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**Public Citizen Written Comment Re: Stakeholder Listening Session on Public Health Emergencies Preparedness and Response Negotiations**

Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress and the courts. Our access to medicines program has provided technical assistance to health agencies and organizations in dozens of countries. We rallied support for a more robust global response to the Covid-19 emergency.

Public Citizen appreciates the U.S. government's commitment to the INB negotiations as well as to global health broadly. We've been glad of your support for regional manufacturing and procurement, including in recent White House statements, supporting African producers, so that countries are better equipped to protect themselves.[1]

The INB negotiations are a key venue to show this commitment to global solidarity and health. However, we are disappointed by some recent U.S. positions on equity, including benefit sharing and intellectual property. We also regret seemingly needless concessions to the pharmaceutical industry, which during Covid-19 frequently delayed access to developing countries and overcharged wealthy and developing countries alike. The approach of the U.S. government should be to assert public power and to hold the pharmaceutical industry accountable, rather than allow prescription drug corporations to lead pandemic response.

Below, we outline certain areas of the text related to access to medicines that are important for advancing equity objectives of the agreement. We ask the U.S. to review its positions and, where possible, bend so that the agreement does not break.

**1. Support global access to medical tools bolstered by public funds (Articles 9 & 13bis)**

We appreciate progress in Article 9, particularly Article 9.4 of the April 16th text on equitable access provisions in government R&D contracts and transparency of the terms of such contracts. We note the broad support for advancing equity in government funding agreements and urge the U.S. negotiators to support specific access terms that apply not only to emergency response, but also to pandemic prevention and preparedness. Further, it would be appropriate to mention conditions in licensing agreements for government-owned technologies in this article, including provisions retaining rights of the funder.

Upstream commitments are one of the most important opportunities we have to ensure equitable access to medical products. The Biden administration has recognized this, attaching reasonable pricing conditions in funding agreements at the Administration for Strategic Preparedness and Response for the

[1] *FACT SHEET: Update on the United States Commitment to Expanding Access to Medicines Around the World*, The White House (March 29, 2024), https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/29/fact-sheet-update-on-the-united-states-commitment-to-expanding-access-to-medicines-around-the-world-2/

development of health security-related medicines.[2] The Coalition for Epidemic Preparedness Innovations (CEPI) has secured access conditions in its R&D funding agreements, including "public health licenses", which can be leveraged to expand affordable supply.[3] Creating norms on conditions to government funding should be a key objective of the pandemic agreement, helping to ensure that publicly supported inventions are not subject to corporate secrecy, monopoly control, and price gouging.

Additionally, provisions in procurement agreements, as in R&D and licensing agreements, are key points of government leverage in a pandemic response. We encourage the U.S. to support Article 13bis language regarding access provisions in government purchase agreements, including those permitting export, modifications to respond to supply gaps, promoting development of global access plans, as well as excluding confidentiality clauses and publishing such agreements.

**2. Facilitate and respect use of TRIPS flexibilities (Article 11)**

U.S. negotiating positions in recent leaked texts show opposition to language on the use of TRIPS flexibilities, a stance that is not supported by international or U.S. practices.

In Article 11.4, the U.S. suggested striking language committing parties to fully respect the use of TRIPS flexibilities to protect health and access to medicines.

U.S. commitments under the 2001 Doha Declaration on the TRIPS Agreement and Public Health affirm the use of TRIPS flexibilities to protect health.[4] Accordingly, USTR has stated U.S. respect toward use of the full range of flexibilities in the TRIPS Agreement.[5]

Considering the language of 11.4 draws on previous U.S. commitments under the Doha Declaration, we believe supporting this provision as it stands in the April 16th text[6] is a simple yet impactful area for the U.S. to show solidarity and a commitment to addressing access concerns.

TRIPS flexibilities can make a difference, particularly in developing countries facing barriers that leave them without viable means of access, such as upper-middle-income countries excluded from voluntary licensing agreements for Covid-19 medicines. Flexibilities will be most effective in a future pandemic

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[2] *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, The White House Briefing Room: Statements & Releases (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/

[3] Zain Rizvi, COVAX's Choices, Public Citizen (Nov. 16, 2020), https://www.citizen.org/article/covaxs-choices/

[4] Declaration on the TRIPS agreement and public health, paragraph 4:

> "4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

[5] 2023 Special 301 Report:

> "The United States respects the right of its trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement, including Article 30, Article 31, and Article 31bis, and the Doha Declaration."

[6] "4. The Parties that are WTO Members reaffirm that they have the right to use, to the full, flexibilities in the TRIPS Agreement, including those reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health in future pandemics, and shall fully respect the use of the TRIPS flexibilities by WTO members."

response if governments are assured that the U.S. and others will not oppose their lawful use and if they are simple to use.

We therefore urge the U.S. to support the proposed Article 11.4bis,[7] committing parties to not challenge the use of TRIPS flexibilities. We ask the U.S. to participate in negotiation of this and similar provisions, instead of outrightly opposing the suggestion. We additionally encourage support for re-inserting the provision recognizing that countries may need to update local laws to make adequate use of flexibilities.[8]

**3. Balance commitments in the PABS system (Article 12)**

Sharing pathogen data, such as genetic sequences and virus samples, is critical to coordinating timely global research efforts and facilitating the expeditious production of effective diagnostics, vaccines and treatments. During the Covid-19 pandemic, despite the sharing of pathogen information that enabled production of effective vaccines, these products were not accessible to many.

The Pathogen Access and Benefit Sharing (PABS) System has been a contentious area of negotiations. It has also become a focal point of equity discussions as the Africa Group, the Equity Group, and others have made clear that the new system must have equal footing between pathogen access commitments and equitable benefit sharing.

We believe recent U.S. suggestions voicing new opposition in the PABS article move the text further from consensus.

It is important that negotiators agree that the "benefits" in the mechanism do not refer to increased surveillance from pathogen sharing. Rather, the benefits refer to those parts of the mechanism aiming to address the inequity of the Covid-19 pandemic by ensuring that data sharing enables equitable distribution of resources. To that end, we encourage the U.S. to work towards a greater balance of obligations between pathogen access and benefit sharing, by strengthening those on benefits.

A recent U.S. suggestion that real-time contribution of medical tools be a maximum of 20% diverges from past iterations of the text and from other delegate positions. Previous versions of the text made clear that this percentage should represent a minimum.[9] Additionally, the Africa Group, Equity Group and others have suggested 30% contributions. We therefore urge the U.S. to find a middle ground instead of suggesting limitations to the provision.

We also note the U.S. suggestion that benefits include a percentage of countermeasures provided at "affordable" instead of not-for-profit prices. Considering the text does not detail how affordability will be

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[7] "4bis. The Parties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO Members to use TRIPS flexibilities at any multilateral, regional, bilateral, judicial or diplomatic forum."

[8] "5. Each Party shall, as necessary and appropriate, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 4 of this Article in a timely and effective manner."

[9] Article 12.4.b.ii.a, Proposal for negotiating text of the WHO Pandemic Agreement (Oct. 30, 2023).

> "in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related products for distribution based on public health risks and needs, with the understanding that each Party that has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and manufacturers;"

determined, this weakens the commitment. This is particularly concerning considering other benefit-sharing options mention tiered pricing, which multiple developing country negotiators opposed in a recent text. Tiered pricing is not a stand-in for affordability and has many flaws in terms of guaranteeing equitable access. Tiered pricing does not ensure that products are affordable for the purchaser, but rather charges a price that is developed by and acceptable to the manufacturer and may not relate to population need or a country's ability to pay.[10]

In addition to providing stronger assurances of affordability, other benefits detailed, such as non-exclusive licensing agreements and arrangements for technology and know-how transfer, bolster broader goals of pandemic preparedness and equitable access through support for local production.

**4. Share technology and know-how**

We note with concern the increasingly espoused U.S. position on technology transfer, often seen in the text as an insistence on language stipulating that sharing be on "voluntary and mutually agreed terms."

The Equity Group and others have emphasized that the requirement that technology transfer be on mutually agreed terms is limiting and will not adequately ensure access nor support local production. This position is understandable considering the extreme reluctance of pharmaceutical companies to share technology and know-how during the pandemic, refusing to license to WHO's Covid-19 technology pool and waiting years to negotiate licenses that would facilitate affordable access in too few developing countries.

Sharing science and knowledge is a key part of supporting global pandemic preparedness. The U.S. can encourage voluntary licensing and technology transfer by supporting health focused mechanisms like the Medicines Patent Pool, WHO's Health Technology Access Pool, and the WHO mRNA Technology Transfer Program.

Explicit mention of technology sharing on voluntary and mutually agreed terms unnecessarily introduces ambiguity that may inhibit governments from taking necessary non-voluntary action against pandemic threats. Removing this language would appropriately provide space for use of government leverage to require technology transfer. The U.S. for example has the power to leverage or invoke the Defense Production Act to compel businesses to accept and prioritize technology transfer contracts and to allocate manufacturing know-how in exchange for reasonable compensation.[11] The U.S. used this leverage at various points during the Covid-19 pandemic, including to incentivize manufacturers to partner to increase production and meet supply expectations.[12]

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[10] Suerie Moon et al. *A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries*, Global Health (Oct. 12, 2011) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3214768/

[11] Rizvi, Ravinthiran, Kapczynski, *Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide*, Health Affairs (Aug. 6, 2021), https://www.healthaffairs.org/content/forefront/sharing-knowledge-president-joe-biden-can-use-defense-production-act-end-pandemic; *A Plan for the People's Vaccine*, Public Citizen (Dec. 8, 2020), https://www.citizen.org/article/a-plan-for-the-peoples-vaccine/

[12] *How The White House Got 2 Pharma Rivals To Work Together On COVID-19 Vaccine*, NPR, (March 3, 2021), https://www.npr.org/2021/03/03/973117712/how-the-white-house-got-2-pharma-foes-to-work-together-on-covid-19-vaccine; *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*, HHS Press Office,

We are concerned that inflexibility on this point may jeopardize the agreement as well as risk undercutting U.S. investments into pandemic preparedness, local production, R&D, and national and global health security.

We appreciate the opportunity to comment. Thank you.

https://public3.pagefreezer.com/content/HHS.gov/30-12-2021T15:27/https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html