# WRITTEN COMMENT RE: IMPLICATIONS OF ACCESS AND BENEFIT SHARING (ABS) COMMITMENTS/REGIMES AND OTHER PROPOSED COMMITMENTS IN THE WHO PANDEMIC AGREEMENT

Submitted by the Johns Hopkins Center for Health Security

*RFC headings without comments are not included.*

## Article 12, Access and Benefit Sharing

*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?*

Rather than thwart or delay research efforts, the proposed PABS System would directly seek to reduce existing impediments arising out of the current international legal system. At present, the Nagoya Protocol operates to govern the bilateral transfer of pathogen samples to or from jurisdictions that have adopted implementing legislation. The financial, resource, and time costs of negotiating agreements for these bilateral transfers are not insignificant, particularly during outbreak scenarios where rapid access to pathogen samples may be critical for research efforts, including to further epidemiological understanding and countermeasure development. A multilateral PABS System would address these barriers by a) instilling an obligation to share, improving comprehensiveness of sharing; b) standardizing the legal agreements governing sharing of samples, data, and benefits, reducing transaction costs and delays; and c) standardizing benefits-sharing, improving trust in the system and incentivizing more rapid and comprehensive sharing.

In contrast, the application of the PABS System to sequence data will be a relatively novel layer of regulation on what is otherwise a largely open-source practice: potentially introducing both obligations to share data, as well as allowing subsequent benefits to arise from the use of that data. At present, sequence data sharing is disproportionately representative of samples in high-income countries and not significantly tied to benefits sharing (with the exception of limited source acknowledgement in user-limited databases such as GISAID). The absence of benefits-sharing has the potential to stymie the sharing of sequence data as countries sharing sequence data currently have no system in place that ensures that any subsequent benefits that derive from the use of sequence data, such as countermeasures, are available or accessible to the sharing country. In the current absence of express international governance in this space, and increasing reliance on sequence data over samples, there is a risk that past incidents involving countries refusing to share pathogen samples because of inequitable access to countermeasures may be repeated with sequence data. Further, there is a risk that express governance of sequence data and benefits-sharing will continue to be developed in other international forums where global health and global health security are not primary considerations. A PABS System is an opportunity to promote research by embedding an obligation to share sequence data along with obligations to share the benefits that arise from the use of that sequence data, building trust and more timely and comprehensive sequence sharing.

However, the potential impacts of the proposed PABS System will depend greatly on its governance and structure. For example, using a Pandemic Influenza Preparedness (PIP) Framework approach to categorize laboratories as within network (eg, GISRS) and out of network, and assign different obligations and contractual arrangements (eg, SMTAs) on that status, may result in the PABS System applying within countries, not simply to international transfers of pathogen samples.

*Does implementation of Nagoya Protocol requirements impede the rapid development or deployment of vaccines, diagnostic test, and treatments? Explain.*

Pathogen samples and sequence data are essential components in the development of vaccines, diagnostic tests, and treatments. Despite not being a party to the Nagoya Protocol, the United States' access to pathogen samples may still be governed by implementing legislation in an origin country. Likewise, onward transfer by the United States to a third country would likely require demonstration of compliance.

The financial, resource, and time costs of negotiating ad hoc bilateral agreements for accessing pathogens – and increasingly, sequence data – compliant with domestic legislative or normative requirements are not insignificant. Here, efforts should be made to reduce potential delays and burdens of Nagoya Protocol compliance. Implementing legislation may specify the use of standardized agreements and benefits-sharing, which may reduce potential delays and costs from ad hoc negotiation. Further, the normalization of benefits-sharing may contribute to building trust between countries, resulting in more comprehensive and timely sharing of samples and data.

Nagoya Protocol requirements are not relevant where research and development (R&D) activities are occurring within the pathogen sample or data origin country, as no international transfer of genetic resources is occurring. Similarly, in such cases, deployment of end-product countermeasures – where no international bilateral transfer of samples or sequences has occurred in the chain of product development – would not typically be significantly impacted by implementation of Nagoya Protocol benefits-sharing arrangements.

*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?*

The rapid and comprehensive sharing of pathogen samples and sequence data is essential to the timely development of effective diagnostics, vaccines, and therapeutics. In the early stages of an outbreak, time is of the essence, and waiting for the spread of an infectious disease to obtain samples – rather than obtaining samples directly from the origin – is unethical, unjust, and risks lives globally.

There is currently no express international legal obligation on countries to share pathogen samples or data (with the exception of data deemed to be 'public health information' under the International Health Regulations (2005)). Establishing a clearly articulated obligation to share samples and data would provide a legal and normative standard for diplomacy, advocacy, and potentially dispute resolution if a country fails to share in a timely and comprehensive manner.

*How might such commitments impact researchers and institutions?*

At the high level, the obligation should be appropriately crafted to manifest when certain domestic internal formal notification requirements have been met, similar but more specific than the existing IHR Article 6 notifications process.

*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?*

Subject to appropriate governance arrangements, a multilateral PABS System would be preferable to the ad hoc bilateral sharing established by the Nagoya Protocol for multiple reasons. First, it could establish pre-negotiated standardized template agreements for the transfer of pathogen samples, reducing transaction costs, delays, and burdens. Second, a PABS System could also support the rapid and timely sharing of pathogen data through recognized databases. Third, a PABS System could, depending on its terms of reference and how it is implemented, establish clear benefits-sharing obligations, delineated by recipient organization type (eg, commercial, academic). Fourth, similar to the PIP Framework's Partnership Contribution, a PABS System could facilitate greater investment in international laboratory networks through financial contributions, formalization of networks and sharing arrangements, and capacity building. Finally, a multilateral system would decouple access from benefits-sharing, addressing critiques of transactionalism. Rather than a direct connection between providing access with receiving benefits under a bilateral Nagoya approach, a multilateral system allows the establishment of sharing obligations on all Parties, while benefits are shared on a public health needs basis – instead of directly to Parties that have shared samples or sequences. This decouples access and benefits-sharing, while upholding the underpinning principles of equity and solidarity.

*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?*

As demonstrated during COVID-19, relying on donations is unlikely to be sufficient during an emergency. The requirement to set aside a certain percentage of pandemic-related products is necessary to ensure any international pandemic-related product distribution mechanism (ie, benefits-sharing mechanism) can operate to equitably distribute products for public health need. Using a percentage is more appropriate than set numbers, which will differ depending on the outbreak and the pandemic-related product, while setting to real-time production would ensure that the products are available for a distribution mechanism from the moment they are developed. Ultimately, the successful sharing of products with WHO will require governments with relevant domestic R&D industries to negotiate contracting vehicles that will allow for fulfilling the benefit-sharing requirements.

While commitments under a PABS System to set aside a percentage of pandemic-related products are necessary, they are not sufficient. Further commitments that facilitate exportability are critical to address potential acts of vaccine nationalism from countries – such as the use of export controls – that could prevent the distribution of pandemic-related products, even where pre-committed. Such an

obligation could also have follow-on effects to scaling investment more broadly: countries have a direct interest in ensuring domestic supply of pandemic-related products; however, rather than utilizing export controls to restrict supply to achieve this goal, there should be greater investment in domestic manufacturing capacity for pandemic-related products.

*Would such a requirement advance or hinder rapid research and development efforts?*

It could be argued that such a commitment may disincentivize R&D due to reduced profits. However, the pre-negotiated percentage may include both donations and reservations at reduced prices for WHO for distribution in countries based on public health need, and at tiered pricing where appropriate depending on the recipient country's income status. This provides a guaranteed market, similar to advance market commitments seen in other vaccine development models that incentivize R&D for diseases that are not prioritized in profits-based incentivization models.

*How would requiring monetary contributions from academic, government, or other non-profit research institutions impact, positive or negative, research?*

Similar to the Partnership Contribution under the PIP Framework, monetary contributions should be limited to commercial entities accessing samples or data in the PABS System. Academic, government, and nonprofit research institutions should be exempt from monetary contributions to accessing pathogen data and samples, and instead, contributions should include appropriate citation and acknowledgement of sample and data sources, facilitating research collaborations with provider institutions to enable capacity building, and where academic institutions are involved in pandemic product innovations, pathways for licensing arrangements to enable technology transfer.

*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?*

Each of these measures seeks to build global capacity to research, develop, and deploy countermeasures. As COVID-19 demonstrated, there is insufficient timely global capacity for pandemic response, and as multiple epidemics, including mpox, have demonstrated, skewed prioritization of R&D depending on domestic and regional priorities. There is pressing need to build global and regional capacities, which would be facilitated by these benefits-sharing provisions. At the same time, "encouraging" is a fairly muted obligation. For these provisions to be useful, there should be further agreement on the extent of what "encouragement" requires and how countries may meet this obligation. These details will be critical for determining whether countries become Parties to the treaty

and the extent of industry involvement. There is a risk that requirements that are too onerous or compelling may reduce the number of innovative companies willing to operate in the pandemic-related product development space, particularly provisions relating to intellectual property or technology transfer.

*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?*

Primarily, participation in the proposed system should provide easy and comprehensive access, with the pre-negotiated legal certainty not guaranteed by ad hoc bilateral negotiations. Such legal certainty can facilitate participation by providing clear and consistent rules, applicable to all similar entities, while transparency of benefits-sharing commitments provides accountability and encourages competitive beneficence. As a result, entities will likely look for clarity and structure in the operation and governance of the PABS System, including, for example, pre-agreed standard material transfer agreements, benefits-sharing requirements and options, and, where applicable, contribution calculations.

*What samples/data are needed the most and how could such a system improve access to needed resources?*

Different pathogens necessitate different requirements. Novel pathogens require a system that facilitates rapid and timely global sharing for characterization and countermeasure development. Pathogens that may be high-impact respiratory pathogens are of particular concern for pandemic risk and removing barriers to the rapid and safe sharing of these pathogens, and the development of countermeasures for equitable distribution on public health need, should be a priority. However, it is also important that barriers to sharing other samples and data are removed. The continuous timely and comprehensive sharing of pathogens that regularly evolve, such as SARS-CoV-2, means that there must be systems in place to easily facilitate consistent sample and data sharing to monitor emergence of potential variants of concern and adapt countermeasures accordingly.