicated in requiring manufacturers to go beyond proving bioequivalence and repeat clinical trials in which efficacious treatments are withheld from a control group. Recognizing the detrimental consequences of these exclusivities in LMICs, DNDi includes the following provision in their collaboration and licensing agreements: "Both Parties agree, where applicable and to the extent that they are able, (a) to not seek or (b) to waive, regulatory exclusivity in relation to any data relating to the Product and arising directly or

¹⁴⁰ Zain Rizvi, Jishian Ravinthiran & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFF. FOREFRONT (Aug. 6, 2021), <https://www.healthaffairs.org/content/forefront/sharing-knowledge-president-joe-biden-can-use-defense-production-act-end-pandemic> (discussing how, after a manufacturer has shared know-how with BARDA, the agency can then help facilitate technology transfer abroad, given its expertise advancing local production of influenza vaccines globally by supporting the training of personnel from other countries).

¹⁴¹ Vincent Ahonkhai et al., *Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization*, 11 PLOS ONE e0166515 (2016).

indirectly from the Marketing Authorization of the Product.”¹⁴² Similarly, MPP has included provisions in agreements with originator companies to provide regulatory exclusivity waivers to sublicensees so they can register products in countries and achieve more equitable access.¹⁴³

Even where inclusion of such a provision is not possible, NIH can require that regulatory exclusivity in any country effectively runs from the date of first registration, by including clauses that require the licensee to disclaim or waive any period of regulatory exclusivity beyond the period that attaches to the first registration.¹⁴⁴ Doing so will incentivize pharmaceutical companies to register their medicines expeditiously in LMICs to retain longer periods of regulatory exclusivity. Another option would be to include a “use-it-or-lose-it” provision, where the licensee has, say, a year from the first date of registration to apply for registration in other countries, or else it waives regulatory exclusivity in those countries.¹⁴⁵ To address delays in registration processes caused by regulatory authorities, the clause can toll the loss of regulatory exclusivity periods for such delay or toll the loss entirely during the regulatory approval process.¹⁴⁶

3. Broader recommendations

3.1. Adopt an equitable access policy for NIH’s extramural research program

The proposed policy applies only to NIH’s intramural research. As the practices of CEPI and the Gates Foundation make clear,¹⁴⁷ it is both feasible and desirable to include equitable access provisions in funding agreements. To the extent practicable, and as soon as possible, NIH should adopt equitable access provisions in its extramural funding agreements, not just its licensing of intramural NIH technologies. As 83% of NIH’s budget is funneled into extramural research,¹⁴⁸ NIH’s inclusion of equitable access conditions in these agreements could have even more transformative consequences for the globe. Attaching public interest conditions to these funding agreements is in line with the Administration for Strategic Preparedness and Response’s practice of integrating a fair pricing standard in contract negotiations for products developed or

¹⁴² Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, *Striking fair deals for equitable access to medicines*, 18 J. INTELL. PROP. L. & PRAC. 323, 327 (2023).

¹⁴³ *Nilotinib* [MPP Agreement with Novartis for Supply of Nilotinib], MEDS. PAT. POOL (Oct. 2022), <https://medicinespatentpool.org/licence-post/nilotinib>.

¹⁴⁴ Brook Baker, *Ending Drug Registration Apartheid – Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L., MED. & ETHICS 38 (2008).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* at 38 n. 191.

¹⁴⁷ *Global Access Statement*, GATES FOUND., <https://www.gatesfoundation.org/about/policies-and-resources/global-access-statement> (last visited July 19, 2024); CEPI, *EQUITABLE ACCESS FRAMEWORK* (May 2023), https://static.cepi.net/downloads/2024-03/CEPI_Equitable%20Access%20Framework_May%202023_0.pdf.

¹⁴⁸ *What We Do: Budget*, NAT. INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> (last visited July 19, 2024).

purchased with its funding.¹⁴⁹ Further, integrating equitable access conditions in extramural funding agreements can overcome the inaccessibility of lifesaving medicines in LMICs.

4. Conclusion

We commend NIH for taking the first steps toward tackling global affordability and supply challenges to products developed with the agency's technology. The licensing practices recommended in this document can truly benefit millions of people who have long been neglected. Through these recommendations, we hope that the agency can ensure its science is available to all who need it.

Sincerely,

Public Citizen

¹⁴⁹ Press Release, U.S. Dep't Health & Hum. Servs., New HHS Actions and Research Highlight How President Biden's Administration is Lowering Prescription Drug Costs (Dec. 14, 2023), <https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html>.

APPENDIX

Case Study: Darunavir

We provide a case study of the drug, darunavir (marketed as Prezista by Johnson & Johnson), to illustrate the potential impact of these equitable access provisions and how NIH can build on its legacy of broadening global access to medicines. Darunavir helps treat HIV infection and was often used when prior therapies failed.¹⁵⁰

The NIH Office of Technology Transfer had granted a nonexclusive license to Tibotec, which was later acquired by Janssen (Johnson & Johnson), for patents on treating HIV infections in patients that had developed resistance to treatments.¹⁵¹ The technology was derived from research by the National Cancer Institute and University of Illinois at Chicago.¹⁵² In 2006, Tibotec received FDA approval for darunavir, which was covered by NIH patents and additional patents held by Johnson & Johnson.

In 2010, NIH took the landmark step of being the first patent holder to share its IP with the newly formed Medicines Patent Pool (MPP), licensing the NIH patents on darunavir.¹⁵³ The license was broad in scope, covering all LMICs (as defined by the World Bank).¹⁵⁴ NIH's licensing contribution helped establish MPP and encourage subsequent licenses from the pharmaceutical industry. To date, licenses through MPP have supplied over 43 billion doses of treatment in 148 countries and averted 38,000 deaths, with 170,000 deaths likely to be averted by 2030.¹⁵⁵ NIH's licensing of patents in darunavir had a seminal impact on access to medicines globally. Now, NIH has the opportunity to build on this historic achievement for global access by integrating specific provisions that can limit profiteering on publicly owned technologies. Johnson & Johnson's actions that limited the efficacy of NIH's licensing of darunavir patents highlight the need for these provisions.

¹⁵⁰ MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 28 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>.

¹⁵¹ Press Release, Medicines Patent Pool, US National Institutes of Health (NIH) First to Share Patents with Medicines Patent Pool As it Opens for Business (Sept. 3, 2010), <https://medicinespatentpool.org/news-publications-post/us-national-institutes-of-health-nih-first-to-share-patents-with-medicines-patent-pool-as-it-opens-for-business>.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Impact*, MEDS. PAT. POOL, <https://medicinespatentpool.org/progress-achievements/impact> (last visited July 9, 2024).

Johnson & Johnson began specifically reporting revenues for the drug in 2011 in its filings with the Securities Exchange Commission¹⁵⁶ and aggregated revenues for the drug with other treatments that rely on the same NIH patents starting in 2015.¹⁵⁷ For the period between 2009 and 2014 – where revenues for the drug were reported individually – Johnson & Johnson made \$7.578 billion from darunavir. In combination with other HIV medications marketed by Johnson & Johnson, which also rely on the NIH patents in question,¹⁵⁸ Johnson & Johnson has made at least \$1.8 billion dollars each year from 2016 through the present.¹⁵⁹ In total from 2009 to 2023, Johnson & Johnson has earned a staggering \$25 billion on these drugs relying on NIH technologies.

Despite the extreme financial success of darunavir, Johnson & Johnson refused to license the secondary patents on the drug to MPP for the benefit of LMICs, even as it secured billions off the publicly owned technology.¹⁶⁰ The Access Campaign at MSF wrote that “[Janssen] has effectively made the NIH licence useless for manufacture and export to countries where Janssen holds a patent.”¹⁶¹ Civil society repeatedly called on Johnson & Johnson to reconsider its refusal to cooperate with MPP,¹⁶² and in 2012, the company announced that it would not enforce its patents on darunavir in least developed countries according to the UN and any countries in sub-Saharan Africa.¹⁶³ That policy would not reach countries like Brazil, where Johnson & Johnson had been charging \$6,000 per patient per year (in Africa, it had been charging \$1,000 per patient per year in 2011, which was still almost eight times more than the standard triple combination therapy).¹⁶⁴ Additionally, Johnson & Johnson engaged in confidential licensing agreements with a

¹⁵⁶ Johnson & Johnson, Annual Report (2012 Form 10-K), Ex. 13 at 28; Annual Report (2013 Form 10-K), Ex. 13 at 5; Annual Report (2014 Form 10-K), Ex. 13 at 5; Annual Report (2015 Form 10-K), Ex. 13 at 5.

¹⁵⁷ Johnson & Johnson, Annual Report (2016 Form 10-K), Ex. 13 at 12.

¹⁵⁸ *Archived HHS-Licensed Products Approved by the FDA*, NAT. INSTS. HEALTH TECH. TRANSFER, <https://www.techtransfer.nih.gov/archived-hhs-licensed-products-approved-fda> (last visited July 19, 2024).

¹⁵⁹ Johnson & Johnson, Annual Report (2024 Form 10-K at 82); Annual Report (2021 Form 10-K) at 76; Annual Report (2018 Form 10-K) at 18.

¹⁶⁰ MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 29 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>.

¹⁶¹ *Id.*

¹⁶² *Johnson & Johnson and The Medicines Patent Pool*, PUBLIC CITIZEN (last visited Apr. 22, 2024), <https://www.citizen.org/article/johnson-johnson-and-the-medicines-patent-pool-2/>.

¹⁶³ James Love, *KEI Statement on the J&J Darunavir Announcement*, KNOWLEDGE ECOL. INT’L (Nov. 30, 2012), <https://www.keionline.org/22079>.

¹⁶⁴ *Johnson & Johnson / Tibotec AIDS Drug Licenses Leave Out Too Many Patients*, MÉDECINS SANS FRONTIÈRES (Jan. 28, 2011), <https://www.msf.org/johnson-johnson-tibotec-aids-drug-licenses-leave-out-too-many-patients>.

manufacturer in India and South Africa to package and distribute the drug for a limited number of countries.¹⁶⁵

Most alarmingly, WHO had recommended darunavir as an alternative second-line treatment for HIV infection in 2015, even though it was better tolerated by patients than other second-line options, in part, due to price considerations.¹⁶⁶ MSF additionally found that the price of darunavir did not decrease significantly with the introduction of a few generic competitors because of the limited markets.¹⁶⁷ UNAIDS and MSF note that Johnson & Johnson's donation program for pediatric patients in a limited number of countries may have made the market even less feasible to enter for generic manufacturers.¹⁶⁸ In 2015, Johnson & Johnson worked with MPP to support the Pediatric HIV Treatment Initiative and expand its policy of not enforcing its patents to 128 LMICs, but only for pediatric uses of darunavir.¹⁶⁹

In this episode of licensing, it is distressing that a superior second-line regimen using publicly owned technology was designated an alternative, in part, because of excessive pricing. Johnson & Johnson has made billions from darunavir to date and, despite the overwhelming profitability of the drug, hampered access in LMICs. The episode highlights how equitable access provisions in NIH licensing agreements can be a lifesaving remedy against such market failures.

¹⁶⁵ MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 29 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>; UNAIDS, UPDATE ON THE ACCESS COMPONENTS OF THE UNAIDS 2016-2021 STRATEGY: REMOVING ACCESS BARRIERS TO HEALTH TECHNOLOGIES FOR HIV AND ITS CO-INFECTIONS AND CO-MORBIDITIES IN LOW- AND MIDDLE-INCOME COUNTRIES ¶¶109-110 (Nov. 19, 2018); Press Release, Johnson & Johnson, Tibotec and Emcure Collaborate on Access to Darunavir for India (Dec. 3, 2008), <https://www.jnj.com/media-center/press-releases/tibotec-and-emcure-collaborate-on-access-to-darunavir-for-india>; Press Release, Aspen Holdings, Tibotec and Aspen Collaborate on PREZISTA™ Access Plan for Africa (Apr. 4, 2007), <https://www.aspenpharma.com/media/aspen-group-news/tibotec-aspen-collaborate-prezista-access-plan-africa/>.

¹⁶⁶ MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 29 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>.

¹⁶⁷ *Id.*

¹⁶⁸ UNAIDS, UPDATE ON THE ACCESS COMPONENTS OF THE UNAIDS 2016-2021 STRATEGY: REMOVING ACCESS BARRIERS TO HEALTH TECHNOLOGIES FOR HIV AND ITS CO-INFECTIONS AND CO-MORBIDITIES IN LOW- AND MIDDLE-INCOME COUNTRIES ¶¶110 (Nov. 19, 2018); MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 29 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>.

¹⁶⁹ Press Release, Johnson & Johnson, Johnson & Johnson Expands IP Policy to Create Broad Access in 128 Countries for Development of New and Optimized HIV Medicine Formulations for Children Living with HIV (May 11, 2015), <https://www.jnj.com/media-center/press-releases/johnson-johnson-expands-ip-policy-to-create-broad-access-in-128-countries-for-development-of-new-and-optimized-hiv-medicine-formulations-for-children-living-with-hiv>.

First, a standard non-assert provision in NIH licensing agreements that prevents licensees and downstream entities from asserting follow-on IP rights in LMICs would have better promoted access, compared to Johnson & Johnson's belated announcement in 2012 that it would not assert its patents in darunavir in least developed nations and sub-Saharan Africa. The geographic scope of NIH equitable access provisions, which would benefit all LMICs, would have effectively broadened the policy to countries like Brazil that were paying exorbitant prices to access darunavir.

More generally, Johnson & Johnson's practices highlight the shortcomings of equitable access provisions that fail to consider how a licensee's background IP may be necessary to practice a sublicense, as well as follow-on IP and other rights that companies can secure in addition to NIH patents. As NIH considers circumstances in which third parties can and should be recruited to address unmet health needs in LMICs, it should consider provisions that prevent IP owned by a licensee from hampering global access. For example, if NIH had a practice similar to that of DNDi, UBC, the Gates Foundation, and CEPI that gave it rights to a licensee's background IP and/or improvements, NIH could have licensed a manufacturer to supply darunavir for LMICs, despite Johnson & Johnson's refusal to license its own patents. Such licensing would not have affected the company's revenue streams in high-income markets.

Johnson & Johnson's recalcitrance in effectuating affordable supply of darunavir in LMICs also underscores the weaknesses of soft pricing obligations and affordable access plans as opposed to more meaningful provisions, like conditions or milestones. Without the leverage of more specific obligations about affordability and measures to advance registration and supply in LMICs, companies can drag their feet and unnecessarily limit access. In darunavir's context, low demand to motivate commercialization by generics and other factors, such as higher production costs for the active ingredient, slow regulatory approval, and longer generic product development timelines (stemming from time consumed for developing a stable generic formulation and completing bioequivalence studies with the branded version) likely delayed access to affordable generics until after 2021.¹⁷⁰ In the absence of alternative manufacturers that can produce lower-cost generics, a concrete affordability provision in NIH's licensing agreement can limit unreasonable pricing on the branded medicine in LMICs and would have been more meaningful in achieving access for darunavir. To prevent licensees from failing to supply these countries at all, NIH can also include provisions for collaborating with WHO and licensing bodies for

¹⁷⁰ MÉDECINS SANS FRONTIÈRES - ACCESS CAMPAIGN, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 9, 28 (18th ed. July 2016), <https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition>; Press Release, Unitaid, Innovative Agreement Launches Affordable, Optimal Second-Line HIV Treatment in Low- and Middle-Income Countries (July 26, 2021), <https://unitaid.org/news-blog/innovative-agreement-affordable-optimal-second-line-hiv-treatment/#en>; Jenny Lei Ravelo, *Pricing Agreement Brings HIV Drug Darunavir within Reach of LMICs*, DEVEX (July 27, 2021), <https://www.devex.com/news/pricing-agreement-brings-hiv-drug-darunavir-within-reach-of-lmics-100478>.

registering and supplying medicines in LMICs to prevent the inequities in global access to darunavir from repeating in future NIH-licensed technologies and products.

Finally, it is useful to analyze how strong accountability measures could have expedited global access to darunavir to all patients who could have benefited from the treatment. Provisions enabling NIH to terminate Johnson & Johnson's nonexclusive license to its patents, and effective step-in rights that would have required the company to license and transfer its knowledge and rights for producing darunavir to manufacturers in LMICs, would have given NIH significant leverage with the company to negotiate access. Even the threat of using those provisions could have impelled Johnson & Johnson to adopt its own terms for achieving global access that aligned with NIH's access objectives. Further, NIH could have advanced local and diversified production of darunavir that could benefit supply chain resilience by requiring transfer to an LMIC manufacturer, instead of Johnson & Johnson's license to certain manufacturers in these countries that was solely limited to packaging and distribution.

NIH can build on its legacy for expanding affordable access to medicines globally. By including access obligations in licensing agreements, NIH can further effectuate the public interest principles that undergirded its licensing of patents on darunavir and helped establish MPP, which has secured billions of doses of treatment in LMICs and saved tens of thousands of lives. We urge NIH to include access provisions that can counteract market failures harming the health of millions in LMICs, which will also ensure the success of the draft policy. As the case of darunavir shows, the consequences can be life or death.