



40 Rector Street, 16th Floor
New York, NY 10006-1703

Tel: (212) 679-6800
Fax: (212) 679-7016

Web: www.doctorswithoutborders.org

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Lawrence A. Tabak
Principal Deputy Director
National Institutes of Health
9000 Rockville Pike
Bethesda MD 20892

Abby Rives
Director, Technology Transfer and Innovation Policy
National Institutes of Health
9000 Rockville Pike
Bethesda MD 20892

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

“Government responsibility [...] can't be just about funding, the responsibilities are a lot broader than that. Governments must invest in needs-driven research and development to produce innovation, contribute to setting the agenda – and at the same time secure access to medicines for those who cannot pay for the drugs or vaccines. Innovation depends on public leadership and not just public funding”

-- Bernard Pécoul, Founder, DNDi

“Innovation is only useful if it is accessible to the patients that need it, and yet many new medical products that stand to save lives and reduce illness in developing countries remain unaffordable.”

-- MSF Access Campaign

Dear Dr. Tabak and Ms. Rives:

Over the last 50 years as an international medical humanitarian organization working with some of the world's most marginalized communities, Médecins Sans Frontières/Doctors Without Borders (MSF) has repeatedly and regularly witnessed the gaps in access to the lifesaving medical products, including vaccines, therapeutics, and diagnostics, that are needed to address the health needs of people suffering in humanitarian and medical crises. We believe that as a result MSF has unique insights into the barriers that prevent lifesaving medical technologies from reaching patients worldwide, and it is with this perspective in mind that we offer our feedback to NIH's request for information on its access planning proposal.

As Lita Nelsen has observed, “research institutions have the most control over optimizing the use of their inventions at the time of licensing,” and access interventions made upstream can determine whether the public meaningfully benefits from these inventions or not.¹ History has demonstrated that sole reliance on companies’ ad-hoc donations or voluntary, non-binding agreements has time and again failed to meet patient needs. As the largest public funder of biomedical research in the world,² NIH is uniquely positioned to leverage its resources and technological innovations to ensure that any licensing agreements for technology with potential to benefit global public health maximize the likelihood that resulting products reach populations most in need. The access planning proposal presents a significant first step towards addressing the shortcomings of current NIH funding and licensing policies by acknowledging the agency’s responsibility to consider and facilitate access to intramurally developed technologies in its licensing practices.

MSF has long advocated for a realignment of medical R&D with the health needs of our patients and wider communities in need.³ Among many of the unaddressed challenges within the R&D system is the fact that while governments rightfully continue to (and in some cases increasingly) fund R&D for key health technologies, both indirectly and directly, they more often than not have abstained from making certain that this funding results in health technologies that are affordable, available and equitably distributed in a timely manner around the world.

This comment outlines MSF’s position on the current NIH proposal, with attention to the areas we see as the most crucial for expansion of the policy’s scope in order to meaningfully improve global access to medicines, vaccines, diagnostics and other key health technologies.

In the first section of this submission, we outline some overall amendments we believe should be made to the policy proposal or regarding the scope of the proposal itself:

- Binding access conditions, rather than voluntary access plans
- Accounting for multiple dimensions of access
- Incorporation of global access requirement
- NIH-led assessment and approval of access proposals
- Commitment to agreement and waiver transparency
- Extension to Extramural Research Program
- Inclusion of relevant third-party IP

¹ Lita Nelsen and Anatole Krattiger, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, ed. Anatole Krattiger, RT Mahoney, and Lita Nelsen (Oxford, UK and Davis, CA: MIHR and PIPRA, 2007), 26.

² Ariella Barel and Laurel Boman, “Clinical Trial Cost Transparency at the National Institutes of Health: Law and Policy Recommendations,” ed. Christopher Morten (Engelberg Center on innovation Law & Policy, NYU Technology Law & Policy Clinic, August 2020), 18.
https://www.law.nyu.edu/sites/default/files/Clinical_Trial_Cost_Transparency_at_the_NIH-Law_and_Policy_Recommendations.pdf.

³ Médecins Sans Frontières Access Campaign, “Lives on the Edge: Time to Align Medical Research and Development With People’s Health Needs,” April 29, 2016, <https://archive.finddx.org/wp-content/uploads/2021/07/Request-for-Proposals-POC-MDx.pdf>.

In the [second section](#), we offer a list of baseline access provisions that should be included in every licensing agreement as a threshold measure for improving equitable access to NIH-funded technologies and as a basic set of provisions that should be part of all access plans:

- Prioritization of non-exclusive licenses
- Reserved rights for humanitarian licensing
- Mandatory survival clauses
- Commitment to R&D cost transparency

In the [third section](#), we offer guidance for the formulation and necessary components of access plans, including a set of core considerations that we believe must be addressed – and subject to NIH’s approval – in every access plan submission, along with suggestions for concrete metrics and strategies to satisfy these criteria:

- Establishing global access milestones
- Identifying access planning partners
- Defining and requiring affording pricing
- Removing barriers to and facilitating availability
- Committing to post-trial access and benefit sharing

Finally, the [fourth section](#) addresses the importance of accountability and enforcement for actual and meaningful implementation of access plans:

- Mandating affirmative reporting
- Guaranteeing transparency and oversight

MSF’s Suggested Amendments to the Overall Scope of the Current Proposal:

- *Moving beyond voluntary access plans toward mandatory access conditions*

MSF has documented and witnessed the limitations of corporate voluntarism in achieving equitable access aims. While we greatly appreciate the significant efforts and important steps NIH is taking by proposing the inclusion of access plans in its intramural licensing agreements, we strongly encourage NIH to structure access conditions as a mandatory and legally enforceable part of its agreements to ensure that access is not left up to licensees’ discretion.

As the COVID-19 pandemic demonstrated, and as we have seen time and time again in the context of treatments for HIV, Ebola, Hepatitis C and other illnesses, leaving access decisions to the goodwill and voluntary action of companies cannot guarantee timely and equitable access to health technologies, particularly in the case of outbreak, epidemic and pandemic response. As we have also proposed in the ongoing INB discussion on a possible pandemic instrument at the World Health Organization, enforceable conditions and provisions are paramount to ensuring access in public/private collaborations. Furthermore, as outlined below, the experience of R&D partners demonstrates that access provisions neither hamper speedy development nor chill innovation. Instead, they ensure accountability for public funding and lead to more responsible R&D practices overall.

Case Study – CEPI’s Equitable Access Policy

MSF engaged extensively in the development of the original equitable access policy of the Coalition on Epidemic Preparedness Innovations (CEPI).⁴ Following the guidance of MSF and other advocacy groups, CEPI’s original access policy contained clear commitments to ensuring affordable prices, transparency and pro-access management of intellectual property generated with CEPI funding – all a reflection of CEPI’s promise of public interest R&D. However, in December 2018, CEPI’s Board adopted a revised policy that undermined these earlier binding commitments for access to CEPI-funded vaccines, a move which MSF has criticized.

In 2022, CEPI commissioned an independent external review by the University of Georgetown’s O’Neill Institute for National & Global Health Law to evaluate how equitable access has been achieved through their COVID-19 vaccine development agreements.⁵ The external review found that CEPI’s agreements may require adaptation and review since they were based on “relational” agreements that are characterized by “relatively high levels of trust between parties” and terms such as “reasonable,” “best efforts,” “best endeavors,” “parties’ expectations,” and similarly non-binding language. CEPI has recently approved an “Equitable Access Framework” in line with their updated 2.0 Strategy, but this document fails to clarify how the organization will address the findings of the O’Neill Institute report and to expand on how CEPI could exercise stronger access conditions as both a funder of R&D and a recipient of public funds.⁶

In MSF’s view, agreements based in voluntarism, “mutually agreed terms,” vague principles, and “best efforts” language are insufficient to ensure equitable access to the health products that were publicly funded. This submission provides additional details along these lines below.

- *Discarding “one or more strategies” language in favor of language which adequately accounts for all dimensions of access:*

“Access, defined broadly to include product affordability, availability, acceptability, and sustainability, is of paramount importance in providing a return on taxpayers’ investment in biomedical research”

Meaningful “access” to medicines implicates a wide range of intersecting issues: What use are technological innovations if they are unaffordable to the vast majority of patients? Is a cheap medication actually accessible if it is only manufactured in small quantities, approved for use in a handful of countries, or ill-adapted for use in settings where need is most urgent? In our experience as frontline healthcare providers in the world’s most challenging and resource-constrained settings, each of these considerations is an integral part of assessing true accessibility – whether our patients can get the drugs that they need – and each must thus be a requisite part of access planning.

⁴ “CEPI Policy Documentation,” 2017, https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf.

⁵ O’Neill Institute for National & Global Health Law, Georgetown Law and Center for Transformational Health Law, “Equitable Access Review of CEPI’s COVID-19 Vaccine Development Agreements,” April 2022, https://static.cepi.net/downloads/2023-12/EQUITABLE-ACCESS-REVIEW-OF-CEPIS-COVID-19-VACCINE-DEVELOPMENT-AGREEMENTS_Final_April-2022.pdf.

⁶ CEPI, “Equitable Access Framework,” May 2023, https://static.cepi.net/downloads/2024-03/CEPI_Equitable%20Access%20Framework_May%202023_0.pdf.

In its current form, while the NIH proposal allows for the disaggregation of these components of access, it only requires that a licensee's access plan include "one or more strategies" for addressing access. NIH is the world's largest funder of biomedical research; to meaningfully achieve its stated goal of using tax-payer dollars to "transform[] knowledge into improved health for all," it must exercise its considerable leverage to set conditions for the licensing of publicly-funded research in a holistic, comprehensive, enforceable and substantive manner. MSF's experience demonstrates that this must entail the use of conditions or plans that take every dimension of access into consideration, rather than allowing for voluntary cherry-picking strategies designed to minimize the burden on licensees. If the goal is meaningful access, then access plans should be designed to meet all of the relevant benchmarks of such access.

MSF's operations have seen firsthand the impacts of drug manufacturers' failures to account for all of these aspects of meaningful access. The first effective treatment for Ebola Virus Disease (EVD) – monoclonal antibody 114 (mAb 114) was developed through the NIH intramural research program and approved for use after entirely publicly funded clinical trials conducted in the most impacted countries, trials which MSF itself supported.⁷ NIH's exclusive licensing agreement with one firm with no preexisting production or R&D capacity – Ridgeback Biotherapeutics – has meant, however, that even after FDA approval, several years later, the product is not sufficiently or regularly available – or potentially even registered – in endemic countries. Indeed, from the limited publicly available information, it appears that the entire global stock of the resultant medication sits unused in the US Strategic National Stockpile and its availability for use subject to the discretion of relevant US government authorities in an informal manner.

MSF operations in Sub-Saharan Africa have been forced to make do with inconsistent donations of the drug, which have been provided informally by the US government at times, but they remain without a mechanism that would enable them to securing sustainable, ongoing access for their patients. This piecemeal approach to distribution also disallows affected countries autonomy in their health decision-making and the ability to adequately prepare for potential outbreaks. This reflects failures across several dimensions of access, including affordability, availability, and sustainability. Failures like this illustrate the necessity of addressing access as a multi-dimensional issue – not merely something that can be solved by employing a single strategy. In this case, establishing diverse manufacturing and distribution plans (including through technology transfer), mandating the use of affordable basis pricing, requiring registration in affected countries, post-trial access commitments and access, and benefit sharing agreements are all necessary to ensure that drugs end up reaching the people they are designed to help, and all must be accounted for in an appropriately designed access strategy or plan. Any of these strategies alone would be insufficient given the complex nature of drug development and provision, and NIH must commit to a technology licensing strategy that incorporates the full spectrum of access considerations relevant to each technology it agrees to license.

- *Removing “and/or” language in favor of a required global access component*

“‘Access Plan’ means Licensee’s plan, and incorporating the plan(s) of its sublicensee(s), as applicable, that describes Licensee’s 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

⁷ Médecins Sans Frontières Access Campaign, “Ensuring Access to New Treatments for Ebola Virus Disease” (Doctors Without Borders, May 2023), <https://www.msfaccess.org/ensuring-access-new-treatments-ebola-virus-disease>.

communities such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality, as defined by Executive Order 13985 and/or (b) populations in low- and middle-income countries, as defined using the World Bank classification system.”

Alongside allowing access plans to account only for one of the many strategies necessary to establish meaningful access, the current proposed language would allow for access plans that focus only on addressing domestic accessibility in the United States, without taking into account global access. Given MSF’s mission, purpose and experience working in environments across the globe and firsthand understanding of access issues caused by the behavior of US-based pharmaceutical corporations, we are firm in our belief that access conditions must account for global access. At a minimum, these plans should be required to account for access in all low- and middle-income countries (LMICs), in addition to securing access for underserved communities in the United States.

- *Mandating NIH-led assessment and approval of the proposed access plans*

“NIH is proposing a new policy within the NIH IRP to require that licensees that succeed in bringing certain products towards market submit a plan outlining steps they intend to take to promote patient access to those products.”

The current proposal requires only that licensees submit access plans, but provides no requirement that NIH meaningfully evaluate the submissions and review their adequacy with respect to achieving access. To that end, NIH must establish clear and specific access-indicators along the dimensions discussed above and/or template conditions against which licensees would measure their proposed access plans in all of the relevant ways, and reserve the right to require amendments for bringing plans into alignment with these indicators. Without concrete, predefined metrics and a complementary assessment mechanism, “access planning” will be determined solely on licensee terms, without any guarantee that true access priorities will be reflected adequately in an proposed access plan. It is incredibly dangerous and counterproductive to allow licensees to determine independently their own metrics for evaluation and define access in whatever ways they see fit. We are concerned that the result will lead to “greenwashing” efforts and to licensees making unwarranted and ungrounded public claims regarding their corporate social responsibility and access efforts. Beyond this, we advocate that NIH establish appropriate benchmarks or milestones for the indicators mentioned above, so that progress against these indicators could be measured over time to better determine the efforts that licensees are making towards achievement of their access plans.

The Drugs for Neglected Diseases Initiative (DNDi), which MSF incubated and helped launch (and for whom MSF now plays a role as both a donor and governance advisor) has developed and made available model licensing agreements that reflect “gold standard” principles for achieving equity in drug access when collaborating with corporate and other partners.⁸ As policy advocacy director Michelle Childs has written, “DNDi’s publication of its licensing model contracts can provide insights on how terms and conditions can be applied in R&D collaborations,” setting a

⁸ Dominique Junod Moser et al., “Striking Fair Deals for Equitable Access to Medicines,” *Journal of Intellectual Property Law and Practice* 18, no. 4 (May 2, 2023): 323–35, <https://doi.org/10.1093/jiplp/jpad025>.

pre-established and publicly available baseline for negotiations that concretely clarifies expectations and articulates access goals.⁹ Providing similar licensing agreement templates or other standards against which access plan proposals can be measured, and establishing methods by which those assessments can be conducted, is essential for codifying an NIH vision for access that can be applied meaningfully across the board.

- *Requiring agreement and waiver transparency*

“To the extent such Access Plan includes proprietary information [to be defined], upon NIH’s request Licensee will also provide a non-confidential version or statement of such Access Plan that NIH may publish or otherwise make available to third parties.”

Transparency throughout the biomedical innovation process, from discovery to delivery, is essential for achieving equitable access to resulting products and ensuring accountability for the use of public funds. As a consequence, NIH must include as a requirement and commit to full disclosure of the terms and conditions of its finalized licensing agreements. The failures of current licensing schemes to achieve widespread access make clear that the status quo of opacity and secrecy cannot continue.¹⁰ In order to effectively serve the public interest, NIH must make certain that the public understands where its money is ultimately going and has the opportunity to evaluate agreements being made on its behalf. Moreover, if NIH maintains that it will require access plans, as compared to harder legal conditionality, it is that much more critical that all terms, conditions, and details of licensing agreements are made public, including the access plans themselves, because accountability will only be achieved through these channels.

The access failures of the Oxford-AstraZeneca COVID vaccine are an example of the perils of secrecy in such agreements. R&D costs and advance purchase orders for the vaccine included over \$2 billion in public funding, including a \$1.2 billion advance purchase commitment from the U.S. government.¹¹ Although there was an early emphasis on access strategies and non-exclusive licensing, Oxford University chose to sign an exclusive license with AstraZeneca, the terms of which were not made publicly available. In public statements, AstraZeneca promised to sell the vaccine without profit during the course of the pandemic, but we subsequently learned that there were no binding commitments to fair pricing or language around the determination of when the pandemic had “ended” included in the agreement.

Even now, the terms of the original agreement remain private, despite multiple freedom of information requests,¹² but a leaked copy of an unredacted sub-license showed that the commitment to no-profit pricing did not carry over into sublicensing agreements and the “pandemic period” had been pre-defined by AstraZeneca. In fact, in direct contradiction to their promise of no-profit sales, the company was selling the vaccine in South Africa for more than double the price in the EU. As MSF has noted, “these experiences show the need for a clear

⁹ “Pro-Access Policies for Intellectual Property and Licensing | DNDi,” April 17, 2020, <https://dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/>.

¹⁰ Médecins Sans Frontières Access Campaign, “Secrets Cost Lives: Transparency and Access to Medical Products,” June 26, 2024, <https://msfaccess.org/secrets-cost-lives-transparency-and-access-medical-products>.

¹¹ Ed Silverman, “U.S. Gives up to \$1.2 Billion to AstraZeneca for Covid-19 Vaccine,” *STAT*, May 21, 2020, <https://www.statnews.com/pharmalot/2020/05/21/astrazeneca-covid19-coronavirus-vaccine-barda/>.

¹² “Agreements between Oxford University, AstraZeneca and Vaccitech Referencing the ChAdOx1 nCoV-19 Vaccine or ChAdOx1 Vector Technology. - a Freedom of Information Request to University of Oxford,” WhatDoTheyKnow, June 3, 2020, https://www.whatdotheyknow.com/request/agreements_between_oxford_univer.

obligation for governments to ensure disclosure of information and to uphold public health interests against commercial confidentiality claims over lifesaving medical products.”¹³

The Medicines Patent Pool (MPP) has demonstrated the feasibility and importance of agreement transparency by committing to making the terms of all of its licensing agreements freely available on its website.¹⁴ The MPP facilitates patent pooling and voluntary licensing agreements between pharmaceutical patent holders and generic drug manufacturers in order to address access gaps in low- and middle-income countries, and to date they have signed agreements with 22 different patent holders, all of which have been published in full.¹⁵ The transparency of MPP’s agreements has allowed governments and civil society stakeholders to scrutinize these agreements, which has at times led to improvements in terms of geographic scope of coverage and similar issues, and otherwise presumably compelled the parties to the agreement to be wary of making them too restrictive or not taking into account the full scope of potential access components (and barriers), given the possibility of public examination.

“NIH also proposed to include a process for licensees to request a waiver or modification of the access planning provision, in whole or in part. The agency would consider such requests on a case-by-case basis and evaluate them according to criteria that would be identified in the guidance for access plans.”

Transparency is also crucial in the case of access planning waivers for potential licensees. While some degree of planning flexibility may be available depending on the specific nature of each licensed technology, the public must have access to the rationales for granting waivers to make certain that both corporate partners and the NIH are being held accountable to the public interest.

- *Extending conditions to NIH’s extramural research program*

“NIH is proposing a new policy that would apply to inventions made by investigators in the NIH Intramural Research Program (IRP) and owned by the agency.”

While MSF commends NIH’s efforts to improve access and include access plans within its licensing agreements for intramurally developed medical technologies, the intramural research program accounts for only ten percent of NIH research funding, while 83 percent is channeled into extramural research programs.¹⁶ It has been documented that NIH funds supported every single new drug granted FDA approval between 2010 and 2019.¹⁷ NIH has an incredible opportunity to fully utilize its leverage and make major strides towards meaningfully improving global access to medicines, but doing so will require access planning requirements to also be incorporated into the extramural funding agreements. Several major philanthropic and research institutions, including the Bill and Melinda Gates Foundation, have implemented global access planning in their

¹³ Médecins Sans Frontières Access Campaign, “Secrets Cost Lives,” 30.

¹⁴ “Patent Pooling & Voluntary Licensing for Public Health - MPP,” March 2, 2020, <https://medicinespatentpool.org/what-we-do/licensing-for-public-health>.

¹⁵ “Agreements with Innovators - MPP,” March 2, 2020, <https://medicinespatentpool.org/progress-achievements/licences>.

¹⁶ “Budget,” National Institutes of Health (NIH), October 4, 2023, <https://www.nih.gov/about-nih/what-we-do/budget>.

¹⁷ Ekaterina Galkina Cleary, Matthew J. Jackson, and Fred D. Ledley, “Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019,” *Institute for New Economic Thinking Working Paper Series*, September 1, 2020, 1–72, <https://doi.org/10.36687/inetwp133>.

agreements with external funding recipients, and NIH's mandate as a distributor of tax-payer dollars only further underlines the importance of access planning across all of its research funding and programs.

The access controversy surrounding Johnson & Johnson's (J&J) lifesaving tuberculosis drug bedaquiline underscores the importance of attaching access planning requirements to extramurally funded research as well. R&D for bedaquiline was supported by an estimated \$455-747 million in public funding, – including substantial funding from NIH – an amount that exceeded the private investment nearly fivefold.¹⁸ Yet the drug, which forms the backbone of all WHO-recommended treatment regimens for drug-resistant tuberculosis, was introduced to the market at prices far beyond the capacity of LMIC governments and humanitarian organizations like MSF to afford on a broad scale. MSF globally contributes to a significant amount of TB treatment provided worldwide, and as a result has an acute sense of access needs in this area. Lack of access to this drug was so pronounced that MSF launched a multi-year public campaign seeking price reductions from J&J.

Following a study that estimated the cost of manufacturing a generic version in the range of \$48-102 for a six-month course of treatment and public pressure from MSF and others, J&J dropped the price in low-income countries from \$900 to \$272, but the company continued to engage in patent filing strategy that sought to extend its market exclusivity in many countries until at least 2027.¹⁹ Subsequent purchase and distribution agreements through the Global Drug Facility have facilitated supply in more LMICs but have left countries with the highest disease burdens, including Russia, China, Ukraine, and Belarus, without access to lowest-priced generics.

It is possible, however, to envision an entirely different scenario, one in which access in high-burden TB countries and for communities most in need would have been prioritized. If NIH and other donors had included at least some limited access planning requirements, or better still conditions, as a part of their funding, they could have exerted some leverage and control over the availability of this essential treatment to key populations significantly sooner. This is even more notable in the case of bedaquiline because, in comparison to many parts of the world, the US and high-income countries have relatively low rates of TB and in that sense are secondary markets for the drug; in light of this dynamic, it was always going to be the case that access would be most necessary in more resource-constrained environments. The outsized contribution of public dollars to the development of treatments like bedaquiline should translate into public benefit through global access provisions, whether the research is funded intramurally or extramurally.

- *Applying conditions to related third-party IP, including follow-on patents and trade secrets*

“Third-party IP (i.e. patents solely owned by NIH’s collaborators and partners) would be outside the scope of this policy.”

¹⁸ Dzintars Gotham et al., “Public Investments in the Clinical Development of Bedaquiline,” *PLoS ONE* 15, no. 9 (September 18, 2020): e0239118, <https://doi.org/10.1371/journal.pone.0239118>.

¹⁹ Christophe Perrin, Shailly Gupta, and Roshan Joseph, “Johnson & Johnson’s Patenting and Pricing Strategy for TB Medicine Bedaquiline: A Cautionary Tale for New TB Medicines,” Substack newsletter, *Geneva Health Files* (blog), October 6, 2023, https://genevahealthfiles.substack.com/p/johnson-and-johnsons-patent-bedaquiline-tb?utm_medium=email.

Because so much of NIH research takes place in the earliest stages of drug development, the technologies that NIH licenses may ultimately be only one of several patented components of a final product. In order to make sure that intellectual property barriers do not impact access to medicines down the line, NIH must ensure that proposed access plans will also address access to third party IP, including background and follow-on patents and trade secrets and technological know-how. Access plans that fail to account for IP beyond the licensed technology will be unable to meaningfully secure access for finalized drug products, which may render the entire exercise meaningless otherwise. Below, we detail several specific baseline access provisions that specifically address third party IP, such as humanitarian licensing rights, and technology transfer requirements. To mitigate against potential barriers, DNDi's licenses, for example, include terms that secure 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 uses.²⁰

MSF's Suggestions Regarding Baseline Access Provisions in all NIH funding agreements

Depending on the stage of development and the nature of each technology, different access measures may need to be considered and there may be some amount of variation among those measures. However, there is also set of baseline access provisions that should be included in every NIH licensing agreement in order to enhance access to publicly funded innovation, appropriately measure and evaluate access plans, and improve health outcomes across the board. As the proprietor and developer of these technologies, NIH commands enormous leverage over their ultimate use and should exercise this leverage to bring license terms into alignment with global and domestic access goals. The inclusion of these baseline access terms is an essential and concrete first step towards establishing global and domestic access as an underlying norm in NIH licensing agreements. This section details MSF's thoughts on what such terms should include.

- *Prioritizing the use of non-exclusive licenses*

While this section focuses on non-exclusive licensing for the purpose of expanding manufacturing and supply of pandemic related health products, it should be noted that non-exclusive licenses may also be relevant for technology development to allow freedom to operate and carry out research, particularly on open science platforms, which may prove particularly important in early-stage scientific research.

The need for non-exclusive licensing and technology transfer as tools to expand access, availability, manufacture and supply of health products has long been an important component of the multilateral policy agenda. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, presented in 2018, encourages the development and dissemination of publicly funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, to enhance the development of health

²⁰ Moser, et al., 323.

technologies related to the public health needs of developing countries on reasonable, affordable and nondiscriminatory terms.²¹

Particularly during pandemics and international public health emergencies, when there is often a heightened need for equivalent health products globally and competition between states around procurement of limited supplies, non-exclusive licensing and technology transfer should be tools to expand supply and manufacturing capacity for the necessary products. An added benefit of such an approach is the potential for the resulting competition to drive down the prices of end products, which may further improve access.

Examples of provisions from other R&D funding agreements which NIH should consider:

Organization	Source of Funds	Provision	Commentary
CEPI	Recipient of public funds	<p>CEPI – Valneva, Chikungunya Vaccine Funding Agreement²²</p> <p>LMIC Manufacturer. To facilitate achievement of the conditions set out in Clauses 14.1 and 14.2, Awardee has agreed to transfer its technology to an LMIC manufacturer as outlined in the IPDP. Without limiting Awardee’s obligations under the IPDP, Awardee will, within [***] of the signature date of this Agreement, or within such other time period as may be set out in the IPDP if the IPDP is amended in accordance with Clause 2.4, sign a Sub-Awardee agreement with an LMIC manufacturer, which Sub-Awardee agreement shall meet the requirements of Clause 3.3 and shall obligate such LMIC manufacturer to manufacture the Product for regular supply in all Non-Traveler’s Market Countries that have a demand for Product and to supply the Product to Non-Traveler’s Market Countries under the conditions of Clause 14.2. Prior to signing such Sub-Awardee agreement with an LMIC manufacturer and prior to completion of technology transfer to enable such LMIC manufacturer to manufacture and supply the Product to Non-Traveler’s Market</p>	<p>Agreement establishes a commitment to transfer the vaccine technology to an LMIC manufacturer. It is a positive step, but it’s not clear why it is limited to one manufacturer.</p>

²¹ World Health Organization, “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,” November 27, 2017, <https://doi.org/10.2471/B09072>.

²² “CEPI – Valneva, Chikungunya Vaccine Funding Agreement,” GHIAA, 2019, https://ghiaa.org/provision_document/cepi-valneva-chikungunya-vaccine-funding-agreement-5/.

		Countries, Awardee shall fulfill manufacturing and supply obligations for Non-Traveler’s Market Countries as set out in the IPDP.	
BMGF	Philanthropy	<p>BMGF and Arsanis, S. Aureus Antibody Strategic Relationship Letter Agreement ²³</p> <p>If the [Funder] reasonably determines that a third-party manufacturer is needed to achieve [Developer’s] price and volume commitments, [Developer] must license and transfer the IP needed for production to the third party at the [Funder’s] expense. The obligation is limited to transfers that allow production for Developing Countries.</p>	<p>Agreement establishes that IP must be licensed and transferred to additional third party manufacturers, at the discretion of the Funder, to meet price and volume commitments. Manufacturing should be in place in developing countries.</p>

Building on the examples above, affirmative steps can and should be taken by NIH to prioritize non-exclusive licensing and include technology transfer as a binding condition within its licensing agreements, especially to share technology and know-how to entities in developing countries. Multiple measures and incentives should be considered to ensure that transfer of technologies is not solely based on voluntary actions, but is backed by mandatory requirements and obligations which contribute towards growing geographically diverse, independent capacity for production and supply of essential medical products.

- *Reserving rights for humanitarian licensing*

MSF believes that it is critical for NIH to reserve the right to grant humanitarian licenses to generic manufacturers when original licensees are unable or unwilling to meet global health demand or when products are otherwise inaccessible in humanitarian settings. Although the preferred course of action would be to avoid such issues altogether through the use of non-exclusive licenses from the outset, where exclusive licenses are already granted or otherwise deemed necessary, MSF believes that agreement terms must allow for humanitarian access exceptions, as determined by NIH and relevant partners.

While licensees may themselves enter voluntary sub-licensing agreements in order to meet humanitarian needs, allowing pharmaceutical companies the exclusive right to dictate public health agendas and outcomes when it is otherwise avoidable is inappropriate ethically and as a matter of public policy. As we saw during the COVID-19 pandemic, this is likely to be especially egregious during global health emergencies when there is already limited supply. As MSF wrote

²³ “Gates Foundation – Arsanis, S. Aureus Antibody Strategic Relationship Letter Agreement,” GHIAA, 2017, https://ghiaa.org/provision_document/bmgf-arsanis-s-aureus-antibody-strategic-relationship-letter-agreement-3/.

in a 2020 report on “Voluntary Licenses and Access to Medicines,” the imposition of territorial limitations in voluntary licensing agreements can ultimately “undermine access to medicines,” because they rely on World Bank gross national income rankings rather than particular countries’ “health needs and domestic capacity” to provide treatment.”²⁴

This disparity is made particularly clear, for example, in the case of Gilead’s voluntary licensing plan for remdesivir, a drug initially believed to reduce hospitalizations from COVID infections. While the licensing agreement covered generic production and distribution for 127 LMICs, the territorial restriction of Brazil, China, Russia, and others from the scope of the voluntary license had the effect of “exclud[ing] nearly half of the world’s population during a global pandemic” from access to generic remdesivir.²⁵ Examples such as this highlight the necessity of additional legal mechanisms for addressing global health exigencies, rather than leaving them solely up to licensee discretion.

Additionally, humanitarian licensing provisions can be deployed to improve technological appropriateness with regard to particular populations or environments which is a key concern for MSF. If licensees decline to pursue development of pediatric drug formulations or delivery methods adapted for settings without robust cold-chain infrastructure, for example, a humanitarian licensing provision would allow NIH to facilitate licensing agreements with other parties who are able to address these research gaps. Where technological adaptations for LMICs specifically are not included in access plans, humanitarian licensing provisions will allow NIH to initiate lines of research that have implications for improving global access but may not be top priority for corporate partners.

MSF’s work in low-resource settings has frequently been contingent on the availability of medical technologies that are appropriately adapted for local use. For example, in wealthy countries, where reliable electricity for refrigeration is readily available, it is easy to ship and store vaccines that require a storage within a narrow temperature range, but in resource-constrained settings, in MSF’s own experience it is often difficult or impossible. Electricity may be unstable, and temperatures in some regions can rise far beyond the safe range for vaccine storage. While MSF Operations have implemented extensive cold-chain systems for vaccine distribution, MSF Cold Chain Logistician Malcolm Townsend has noted that often “what’s needed is a solution that takes the fridge out of the equation.”²⁶ Innovative follow-on research, such as the development of a heat-tolerant vaccine formulation, that is tailored to the needs of humanitarian settings may not be a profitable endeavor for licensees, and it may not be feasible to mandate R&D investments for these particular kinds of research. Yet, the pursuit of these critical lines of research for humanitarian purposes must not be obstructed by the existence of licensing agreements. NIH’s ability to reserve licensing rights for humanitarian purposes would allow it to enlist other researchers committed to developing drug formulations and delivery mechanisms better adapted for use in LMICs.

A reserved right to the originally licensed patent may not be sufficient on its own to actually guarantee that an end-product can be made available for humanitarian use. Reserved humanitarian licensing rights must also be accompanied by complementary access provisions, including non-

²⁴ Médecins Sans Frontières Access Campaign, “Voluntary Licenses and Access to Medicines,” October 2020, 3, 7, https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

²⁵ Ibid, 8.

²⁶ Médecins Sans Frontières Access Campaign, “Vaccines: A Delicate Balance,” April 16, 2014, <https://msfaccess.org/vaccines-delicate-balance>.

assert clauses covering licensees' follow-on patents, commitments to relevant technology transfer and knowledge sharing, as discussed above, and agreements to waive data exclusivity for expediting generic registration.

- *Ensuring continuity of terms through survival clauses*

As the Oxford-AstraZeneca vaccine example also makes clear, including access terms in an original licensing agreement may not be sufficient for ensuring access is prioritized in subsequent sublicensing agreements.²⁷ NIH access policy and its licensing agreements themselves should stipulate that any access provisions must be carried over into downstream sublicensing contracts, especially given the early-stage nature of many NIH-developed technologies. Similar provisions are also reflected in funding agreements celebrated by the Bill and Melinda Gates Foundation for Novavax vaccine development²⁸ and also licensing agreements carried out with MPP. For MSF, it is critical that access provisions are carried over or included within sublicensing agreements because what we have learned is that in many instances domestic sublicensees in the places in which we work (or who may otherwise have an impact on the market in those places) at times must also be compelled to ensure that access is an explicit part of their approach, even though the significant price reductions resulting from such licenses are a major step towards ensuring access.

- *Committing to R&D cost transparency*

In the RFI, NIH expresses interest in “Promoting transparency in the biomedical research enterprise and return on investment” and “hearing from potential partners on how access plans could incorporate transparent cost accounting measures to assist NIH in driving down costs associated with innovation and making clearer what costs are incurred along the way and how those affect product costs.” In MSF’s view, a baseline provision in licensing agreements requiring licensees to disclose the costs of clinical trials they conduct using NIH technology would serve the ends NIH describes here and meaningfully facilitate access in several ways.

As MSF has previously outlined, “making clinical trial cost information public would allow governments and other purchasers of medical tools to: interrogate claims about the need to recoup R&D costs through high prices; estimate more accurately the true cost of late-stage clinical research; and ultimately – when such transparency is expanded and coupled with the capability to negotiate prices – negotiate more effectively, less hobbled by information asymmetry. It would also help the US and other funders to invest effectively in late-stage R&D, shedding light, for example, on the relative efficiency of NIH intramural versus extramural investment for conducting certain kinds of research. Clinical trial cost transparency would also help diversify the R&D enterprise by equipping non-traditional actors with information regarding costs. MSF, for example, has run clinical trials when there are research gaps that we are well placed to fill – such as the TB-PRACTECAL clinical trial that helped identify a shorter, all-oral treatment regimen for drug-resistant tuberculosis – and can attest that it is difficult to budget for such undertakings because of

²⁷ Médecins Sans Frontières, “Secrets Cost Lives,” 30.

²⁸ Bill & Melinda Gates Foundation and Novavax, Inc., “Grant Agreement Investment ID OPP1127647” (Securities and Exchange Commission, December 31, 2021), https://www.sec.gov/Archives/edgar/data/1000694/000114420415063483/v422902_ex10-1.htm.

the dearth of available information on trial costs.²⁹ US leadership on clinical trial cost transparency would not only unlock key data, but would set a new standard against which all funders across the global biomedical innovation ecosystem will be measured, much as its leadership on trial results transparency did.

Studies have attempted to approximate clinical trial costs, with estimates ranging from \$30 million to over \$3 billion, but the data they rely on is often unreliably reported or incomplete.³⁰ The question of ascertaining actual R&D costs is especially salient when public money is involved. In order for NIH to ensure that sound investments are being made in the interest of the public good, the agency must demand transparency about how its grants and technologies are being used by corporate partners. Uncovering the true costs of pharmaceutical R&D is the first step toward being able to improve efficiency and economy in the drug development process, leading to lower drug prices overall. Crucially, this kind of transparency will also help the NIH, interested civil society actors, and patients ascertain the components of pricing determinations for themselves – and hold companies accountable when monopolistic price gouging occurs.³¹

Clinical trial cost transparency is also practicable. MSF has set an example by disclosing the full cost breakdown of its own TB-PRACTECAL trial, representing the first time that disaggregated costs for a single trial have ever been shared publicly.³² The trial, which identified a shorter, all-oral treatment regimen for drug-resistant tuberculosis, cost 34 million euros to conduct, directly challenging dominant narratives about ballooning costs of clinical trials. Drawing on experience from the TB-PRACTECAL trial, MSF has put together a tool-kit for clinical trial cost reporting going forward, with easy adaptability for both internally conducted trials at MSF and trials conducted by other research institutions and companies.³³ NYU researchers, in collaboration with MSF, have also established a framework for clinical trial cost reporting, with an emphasis on producing disaggregated costs per patient, per year, and per site across the following categories of expenses:

1. *Personnel costs (including salary and benefits)*
 - a. *Administrative staff*
 - b. *Clinical staff*
2. *Materials and supplies*
3. *Clinical procedures*
4. *Site management*

²⁹ “Roundtable: Disclosing Clinical Trial Costs -- Why and How Should It Be Done?” (Médecins Sans Frontières Access Campaign, November 17, 2022), <https://www.msfacecess.org/roundtable-disclosing-clinical-trial-costs-why-and-how-should-it-be-done>.

³⁰ Thomas J. Moore et al., “Variation in the Estimated Costs of Pivotal Clinical Benefit Trials Supporting the US Approval of New Therapeutic Agents, 2015–2017: A Cross-Sectional Study,” *BMJ Open* 10, no. 6 (June 1, 2020): e038863, <https://doi.org/10.1136/bmjopen-2020-038863>.

³¹ Carolyn Y. Johnson and Brady Dennis, “How an \$84,000 Drug Got Its Price: ‘Let’s Hold Our Position ... Whatever the Headlines,’” *Washington Post*, November 25, 2021, <https://www.washingtonpost.com/news/wnk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/>.

³² “In Precedent-Setting Move towards Drug-Development Cost Transparency, MSF Reveals Cost of Its Landmark TB Clinical Trial_ €34 Million,” *Médecins Sans Frontières Access Campaign* (blog), April 25, 2024, <https://msfacecess.org/precedent-setting-move-towards-drug-development-cost-transparency-msf-reveals-cost-its-landmark-tb>.

³³ Médecins Sans Frontières Access Campaign, “Transparency CORE: Clinical Trial Cost Reporting Toolkit,” April 24, 2024, <https://msfacecess.org/transparency-core-clinical-trial-cost-reporting-toolkit>.

- a. *Site monitoring costs*
 - b. *Site retention*
 - c. *Other*
5. *Central laboratory*
6. *Equipment*
7. *Other direct costs*
 - a. *Publication costs*
 - b. *Subawards/consortium/contractual costs*
 - c. *Other*
8. *Indirect costs*
9. (1) R&D tax credits, (2) disaggregated costs of R&D for failed candidates, and (3) other funding contributions, including insurance reimbursements ³⁴

Although MSF recognizes that uniform disclosure of disaggregated trial costs is not a simple undertaking, the benefits of disclosure and the government's responsibility to the public warrant the administrative and technological resources that would be required for implementation. Several government agencies, including the Veterans' Administration and state-level institutions, readily furnish comprehensive accountings of per-patient costs of individual trials upon request, and NIH officials have disclosed that large-scale clinical trial consortia that received funding through NIH's extramural program have uniform cost reporting and data retention practices already in place.³⁵

Standardizing this kind of data collection across the intramural and extramural research programs will be of great benefit to NIH itself and sharing it with the public through already-established platforms, such as clinicaltrials.gov, should be a default requirement of all NIH licensing agreements concerning technology that will undergo clinical trials.³⁶ The incorporation of clinical trial cost transparency as a requirement of licensing agreements across the board is a vital step towards NIH's mission of achieving broader equitable access to its medical innovations.

Access Planning: Relevant Areas to Cover and Necessary Metrics

- *Establishing global access milestones*

MSF strongly advocates for the use of baseline access *conditions* in all medical technology licensing agreements, rather than the current proposal for "Access Planning" from licensees. However, if NIH does decide to proceed more narrowly with access planning, there are several crucial criteria that must be included in accepted access plans. Successfully achieving access to global health technologies must be responsive to identified public health needs and local disease burdens, and may include metrics such as: "how many poor [or affected] people a product will reach, how easily it will be available to them, and who and how many will be able to afford the

³⁴ Barel and Boman, 28.

³⁵ Doctors Without Borders, USA et al., "The US Government Should Disclose the Costs of Clinical Trials It Funds to Make Medical Tools Affordable, Accessible, and Suited to Public Health Needs," January 31, 2022, <https://www.doctorswithoutborders.org/sites/default/files/documents/CTJan2022OpenLetter.pdf>.

³⁶ Barel and Boman, 43

product.”³⁷ The use of defined global access milestones in licensing agreements can ensure that each of these considerations is adequately addressed.³⁸

Global access milestones “balance the commercial interests of industry partners with a [research institution’s] mission of facilitating affordable access to their health technologies,” by articulating benchmarks for global access that must be met in parallel to a for-profit drug development timeline.³⁹ Milestones themselves can be flexible depending on the specifics of the technology in question, and can be structured based on particular calendar dates (i.e. first clinical trials by x date) or with relation to other events in the drug development timelines (i.e. simultaneous drug registration in the US and LMICs).

- *Identifying access planning partners*

Licensees themselves may not be equipped to identify relevant global health needs or develop appropriate access milestones that are directly responsive. MSF thus advocates for the inclusion of credible third-party partners who may have operations in endemic countries or other first-hand accounting of on-the-ground access needs in the formulation of access plans and related decision-making. Civil society organizations such as MSF or international bodies such as the WHO can provide detailed insights that will help to ensure that planning strategies are customized to address specific access needs and that resources are strategically deployed.

- *Defining and requiring affordable pricing*

The provision of medical products at an affordable price is a cornerstone of accessibility, particularly in setting such as those MSF works in, where individuals may need to pay for their medical products directly out of pocket.

As explained above, however, there is little transparency around how pricing determinations are made for most name-brand drugs, and high prices have been attributed to a wide variety of factors, from actual R&D costs to medical utility and risk-mitigation. Time and again, ex-ante investigations of drug pricing have shown that profit motives have been the true driver of price determinations, even as companies publicly cite other costs. For example, a Senate Finance Committee investigation of the \$84,000 price tag on Gilead’s blockbuster drug, Sovaldi, found that the company had “pursued a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences. There was no concrete evidence in emails, meeting minutes or presentations that basic financial matters such as R&D costs or the multi-billion dollar acquisition of Pharmasset, the drug’s first developer,

³⁷ Joachim Oehler, “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, ed. Anatole Krattiger, RT Mahoney, and Lita Nelsen (Oxford, UK and Davis, CA: MIHR and PIPRA, 2007), 119, https://themys.sid.uncu.edu.ar/rpalma/Toma_Decision/Intellectual%20Property%20Management%20Handbook/gsd/collect/iphandbook/index/assoc/iphb0023/iphb0023.pdf.

³⁸ Mohammad Shahzad, “Promoting Global Access to Health Technologies: A Licensing Toolkit for Public Sector Institutions Part I,” *Les Nouvelles -- Journal of the Licensing Executives Society*, September 2022, https://ghiaa.org/wp-content/uploads/2022/08/GAL-Toolkit-2022_public-institutions.pdf.

³⁹ *Ibid*, 25.

factored into how Gilead set the price.”⁴⁰ Researchers additionally found that an estimated \$60.9 million in public dollars had been invested in the development of the underlying drug, sofosbuvir,⁴¹ and that predicted manufacturing costs could be as low as \$68-\$136 for a twelve-week course of treatment.⁴²

Given the inconsistency and opacity of current pricing schemes, it is essential that NIH access plans both set forth clear definitions of “affordability” based on pre-defined metrics and full disclosure of relevant information, and establish milestones for the provision of medical products at an affordable price point in LMIC settings, whether through in-house production or generic sub-licensing. MSF advocates for the use of an affordable pricing metric based on an auditable cost of goods sold (COGS) plus a reasonable, pre-agreed margin of profit.

Such auditable pricing formulations and “no profit-no loss” models are critical to ensure affordability of health products, particularly when developed through the use of public funds. It is important to note that the disclosure of the pricing and cost of goods of health products developed with the use of public funding is often shared only with the funder for auditing purposes, but not with the general public. This is an unnecessary and inappropriate limitation of this information given its utility in procurement negotiations particularly in LMICs. In order for not-for-profit commitments and provisions to be adequately monitored and enforced, transparency of certain information, particularly on the cost of goods (production) and also of sales, needs to be reported and made publicly available.

Numerous examples as to how NIH may request additional information regarding and to measure affordability in their licensing agreements can be found in agreements generated by other donors or organizations such as DNDi, FIND and Unitaid:

Organization	Source of Funds	Provision	Commentary
FIND and Unitaid	Recipient of Public Funds and philanthropic	FIND/Unitaid Call for Proposal ⁴³ “a COGS [cost of goods]-based pricing model and expected business model. Include the pricing structure, indicating the expected cost of manufacture,	In recent call for proposals from FIND to fund diagnosis product development Global Access Commitments where set, which include specific obligations for applicants to submit in their application a pricing model close to the cost of goods, as well provide

⁴⁰ Thomas Sullivan, “Senate Finance Committee Releases Results of Investigation Into Gilead’s Pricing Strategy for Hepatitis-C Drugs,” *Policy & Medicine*, May 5, 2018, <https://www.policymed.com/2015/12/senate-finance-committee-releases-results-of-investigation-into-gileads-pricing-strategy-for-hepatitis-c-drugs.html>.

⁴¹ Rachel E. Barenie et al., “Public Funding for Transformative Drugs: The Case of Sofosbuvir,” *Drug Discovery Today* 26, no. 1 (January 1, 2021): 273–81, <https://doi.org/10.1016/j.drudis.2020.09.024>.

⁴² Andrew Hill et al., “Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries,” *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America* 58, no. 7 (April 1, 2014): 928–36, <https://doi.org/10.1093/cid/ciu012>.

⁴³ “Request for Proposals: Accelerating the Development of Molecular Diagnostic Platforms for Decentralized Diagnosis of Acute Respiratory Illness” (FIND, 2022), <https://archive.finddx.org/wp-content/uploads/2021/07/Request-for-Proposals-POC-MDx.pdf>.

		markup, royalties, expected distributor margin ...”	transparency in sales volumes and COGS of the marketed product post-funding.
DNDi	Recipient of Public Funds and philanthropic	<p>DNDi⁴⁴ template agreement</p> <p>“Affordable Basis shall mean pricing a Product at the lowest sustainable level that may include only:</p> <ul style="list-style-type: none"> - full production costs, as optimised without compromising the quality of the Product; - direct distribution costs; - a reasonable margin, not to exceed <to be completed> percent of the foregoing costs, for the selling Party. (...) - DNDi may mandate an independent and experienced auditor to verify the conformity of Partner’s current prices of the Product with the Affordable Basis definition. 	Agreements articulates that affordable product relies on a requirement to price products at pre-agreed (transparent and auditable) cost of Goods + reasonable margin.

As with all other access planning provisions, these equitable pricing commitments must carry over into sublicensing agreements as well. While the introduction of generics is often the most effective tool for lowering prices,⁴⁵ this may not be the case when the market for a product is too small to support robust competition, as is often the case with neglected tropical diseases.⁴⁶ Relying on market competition between generic sublicensees as a means of addressing affordability cannot therefore always serve as a replacement for securing equitable pricing commitments with primary licensees from the outset.

- *Removing barriers to and facilitating availability*

Affordable drugs are of no use to MSF’s patients if they are not also meaningfully available in high-need settings in which we work. Access plans must therefore include strategies for ensuring that sustainable manufacturing and distribution chains are in place for licensed medical technologies. Numerous examples of disappointing drug donation schemes have demonstrated the

⁴⁴ Moser, et al., 331.

⁴⁵ Universities Allied for Essential Medicines, “Global Access Licensing Framework,” April 2020, <http://www.essentialmedicine.org/>.

⁴⁶ Médecins Sans Frontières Access Campaign, “How a Global R&D Convention Could Fill the Gaps Left by Today’s Medical Innovation System,” 2012, 7, <https://msfaccess.org/how-global-rd-convention-could-fill-gaps-left-todays-medical-innovation-system>.

major shortcomings of discretionary charitable distribution methods.⁴⁷ As Amy Kapczynski has written, issues of “accountability and control” make these kinds of pharmaceutical donation programs “unacceptable, because they leave power over life in the hands of private actors, who retain the privilege of charity, the privilege to make good on their promises or not.”⁴⁸

An MSF report on the failures of the vaccines pillar of the COVID-19 Tools Accelerator (COVAX) observed that an “overreliance on donations has created a seemingly haphazard and piecemeal approach to dose allocation in AMC [advance market commitment] countries” and that donated vaccines presented a wide array of access challenges, including “transaction costs such as shipping fees and added logistical challenges, such as the possibility of short expiration times and limited time for countries to plan.”⁴⁹ As the head of one African health institution put it in the context of COVID-19, “the whole vaccine supply system to Africa is now dependent on donations and goodwill. It keeps us totally dependent and unable to control how we deal with the pandemic.”⁵⁰

Acceptable access plans must avoid the pitfalls of donation-based systems for drug distribution by both by requiring licensees to meet milestones based on building themselves or supporting the development of local manufacturing capacity, entering generic licensing agreements to such ends, facilitating regulatory approval in LMICS, and prioritizing access and benefit sharing in communities that have contributed to drug development through participation in clinical trials or donation of biological resources and establishing meaningful indicators on these issues that allow for true evaluation of such plans.

To enable and monitor availability commitments, NIH as part of what it expects from credible access plans should indicate that licensees develop and publicize their regulatory strategy, with particular focus on where registration will be pursued in LMICS. Minimum requirements should be set for registration to be requested in the countries where clinical trials have been conducted, as well as in endemic countries, particularly in LMICS. To enable regional availability, NIH should request that access plans include licensees progress on pursuing regional supply through regional procurement bodies, such as the PAHO Strategic Fund or Revolving Fund, in the case of the WHO Region of the Americas. Also to further enable global access, WHO Prequalification should be required for licensees as soon as reasonably possible. Additionally, to ensure continuation of supply and prevent stockouts, licensees should report risks of disruption of stocks both to National Regulatory Agencies, when requested by national regulation, but also to NIH to explore the potential need of licensing the technology of the product to additional suppliers to mitigate the impact of stockouts. To monitor availability of products developed through NIH funding, the licensee should report yearly the registration status and doses supplied per country, including pricing information.

- *Committing to post-trial access and benefit sharing*

The current and predominant licensing model of “exchanging” exclusive IP protections for investments in R&D and drug commercialization recognizes only economic contributions to and

⁴⁷ See e.g. Sophie Harman et al., “Global Vaccine Equity Demands Reparative Justice — Not Charity,” *BMJ Global Health* 6, no. 6 (June 2021), <https://doi.org/10.1136/bmjgh-2021-006504>

⁴⁸ Amy Kapczynski, “Access to Knowledge: A Conceptual Genealogy,” in *Access to Knowledge in the Age of Intellectual Property*, ed. Gaëlle Krikorian and Amy Kapczynski (New York: Zone Books, 2010), 39.

⁴⁹ Médecins Sans Frontières Access Campaign, “Issue Brief: COVAX: A Broken Promise to the World,” December 21, 2021, 8, <https://msfaccess.org/covax-broken-promise-world>.

⁵⁰ *Ibid*, 13.

investments in the development process for new pharmaceutical products. Yet, myriad crucial non-economic or indirect contributions are made by actors, including by participants in clinical trials, infection survivors who donate biological materials, and traditional knowledge bearers, with no guarantee that treatments derived from these contributions will ultimately be available in affected communities.⁵¹ This prevailing dynamic is in fundamental conflict with the ethical guidelines established by the Council for International Organizations of Medical Science (CIOMS) and the WHO for Health-related Research Involving Humans.⁵² The CIOMS guidelines⁵³ are an attempt to ensure the fair distribution of the benefits and burdens of hosting clinical trials, and expand the concept of post-trial access to include other benefits targeting not only participants of clinical trials, but also the communities where the trial was hosted, particularly when the research is carried out in resource limited settings. It is important to clarify that the CIOMS guideline considers that low-resource settings can be situated in both LMIC and HIC.

As outlined in Guideline 2, clinical-trial sponsors and researchers have an obligation to “ensure that the[ir] research is responsive to the health needs or priorities of the communities or populations where the research will be conducted,” and this includes an obligation to “make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.”⁵⁴

Specific to this situation and NIH’s access planning proposal, this means the establishment of post-trial access plans to make sure that the health technologies are made available, e.g., registered, and affordable for the local communities and health authorities where they were trialed. These plans, when applicable, should consider the conditions of authorization for distribution, and decisions regarding payments, royalties, subsidies, technology and intellectual property, as well as distribution costs, when such information is not proprietary.

Post-clinical trial access requirements, as recommended in the guidelines, are applicable to and should be enforceable for all stakeholders involved in clinical trials, including: sponsors, implementers, ethical review committees, research councils, and regulatory agencies who are responsible for registering clinical trials. It is also applicable to all types of biomedical products.

Returning to the recently developed monoclonal antibody (mAb) treatments for EVD provides an example of community participation in treatment development with no reciprocal benefit sharing in the post-development stage. Both mAb treatments currently approved for use in EVD patients – NIH’s own mAb 114 (licensed to Ridgeback Biotherapeutics as discussed above) and Regeneron’s Inmazeb – were developed using virus samples isolated from EVD survivors in the DRC, and clinical samples that have served as the basis for further research across the globe were collected from survivors of the 2014-2016 outbreak in West Africa.⁵⁵ Furthermore, the PALM

⁵¹ Médecins Sans Frontières Access Campaign, “MSF Position Paper: Ensuring Timely and Equitable Access to Medical Products in Global Public Health Emergencies,” July 2023.

⁵² Council for International Organizations of Medical Sciences (CIOMS), “International Ethical Guidelines for Health-Related Research Involving Humans” (Council for International Organizations of Medical Sciences (CIOMS), 2016), <https://doi.org/10.56759/rgxl7405>.

⁵³ International Ethical Guidelines for Health-related Research involving Humans, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) - Available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

⁵⁴ *Ibid*, 3.

⁵⁵ Médecins Sans Frontières Access Campaign, “Ensuring Access to New Treatments for Ebola Virus Disease, 17.

clinical trial, which was supported by MSF and which first demonstrated the efficacy of these groundbreaking treatments, was conducted with the participation of EVD-affected communities in the DRC in our own clinics and ultimately led to both drugs' approval. In a nutshell, as an MSF report notes, "the contributions of EVD patients and survivors to the R&D of treatments for EVD through the provision of clinical samples and participation in clinical trials have been critical."⁵⁶ Despite these "critical" contributions, however, the communities most impacted by EVD have yet to see meaningful and consistent access to the treatments they helped to develop. The inability of EVD patients to access lifesaving medicines, while effective treatments sit unused in counties with no disease burden, underlines the profound failures of current R&D models.

NIH must commit to discontinuing these cycles of resource extraction without just compensation for local participating communities by implementing access and benefit sharing (ABS) principles in its licensing agreements and, at a minimum, include this among the group of specific indicators included in relevant access plans. ABS provisions, exemplified in international instruments including the WHO Pandemic Influenza Preparedness framework and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, require private sector entities who make use of local biological resources or conduct research in affected communities to share monetary and non-monetary benefits, such as medicines, with countries and communities of origin. As a baseline, MSF advocates for the establishment of legally binding ABS mechanisms in licensing agreements that will ensure:

- "Dedicated production and supply reserved and used for addressing medical needs of people living in resource-limited settings, in humanitarian contexts and other vulnerable situations that can benefit from globally coordinated allocation;
- Transfer of technology and know-how to address growing needs to establish, improve and maintain geographically diverse and independent capacities of developing, producing and supplying lifesaving medical products, both during emergencies and beyond;
- Incorporation of key elements of ethics in health research from the "International Ethical Guidelines for Health-related Research Involving Humans", such as obtaining informed consent, benefit sharing and post-trial access and registration of medical products, as mandatory provisions."⁵⁷

Accountability and Enforcement

Access measures will only be successful if there are meaningful ways to ensure licensee accountability and adequate enforcement measures available for when obligations are not met. Structuring access provisions as legally binding conditions, rather than voluntary "plans," is necessary for NIH to guarantee that publicly funded medical technologies actually end up in the hands of those who need them. Without providing possibility for enforcement, access plans risk becoming another entry on the long list of empty access promises that fail to come to fruition. However, if NIH proceeds more narrowly, simply with voluntary access plans, it is equally critical that it identify and establish specific and measurable access and availability indicators (set alongside reasonable benchmarks) as discussed throughout this submission and make all necessary

⁵⁶ Ibid.

⁵⁷ Médecins Sans Frontières Access Campaign, "MSF Position Paper: Ensuring Timely and Equitable Access to Medical Products in Global Public Health Emergencies," 7; Council for International Organizations of Medical Sciences (CIOMS), "International Ethical Guidelines for Health-Related Research Involving Humans."

information, including the terms of its agreements and access plans, publicly available to ensure some form of scrutiny and accountability.

The current proposal provides only that “within 30 days of NIH’s request (no more often than once annually), Licensee agrees to confer with NIH to review Licensee’s progress, and to consider in good faith any reasonable modifications suggested by NIH with respect to the Access Plan,” and includes no concrete mechanisms for addressing discrepancies between plan terms and actual licensee progress. MSF believes that the indefiniteness of licensee reporting responsibilities and the lack of a clearly established method for enforcing agreement terms in the proposal would be detrimental to ultimately achieving stated access goals. MSF advocates instead for the inclusion of affirmative and regular progress reporting requirements for licensees based on a core set of access and availability indicators based on the parameters discussed above, with articulated consequences in the case of continued breach of access agreements and with all such information made publicly available.

- *Mandating affirmative reporting*

Rather than being subject to irregular and infrequent agency requests, licensee reporting should be affirmatively required to conform to an established schedule. This will encourage both the implementation of incremental access-building strategies and consistent attention to progress towards milestones, and also the use of consistent record-keeping practices. NIH should also retain the right to audit any additional information it believes is necessary to accurately assess progress on access goals.

- *Guaranteeing transparency & oversight*

Additionally, these progress reports, as well as any additional information that NIH uses to assess compliance with agreement terms, should be made publicly available. By building in transparency commitments at every stage of the process – from the publication of original contract terms to licensees’ adherence to those terms – NIH will signal its dedication to serving the interests of the public, rather than helping licensees maintain current corporate secrecy practices. Transparency here will also allow the public to hold licensees accountable when they do not uphold their end of the bargain.