

**Comments on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments Being Considered Under a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response**  
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**Submission of Comment to HHS From:**

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The United States’ stated goals in the treaty negotiations are to be applauded and require no revisions. However the current stances in negotiations do not achieve the outcomes desired. We therefore propose the following. We also note that the domestic policies of the Biden administration—including the use of “march in rights” etc. to lower prices—should be mirrored in the pandemic treaty negotiations.

**Equitable access conditionalities**

*The Request for Comments asked: What are respective pros and cons of, the following proposed language in the Negotiating Text: “in accordance with national laws and considering the extent of public funding provided, publish[ing] the terms of government-funded research and development agreements for pandemic-related products, including information on: (a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability and reusability principles; (b) the pricing of end-products, or pricing policies for end-products; (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic”? In your view, are there alternative recommended actions or commitments that could be considered? And “Are there provisions that could reasonably be included in government-funded research or advanced development agreements, or policies related to licensing of government-owned and/or government-funded technology that would promote global access to pandemic-related products, without disincentivizing innovation or partnering with the U.S. government around research and development?”*

Public and philanthropic funding led to the development of various COVID-19 vaccines in less than a year after SARS-CoV-2 emerged, one of the most remarkable scientific achievements in history. According to several accounts, the United States alone invested tens of billions of dollars to develop mRNA vaccines.<sup>12</sup> But the United States government failed to secure strong contractual terms requiring mRNA developers

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<sup>1</sup> Lalani H S, Nagar S, Sarpatwari A, Barenie R E, Avorn J, Rome B N et al. US public investment in development of mRNA covid-19 vaccines: retrospective cohort study BMJ 2023; 380 :e073747 doi:10.1136/bmj-2022-073747

<sup>2</sup> Congressional Budget Office. (2021, April). Research and Development in the Pharmaceutical Industry. <https://www.cbo.gov/publication/57126>

to share their knowledge with others.<sup>3</sup> Other funders outside the United States also failed to secure strong contractual requirements to share knowledge. Without strong contractual requirements to share manufacturing knowledge, mRNA developers had significant power to decide where their COVID-19 vaccines were produced and how they were allocated globally. Predictability, mRNA developers prioritized their commercial interests and placed rich countries in front of global distribution lines.<sup>4</sup> Failure to ensure strong conditionalities in exchange for public funding was therefore a critical driver of vaccine inequity.

Earlier drafts of the pandemic accord<sup>5</sup> proposed stronger language than what is above and would have required governments to seek equitable access contractual terms in their funding agreements.<sup>6</sup> Yet, these proposals have been watered down in recent negotiating drafts<sup>7</sup> despite support from several developing<sup>8</sup> and developed countries.<sup>9</sup> Weakening these proposals is a mistake and the United States should help reverse it. Creating norms requiring funders to embed contractual equitable access commitments in their agreements with product developers should be a critical objective in the negotiations.

Governments and philanthropic funders can secure equitable access commitments from product developers even in the absence of international norms. The United States recently entered into an agreement with Regeneron including price limits.<sup>10</sup> The Coalition for Epidemic Preparedness Innovations (CEPI) have secured “public health licenses” in agreements with product developers, which can be triggered to scale up manufacturing if certain conditions are met.<sup>11</sup> Neither of these provisions are perfect or comprehensive.<sup>12</sup> Yet both examples illustrate that securing contractual commitments capable of promoting access is possible even in the absence of international norms.

International norms, however, can facilitate efforts to secure equitable access commitments. A key outcome from adopting this obligation would be to vest funders with more legitimacy and leverage to seek equitable access terms in negotiations with industry. Paradoxically, if funders have unchecked discretion to decide whether and how they secure safeguards in their agreements with product developers, their counterparts will have stronger bargaining power to persuade them against strong

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<sup>3</sup> Kavanagh, Matthew M., and Renu Singh. "Vaccine politics: Law and inequality in the pandemic response to COVID-19." *Global Policy* (2023).

<sup>4</sup> Schellekens P. Trackers of vaccination by income group. Pandem-IC, 2022. <https://pandem-ic.com/trackers-of-covid-19-vaccination-by-world-bank-income-group/>

<sup>5</sup> Conceptual Zero Draft Art 8.2.a.iii.a proposed “measures to support the collective development and use of principles and norms and sets of practices that ensure that public financing of research and development for pandemic response products results in more equitable access and affordability, including through conditions on distributed manufacturing, licensing, technology transfer and pricing policies.”

<sup>6</sup> <https://oneill.law.georgetown.edu/publications/pandemic-treaty-the-conceptual-zero-draft/>

<sup>7</sup> <https://healthpolicy-watch.news/exclusive-updated-pandemic-accord-draft-sees-watered-down-text-on-publicly-funded-r-pathogen-access-and-benefit-sharing-linkage-remain/>

<sup>8</sup> For instance, Mexico

<sup>9</sup> For instance, Norway

<sup>10</sup> <https://www.statnews.com/2023/09/13/covid-regeneron-white-house-price-limits/>

<sup>11</sup> <https://oneill.law.georgetown.edu/publications/equitable-access-review-of-cepis-covid-19-vaccine-development-agreements/>

<sup>12</sup> See, for instance: Martin, Manuel. "Embedding equitable access in vaccine R&D: Why CEPI's access policy and governance need an overhaul."

conditionalities. Yet if funders are legally bound by international obligations under the pandemic accord those commitments will give them more legal and political leverage to counteract opposition to equitable access at the national level from industry partners.

Therefore, adopting international norms requiring equitable access commitments would give the United States and other governments more leverage to secure these types of terms in agreements with industry. This would help the United States implement policies that it is already considering or pursuing, for instance in the funding agreement with conditionalities entered into with Regeneron. Failing to adopt these norms would in contrast weaken funders. Adopting norms requiring funders to seek equitable access terms would therefore be responsible policymaking.

Since they will require other funders to seek similar equitable access terms in their negotiations with industry, international norms could also increase global cooperation and collective bargaining power relative to product developers. Unitaid, for instance, recently explained that a key challenge limiting their ability to secure equitable access commitments is the fact that they often operate in predefined spaces where product developers have already signed contracts with other private, public, academic, and philanthropic actors.<sup>13</sup> Competing contractual arrangements may prevent subsequent research and development funders from securing equitable access commitments. International commitments could serve as a framework for funders to increase coordination around which specific equitable access conditionalities they pursue, when, and how.

Relevance of specific provisions relating to equitable access will depend on several factors, including the type of technology and product characteristics. Generally, funding agreements should include binding contractual terms requiring (1) technology transfer; (2) open science; (3) product suitability; (4) affordability; (5) availability; and (6) healthy supply. Funders should also secure commitments requiring transparency around research and development costs, contracts, pricing policies, patent landscape, and commercialization plans and market registration status.

We note that these can be crafted to ensure that incentives remain for investment of R&D and effective commercialization of products produced out of publicly funded R&D. We note that publicly funded R&D itself is an incentive and few if any researchers are likely to balk at access conditions. That said there are limitations that can be placed on obligations, which might be accomplished in various ways include sharing of information and know how through entities such as the Medicines Patent Pool or the proposed UN Technology Transfer hubs which focus on certain geographies and producers and ensure appropriate licensing and royalty rights. Protection in U.S. and high-income country markets does not have to be

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<sup>13</sup> World Health Organization. (2023, October). Strategies to facilitate sharing of technology and knowledge through WHO COVID-19 Technology Access Pool. WHO. <https://www.who.int/publications/i/item/9789240073951> Citing Tenu Avafia of UNITAID during the C-TAP 2nd Anniversary Webinar convened by the WHO on 16 June 2022, stating that “by the time [UNITAID] get involved in negotiations, there may already be – and very often are – multiple agreements in place. There may be licenses, there may be contracts already in place before we engage. Also, the originator or the developer may have in-licensed technologies with certain requirements and constraints. And so, [UNITAID] find [themselves] having to operate within a predefined space.”

conflated with global markets, giving plenty of space for commercialization by a single manufacturer in some cases alongside licensing.

### **Contract transparency**

Like commitments to seek equitable access terms in funding agreements, contract transparency has the potential to increase negotiating leverage for the United States. Contract transparency will increase oversight and allow third parties to demand compliance of equitable access commitments. Moreover, contract transparency will increase public understanding about the terms that funders have already secured and which developers have agreed to be bound by them. An increased understanding of these contract terms will give funders further insights and leverage to seek equitable access terms in future agreements with industry developers. These types of contract transparency commitments therefore also constitute responsible policymaking.

**Proposed Position on the Treaty: The United States should move to support the inclusion of commitments to include access provisions in R&D funding contracts wherever possible and where the research has implications for future pandemic countermeasures, as envisioned in earlier drafts.**

### **Intellectual property waiver**

*The Request for Comments asked: What net impacts, positive or negative, would you envision arising from commitments presently outlined in Article 11.3, including: ○ “(a) commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;*

Another priority for the United States should be to refrain from opposing and support intellectual property waivers. We are aware that the International Federation of Pharmaceutical Manufacturers and Associations reportedly called for no treaty at all rather than this current text—claiming it will undermine development of new pandemic products.<sup>14</sup>

This is not only wrong but it should be understood simply as strategic framing to close what political scientists call a “window of political possibility.”<sup>15</sup> By labeling a relatively timid policy move toward sharing technology as radical and harmful, lobbyists seek to foreclose more substantive policy change.

Waiving intellectual property during a pandemic is a simple act of responsible policymaking—necessary and not sufficient. When a pandemic hits, the world has no time to lose producing as much medicine, vaccine, diagnostics as possible to stop it. Yet pandemic-related products are covered by a thicket of

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<sup>14</sup> Ashley Furlong, *Fears Grow That New Pandemic Treaty Won't Correct COVID-19 Mistakes*, POLITICO, Oct. 17, 2023, <https://twitter.com/ashleighfurlong/status/1714193014149550329> (last visited Oct 20, 2023).

<sup>15</sup> JULIA LYNCH, *REGIMES OF INEQUALITY: THE POLITICAL ECONOMY OF HEALTH AND WEALTH* (2020).

dozens or hundreds of patents and other IP, creating a legal monopoly over producing them. Industry groups insist this is not a problem. But scientists working to set up an mRNA manufacturing hub in South Africa found patents slowed efforts to build factories and secure investment.<sup>16</sup> The obvious solution is that when a pandemic is declared, a waiver on IP comes with it. A waiver does not cancel any patents or take away intellectual property. All it does is return policymaking to national governments, temporarily suspending global rules so each country decides its own policy during the pandemic. Waivers in general are standard, regularly-used mechanisms in international trade law.<sup>17</sup>

During COVID-19, mRNA vaccine producers made most of their sales and profits in high-income countries.<sup>18</sup> Even though these governments sometimes limit patents to help their companies produce needed products,<sup>19</sup> they pledge to enforce pandemic patent monopolies, waiver or not. So incentives to innovate change little. Some African, Asian, and Latin American governments might suspend patents in a pandemic to facilitate manufacturing for their populations. But multinational pharmaceuticals showed these are not markets they value by refusing to prioritize their COVID-19 orders.<sup>20</sup> To work, the Pandemic Treaty needs stronger, not weaker language—committing simply to waive IP in a pandemic, not sending the question to the WTO where we already know from COVID-19 that institutional design and political interests will block rapid action.<sup>21</sup>

Meanwhile, waivers are just one part of what is needed for the next pandemic. Governments should commit to pro-actively share pandemic technology. The current draft commits states to share government-owned technology, which could be important. Beyond that, however, the text only obligates states to “encourage” and “coordinate with, collaborate with, facilitate and incentivize” companies to share know-how. Even that is only on “mutually agreed terms,” despite the experience during COVID-19 that companies simply refused to agree any terms. Southern governments and civil society have noted this weakness.<sup>22</sup>

Instead the treaty should include commitments to condition research and development funding on sharing technology and know-how with low- and middle-income countries and, more broadly, transform

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<sup>16</sup> Sara Jerving, *Moderna’s Patents Stand in Way of mRNA Vaccine Hub’s Grand Vision*, DEVEX (2022), <https://www.devex.com/news/sponsored/moderna-s-patents-stand-in-way-of-mrna-vaccine-hub-s-grand-vision-103055> (last visited Apr 18, 2023).

<sup>17</sup> Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 154 (1994), [https://www.wto.org/english/docs\\_e/legal\\_e/04-wto\\_e.htm#articleIX](https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleIX) (last visited Oct 22, 2023); WTO, ANNUAL REPORT 2022 (2022), [https://www.wto.org/english/res\\_e/booksp\\_e/anrep\\_e/anrep10\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/anrep_e/anrep10_e.pdf) (last visited Oct 24, 2022).

<sup>18</sup> DUKE UNIVERSITY GLOBAL HEALTH INNOVATION CENTER, *Launch and Scale Speedometer*, (2021), <https://launchandscalefaster.org/covid-19/> (last visited May 9, 2021).

<sup>19</sup> Lee Fang, *Moderna Among Firms Quietly Granted Powers to Seize Patent Rights During Early Days of Covid Pandemic*, THE INTERCEPT (2022), <https://theintercept.com/2022/08/23/covid-vaccine-patents-moderna-big-pharma-section-1498/> (last visited Oct 26, 2023).

<sup>20</sup> Matthew M Kavanagh & Renu Singh, *Vaccine Politics: Law and Inequality in the Pandemic Response to COVID-19*, 14 GLOBAL POLICY 229 (2023).

<sup>21</sup> Sara E Fischer et al., *Intellectual Property and the Politics of Public Good in COVID-19: Framing Law, Institutions, and Ideas during TRIPS Waiver Negotiations at the WTO*, JOURNAL OF HEALTH POLITICS, POLICY AND LAW 10910269 (2023).

<sup>22</sup> Third World Network, *WHO: INB Bureau Proposes Unbalanced Draft Negotiating Text; No Concrete Deliverables on Equity*, TWN INFO SERVICE ON HEALTH ISSUES, Oct. 19, 2023, <https://twn.my/title2/health.info/2023/hi231006.htm> (last visited Oct 25, 2023).

the R&D ecosystem to place equity at its center.<sup>23</sup> Countries should commit to use national legal authority to compel companies to share technologies in a crisis; create predictable arrangements for accessing pandemic research and development results; fund coordinated building and maintenance of production capacity in LMICs; and establish a right to access scientific knowledge to fight pandemics, similar to the Biological Weapons Convention.<sup>24</sup>

Recent pandemics have been so destructive, in part, because of failure to share technology. A new pandemic agreement could overcome this—but only if governments ignore the industry’s misleading framing and make bolder commitments to act in the interest of public health before and during a pandemic.

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<sup>23</sup> Els Torreele et al., *It Is Time for Ambitious, Transformational Change to the Epidemic Countermeasures Ecosystem*, 401 THE LANCET 978 (2023).

<sup>24</sup> Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction., UNTS Vol. 1015, [https://www.un.org/en/genocideprevention/documents/atrocity-crimes/Doc.37\\_conv%20biological%20weapons.pdf](https://www.un.org/en/genocideprevention/documents/atrocity-crimes/Doc.37_conv%20biological%20weapons.pdf) (last visited Oct 23, 2023).