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July 7, 2023

***Written Comment Re: Stakeholder Listening Session 2 for the INB***

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen’s Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

We welcome the opportunity to provide comments related to the Intergovernmental Negotiating Body (INB) and the proposed Pandemic Accord. We also appreciate U.S. efforts to ensure coordination and complementarity between the INB and Working Group on Amendments to the International Health Regulations (2005) processes.

Our comments will reference articles from the “Bureau’s Text”<sup>1</sup> released June 2, 2023.

**Article 9. Research and development**

We are concerned about the removal of the obligation on conditions for access in research and development (R&D) agreements. Article 9.2b now focuses on transparency and the publication of upstream contractual terms. While we support the obligation to publish contract terms, we wish to advocate for the reintroduction of the obligation to include conditions on publicly funded R&D. Both transparency and upstream access conditions are necessary to ensure timely and equitable access to health tools. We recommend including provisions to facilitate the sharing and licensing of intellectual property, technology, and know-how for publicly funded innovations, if not as a binding requirement, then in a normative capacity.

We urge U.S. government engagement with proposals to reimagine or broaden Article 9 to support access to medical tools, particularly for publicly funded or publicly owned tools and technologies. During the COVID-19 pandemic, the National Institutes of Health (NIH) licensed pandemic-related technologies to WHO’s COVID-19 Technology Access Pool.<sup>2</sup> Additionally, the U.S. contract for Covid treatment Paxlovid (nirmatrelvir + ritonavir) included a “Most Favored Nation Clause,” which provided that the U.S. was entitled to the lowest price of the drug among

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<sup>1</sup> [https://apps.who.int/gb/inb/pdf\\_files/inb5/A\\_INB5\\_6-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb5/A_INB5_6-en.pdf)

<sup>2</sup> <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses>

G7 countries.<sup>3</sup> We would be encouraged to see these practices endorsed in the Pandemic Accord.

These upstream access conditions can bring substantial benefit to the American people. The U.S. government was a full partner in development of the NIH-Moderna vaccine, yet the absence of contractual access conditions meant Moderna was free to charge high prices from the outset and then quadruple those prices this year, harming the U.S. and global vaccination efforts. Had the U.S. research and development contracts that supported nearly all development of the NIH-Moderna vaccine included provisions for reasonable pricing, equitable supply, accountable supply schedules, transparency or the sharing of research, know-how and technology, the U.S. government would have been empowered to better support global vaccine access, to curb the pandemic, and establish expectations or otherwise negotiate with Moderna.

In decades past, NIH routinely included reasonable pricing terms in its R&D contracts. Senate HELP Committee Chair Bernie Sanders (I-VT) has proposed bringing this practice back.<sup>4</sup>

The Coalition for Epidemic Preparedness Innovations (CEPI), a key U.S. partner in global health, has called on national governments to begin including stronger access conditions in funding contracts, to better support access to the resulting products.

#### **Article 11. Co-development and transfer of technology and know-how**

We are glad to see the inclusion of technology transfer and know-how in the Bureau's Text. We support Option 11.A because it creates stronger and more specific commitments regarding the multilateral environment on intellectual property. We would also point out that Options 11.A and 11.B are not mutually exclusive. For example, Option 11.B emphasizes the voluntary sharing of technology, which does have a role to play and can be included among other methods that enable sharing of technology and knowledge.

In Option 11.A, we welcome the acknowledgment that more equitably distributed manufacturing capacity is needed to address the inequitable access to pandemic-related products seen during the COVID-19 pandemic. However, more specific obligations are needed to facilitate the sharing of IP, technology, and know-how for the development of pandemic-related products, particularly with manufacturers in developing countries.

Additionally, we welcome the inclusion of supporting time-bound IP waivers and full use of flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights

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<sup>3</sup> <https://www.npr.org/sections/health-shots/2022/02/01/1075876794/feds-contract-with-pfizer-for-paxlovid-has-some-surprises>

<sup>4</sup> <https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-6.9.23.pdf>

(TRIPS Agreement). We also wish to emphasize that trade agreements should not impose TRIPS-plus measures or interfere with the full use of TRIPS flexibilities.

### **Article 12. Access and benefit-sharing**

We would like to emphasize the importance of access and benefit sharing referenced in Article 12 of the Bureau's Text. The risk of not including benefit sharing is that an agreement may come to resemble surveillance of the Global South without the spirit of partnership and respect that the pandemic experience has recommended. Both Option 12.A and 12.B fail to detail specifics and mechanisms through which benefits would be shared. The Accord should incentivize not only open sharing of pathogen data, but also sharing of the technology, knowledge, and know-how needed to produce medical countermeasures. We note Knowledge Ecology International's proposal<sup>5</sup> on the open-source dividend as one model for benefit sharing and encourage continued engagement with proposals on this topic.

We appreciate the opportunity to comment. Thank you.

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<sup>5</sup> <https://www.keionline.org/wp-content/uploads/Open-Source-Dividend-INB-24June2022.pdf>