Code: 4150-38

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice and Request for 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

AGENCY: Office for Global Affairs, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: This Request for Comment seeks information from stakeholders, broadly defined, on concepts currently under consideration by parties negotiating a World Health Organization (WHO) Pandemic Preparedness Agreement. It seeks information on how stakeholders' efforts to facilitate response efforts, including the rapid creation and equitable deployment of safe and effective vaccines, diagnostic tests, and treatments, can be advanced or hindered by concepts and commitments under consideration by the negotiating parties as reflected in current negotiating text.

DATES: To be assured consideration, written comments must be received by 5 p.m. Eastern time on [Insert date 30 days after date of filing for public inspection at the **Federal Register**]. Written comments should be emailed to OGA.RSVP@hhs.gov with the subject line "Written Comment Re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement" by [Insert date 30 days after date of filing for public inspection at the **Federal Register**]. Comments received after that date will be considered to the extent practicable.

The Department's policy is to make all comments received from members of the public available for public viewing on the Federal eRulemaking Portal at www.regulations.gov. In this instance, business confidential submissions will also be accepted. Note that relevant comments submitted to

regulations.gov will be posted without editing and will be available to the public; therefore, business-confidential information should be clearly identified as such and an accompanying redacted version should be submitted for posting on regulations.gov.

FOR FURTHER INFORMATION CONTACT: Susan Kim, Office for Global Affairs, Office of the Secretary, HHS, Room (639H)- Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, (202) 235-3537.

SUPPLEMENTARY INFORMATION:

Background: In December 2021, WHO's Member States decided at a Special Session of the World Health Assembly to establish an intergovernmental negotiating body (INB), representing all regions of the world, to draft and negotiate a WHO convention, agreement, or other international instrument on pandemic prevention, preparedness, and response. More information about the INB process can be found here: https://inb.who.int/home/inb-process. The INB currently intends to submit its outcome to the Seventy-seventh World Health Assembly in May 2024.

The United States has expressed support for the development of an international instrument to protect the world from pandemic health threats now and in the future, and in a more rapid and equitable manner.

The United States is seeking the following key outcomes in the negotiations:

- Enhance the capacity of countries around the world to prevent, prepare for, and respond to pandemic emergencies and provide clear, credible, consistent information to their citizens.
- Ensure that all countries share data and laboratory samples from emerging outbreaks quickly, safely, and transparently to facilitate response efforts and inform public health decision making regarding effective disease control measures, including the rapid creation of safe and effective vaccines, diagnostic tests, and treatments.
- Support more equitable and timely access to, and delivery of, vaccines, diagnostic tests, treatments, and other mitigation measures to quickly contain outbreaks, reduce illness and

death, and minimize impacts on the economic and national security of people around the world.

Purpose: The U.S. Department of Health and Human Services (HHS) and the Department of State are charged with co-leading the U.S. delegation to the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness, and response.

This Request for Comments procedure is designed to seek input from stakeholders and subject matter experts to help inform the U.S. government negotiating position, including new approaches, proposals, or concerns with the current version of the negotiating text.

The most recent Negotiating Text of the WHO Pandemic Agreement (Negotiating Text) can be found here: https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf.

Representatives from HHS, State and the Department of Commerce will review written submissions and share them, as appropriate, with staff from other Federal Agencies to inform U.S. Government policy and our international engagements on these issues. U.S. officials may contact individuals making submissions for further information or explanation.

Respondent information. Please note the following information is not required but will assist us in contextualizing responses. If possible, in your submission, please include institution or organization name and type; for foreign-based entities, please specify country/ies in which the institution or organization is headquartered; if your institution or organization is a potential provider of pandemic-related products or services, please specify the types of products or services with which you are commonly associated or seeking to develop. All personal identifying information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible.

Specific topics and questions: Stakeholders are invited to provide comments on any and all issues raised by the negotiating text, including potential vehicles and means for implementation of commitments to which the U.S. may subscribe. To the extent commenters choose to comment on specific provisions of the negotiating text, it is helpful to reference any articles or sub-articles being addressed.

In addition, stakeholders are invited to respond to any or all of the following questions.[1] Unless otherwise indicated, quotations are from the relevant article of the Proposal for negotiating text.

Article 9, Research and Development

- What approaches or incentives might be provided to governments, research institutions, or the private sector to encourage participation of relevant stakeholders to, as proposed in the Negotiating Text, "accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential"?

- What voluntary steps could Research & Development (R&D) stakeholders take that would build capacities and promote more inclusive research collaborations and participation from basic science through advanced development and clinical research, addressing the global calls for equity and inclusion?

- What national policies might be developed that (as proposed in the Negotiating Text), "support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications"?

- 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,

[1]The content or phrasing of questions in this Request for Comment should not be taken to indicate that the U.S. is favoring or preparing to accept commitments and/or not engage in further negotiation over them. Rather, we are seeking to learn more about stakeholder positions on these pivotal questions to further refine the U.S. delegation's negotiating stance.

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?

- What is the appropriate role for WHO in facilitating the R&D process in areas focusing on infectious diseases?
- 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?

Article 10, Sustainable Production

- What approaches or incentives might be used to encourage manufacturers and others "to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licenses to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries"?
- How helpful or harmful would the following proposed obligations for governments be for public health, business, and innovation interests generally:
    - "(a) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;
    - (b) promote the publication, by private rights holders, of the terms of

licensing agreements or technology transfer agreements for pandemic-related products; and

- (c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks."

- How can we work to promote a globally sustainable medical countermeasures (MCM) manufacturing system, including leveraging regional approaches to production and maintaining readiness of facilities between pandemic emergencies?

Article 11, Transfer of Technology and Know-how

- What measures could be taken, or incentives provided, to "strengthen existing, and develop innovative, multilateral mechanisms [under WHO], including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries"?

- What measures could be taken, or incentives provided, to "make available non-exclusive licensing of government-owned technologies, on mutually agreed terms as appropriate, for the development and manufacturing of pandemic-related products, and publish the terms of these licenses"?

- In your view, is there a lack of transparency concerning information regarding pandemic-related products, their technological specifications, and manufacturing details? If so, could the establishment of a new mechanism at the WHO effectively address this lack of transparency?

- 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;

- (b) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and
- (c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, with qualified third-party manufacturers when the withholding of such information prevents or hinders urgent manufacture by qualified third parties of a pharmaceutical product that is necessary to respond to the pandemic"?

Article 12, Access and Benefit Sharing

- A key negotiating objective of the United States has been to ensure that all countries share pathogen samples and associated data, including genetic sequence data, from emerging outbreaks quickly and transparently to facilitate response efforts, including the rapid creation of safe and effective vaccines, diagnostic tests, and treatments.
  - What sample and data access impediments have you encountered in the past or what impediments would you envision based on the proposed Pathogen Access and Benefit Sharing (PABS) System in the Negotiating Text that might thwart or delay research efforts?
    - Does implementation of Nagoya Protocol requirements impede the rapid development or deployment of vaccines, diagnostic test, and treatments? Explain.
  - How important is a commitment by negotiating parties to provide parties with

the access to pathogen samples and data that are needed to contribute to rapid creation of safe and effective vaccines, diagnostic tests, and treatments?

- Are alternative strategies for "access" to samples and data available and how do they compare in terms of effectiveness and efficiency?
- How might such commitments impact researchers and institutions?

- The Article 12 negotiating text proposes that sanctioned use of the WHO PABS System would be recognized as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol; such recognition would provide for the exemption of the pathogens covered under the PABS System from additional access and benefit sharing requirements.
  - How valuable would such an "exemption" be to U.S. stakeholders? What pathogens would benefit from exemption status?
  - What additional incentives might be needed to encourage participation in an ABS system exempt from Nagoya Protocol requirements?
- The Article 12 negotiating text envisions parties agreeing to set aside certain percentages of pandemic-related products (proposed in the current negotiating text as a minimum of 20%) and facilitating their exportability.
  - What, from your perspective, are the pros and cons of such a requirement?
  - Would such a requirement advance or hinder rapid research and development efforts?
- The Article 12 negotiating text further envisions required monetary contributions from recipients of shared samples or data, including researchers and manufacturers, for privileges of access. What in your view is the monetary value of access that would be provided in terms of an annual or percentage-based contribution from your organization? How would requiring monetary contributions from academic, government, or other non-profit research institutions impact, positive or negative, research?

- The Article 12 negotiating text specifies other benefits that should be considered for provision to developing countries, including "(i) encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries . . . to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products; (ii) tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products . . .; and (iii) encouraging of laboratories . . . to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials."
    - How helpful would these additional measures be in advancing the rapid creation and/or production scale-up of safe and effective vaccines, diagnostic tests, and treatments? What are the risks or potential negative impacts could come from including such provisions?
    - What incentives might be provided to stakeholders to encourage/assure participation in such voluntary measures?
- What provisions might companies, academic research institutions, and other industry stakeholders look for when assessing voluntary participation in such a proposed Access and Benefit Sharing system? What samples/data are needed the most and how could such a system improve access to needed resources? What provisions are missing that would incentivize broad participation in the system that Member States should consider?

Article 13, Global Supply Chain and Logistics (SCL) Network

- The WHO SCL Network proposed in Article 13 envisions performing a range of functions ordinarily left to individual governments, institutions, or organizations.
    - What functions of Access to COVID-19 Tools-Accelerator (ACT-A) should or should not be institutionalized?
    - Should the U.S. consider incentives to encourage U.S. stakeholders' participation in such an effort and what would compelling incentives be?

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Office for Global Affairs.

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