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Director, Office of Trade and Health
U.S. Department of Health and Human Services

Steven T. Smith
National Institute of Allergy and Infectious
Diseases (NIAID) Representative,
Geneva, Switzerland

Dear Emily and Steven,

I am writing regarding a specific provision in the most recent version of the negotiating text for a WHO agreement on pandemic preparedness and response, concerning the obligation to publish the access provisions in government funded research and development (R&D) contracts.

Article 9, paragraph 5 of the September 17th, 2024 version of the text contains an obligation to provide provisions in contracts "for the development of pandemic-related health products that promote timely and equitable global access to such products." In the current text, the United States has insisted that negotiators strike language that would require "the publication of such terms."

The putative rationale for this requested deletion was that the language was inconsistent with language in the newly revised WHO International Health Regulations (IHR), and specifically Article 13, paragraph 9(c).

Article 13, paragraph 9(c) of the IHR provides an obligation to make available relevant terms of R&D government contracts relating to equitable access when there is a "request of other States Parties or WHO," and "to support WHO-coordinated response activities." It does not require the publication of these terms. The limited obligation in the IHR falls short of the proposal in Article 9, paragraph 5 of the pandemic agreement negotiating text, which would require "the publication of such terms." The obligation to publish the terms of equitable access provisions is important.

Publication makes the information available to everyone. For product development contracts, publication of the equitable access provisions should occur before there is a product or even a specific need for a product. Publication of the access terms in R&D contracts is essential for the public to evaluate the policies of governments in addressing equitable access, or the measures taken by companies to satisfy the obligations.

As pointed out by KEI, DNDi and MSF during their interventions at the INB negotiations, the publication obligation in Article 9.5 of the pandemic agreement is consistent and complementary to the IHR text, but not the same.

KEI has a deep interest in this issue. In the case of the COVID 19 pandemic response, and in connection with concerns regarding equity, it was necessary to use the Freedom of Information Request Act (FOIA) to request funding agreement contracts. Such requests always involve delays and disputes over redactions. We are currently litigating redactions in hundreds of contracts[1] four years after our original FOIA requests. This includes multiple cases of redactions involving important public health safeguards in Other Transaction Agreements (OTAs).[2]

Efforts to obtain copies of contracts, including funding agreements, CRADAs, and licenses, involve long delays and impose significant costs on agencies responding to the legal requirements of FOIA.

By having a policy that certain contract terms will be routinely published, not only will agencies (and the requester) avoid the burden of a case-by-case review of each FOIA request, but the public can benefit from timely access to the information needed to evaluate agency policies and monitor the implementation of the public health safeguards. As any researcher or journalist can attest, timely access to information is important, particularly during a crisis, but also when conducting research or evaluations of government policies, when it is not practical to wait years for a FOIA request to be processed and resolved.

Related to our concerns is our frustration that the United States has consistently ignored the transparency norms set out in the World Health Assembly resolution WHA72.8 on Improving the transparency of markets for medicines, vaccines, and other health products. Colin McCiff was the lead U.S. negotiator on this resolution, and the U.S. was among the strongest supporters of the resolution. KEI had made many interventions at the INB and in communications to the U.S. government asking that the norms in WHA72.8 be implemented in the pandemic agreement. This has not happened, and we would like an explanation as to why in an agreement on pandemic preparation and response, the transparency norms contained in WHA72.8 are not fully implemented.

As regards the INB process itself, KEI appreciates the recent transparency expanding decision by member states to share timely versions of the negotiating text with NGOs. We also ask the United States delegation to propose to the INB Bureau that video recordings of the daily NGO interventions be published by the WHO to provide the public with more information regarding negotiations.

In closing, it is deeply troubling that the U.S. government, the most important funder of biomedical research in the world, is also the country objecting to the publication of the provisions in contracts relating to equitable access.

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[1] https://www.keionline.org/covid-contracts

[2] For example, see: Kathryn Ardizzone, "$1.3 Billion Johnson & Johnson COVID-19 Vaccine Development Contract Contains Broad RedactionsRelating to Public's Rights in Inventions, April 1, 2021 https://www.keionline.org/35793

Sincerely,

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Cc: Several other members of the US delegation to INB11
Stephanie Psaki, NSC
Michelle Childs, DNDi
YuanQiong Hu, PhD, MSF