March 10, 2023

The Honorable Joseph R. Biden The White House 1600 Pennsylvania Ave. Washington, DC 20500

Dear President Biden.

Our organizations write today in support of the request from the mRNA Technology Transfer Hub Program¹ partners for your administration to expand U.S. support for the initiative by providing a contribution of \$100 million, joining other countries in providing financing for its vital work enhancing global pandemic preparedness and response capabilities.

The COVID-19 pandemic has laid bare vulnerabilities in the world pandemic preparedness and response architecture. Time and again, countries with greater control over vaccine manufacturing and supply used that power to prioritize securing vaccines for their residents, often building a vaccine surplus, while billions of people in poorer countries went without. More than 13 billion COVID-19 vaccine doses have been administered globally, yet still more than two-thirds of people in low-income countries have not received a single dose. Vaccine inequity has cost millions of lives, damaged the global economy, and increased the risk of new variants.

In July 2021, the World Health Organization (WHO) launched its groundbreaking program to build capacity in low- and middle-income country (LMIC) mRNA vaccine manufacturing.³ The aim of the Hub Program is to contribute to enabling equitable access to mRNA vaccines, by increasing the distribution of sustainable manufacturing capacity across countries, enhancing regional and inter-regional collaborations, and developing and empowering local workforce through tailored and inclusive trainings and expert support. Its goal is to empower local producers to make vaccines that target indigenous health threats and potential outbreaks, instead of once again waiting at the back of the line for scarce supplies.

Already, the Hub Program has succeeded in making mRNA vaccines at lab scale at the Afrigen facility in Cape Town and has selected technology recipients in LMICs spanning continents. The Program is progressing in building local skilled workforces as well. Scientists from fifteen regional manufacturing "spokes" are training in mRNA techniques at the Afrigen facility. The U.S. Government has contributed trainings for Hub-affiliated scientists at its Center for Innovation in Advanced Development and Manufacturing in Texas. Top scientists affiliated with the U.S. National Institutes of Health are providing their guidance and expertise.

We are grateful for this and other technical support that the United States has provided so far, as well as recognition by your administration that humility, multilateralism, and partnerships, must serve as core

¹ Henceforth, the "Hub Program"

² https://ourworldindata.org/covid-vaccinations. Accessed February 21, 2023.

³ https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

 $^{^{4}\,\}underline{\text{https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/recipients-of-mrna-technology-from-the-who-mrna-technology-transfer-hub}$

⁵ For further detail on progress of the Hub towards meeting program objectives, see Appendix 1 below.

principles in our global COVID-19 response and recovery. We applaud you for affirming the United States' commitment to supporting the Hub through the recent G20 Bali Leaders' Declaration, stating:

We recognize the need for strengthening local and regional health product manufacturing capacities and cooperation as well as sustainable global and regional research and development networks to facilitate better access to VTDs [vaccines, therapeutics and diagnostics] globally, especially in developing countries, and underscore the importance of public-private partnership, and technology transfer and knowledge sharing on voluntary and mutually agreed terms. We support the WHO mRNA Vaccine Technology Transfer hub as well as all as the spokes in all regions of the world with the objective of sharing technology and technical know-how on voluntary and mutually agreed terms. We welcome joint research and joint production of vaccines, including enhanced cooperation among developing countries.

Secretary Blinken reaffirmed U.S. support for the Hub at the U.S.-Africa Leaders Summit:⁸

Right now, the public and private sectors are working with the World Health Organization in South Africa to create the first COVID-19 mRNA vaccine technology transfer hub. This ensures that we're not only providing emergency aid to African countries, but we're investing – investing in future tech know-how and production in Africa, by Africans, with all of the health, science, and economic benefits that this brings. [...]

Yes, of course, we all have to face and deal with emergency situations. We're acutely aware of that and acutely invested in that. But even more important is making these investments in sustainable capacity in Africa for the long term, so that whether it comes to dealing with climate, whether it comes to dealing with COVID and global health, whether it comes to dealing with food security, that capacity exists for the long term in Africa. That's what this is all about and what we have to be about together.

We agree. Now, it is time for the United States to join numerous countries and other stakeholders in providing the Hub with the financial resources it needs to build off its initial successes. Already, funding contributions to the Hub have been provided by France, Canada, Norway, Belgium, Germany, South Africa, the European Commission, the African Union, and others. With an investment of around one one-hundredth of one percent (0.01%) of annual U.S. military spending, the United States can help prevent and respond to pandemics that cost trillions of dollars.

A modest contribution of \$100 million from the United States would support sustaining the Hub Program, helping to realize decentralized, local and regional mRNA manufacturing capabilities that the world needs.

Through this contribution, the United States can complement investments of other donors to support the establishment of the South African hub; support the 15 "spokes" to enable successful technology transfer; develop improved second-generation mRNA technology and a pipeline of novel vaccine candidates for SARS-CoV2 and other diseases relevant to low- and middle-income countries, including advancing at least one mRNA candidate vaccine to Phase 1/2a; and manufacturing for late-stage efficacy trials and vaccine introduction, pending trial results.

U.S. pandemic preparedness is inseparable from the health of others a world away. Please support global health and pandemic preparedness through providing funding for the Hub Program without delay.

⁶ https://www.whitehouse.gov/wp-content/uploads/2022/09/U.S.-COVID-19-GLOBAL-RESPONSE-RECOVERY-FRAMEWORK-clean 9-14 7pm.pdf

 $^{^{7}\,\}underline{\text{https://www.whitehouse.gov/briefing-room/statements-releases/2022/11/16/g20-bali-leaders-declaration/}$

⁸ https://www.state.gov/secretary-antony-j-blinken-at-the-u-s-africa-leaders-summit-foreign-ministers-dinner/

Sincerely,

Public Citizen

American Friends Service Committee

AVAC

Drugs for Neglected Diseases initiative (DNDi)

Foundation for Integrative AIDS Research (FIAR)

Global Citizen

Global Health Technologies Coalition Policy Cures Research

Health GAP (Global Access Project)

Justice is Global

Network Lobby for Catholic Social Justice

Oxfam America

Partners In Health

PrEP4A11

R2H Action [Right to Health Action]

RESULTS

Sojourners

Speak Up Africa

Treatment Action Group

Yale Global Health Justice Partnership

Appendix 1 – The mRNA Technology Transfer Hub Program progress to date:

To achieve the Program objectives by promoting regional research and development (R&D) collaborations and enhancing the global distribution of mRNA vaccine manufacturing capacity across all continents, WHO and the Medicines Patent Pool (MPP) have:

1) Initiated a collaboration with the **South African mRNA Hub consortium** (Afrigen/Biovac/SAMRC) to: (i) establish a hub/spoke model, where Afrigen/Biovac are developing an mRNA-based vaccine technology (first-generation) and manufacturing process at commercial scale; and (ii) conduct R&D activities in South Africa (in collaboration with SAMRC) to develop an improved second-generation mRNA technology (focused on freedom to operate, reduced cost of goods and reduced supply chain complexities, i.e. enhanced product thermostability) and an R&D pipeline relevant for the South African context.

- 2) Identified **14 additional recipient manufacturing facilities** (**spokes**) all around the world that have expressed their interest in the Programme to receive the technology developed by Afrigen and industrialized by Biovac. The aim of these manufacturers receiving the technology will be to establish their own mRNA vaccine production capacity, supported by a strong local regulatory framework, with a product development pipeline that will support inter-pandemic sustainability and pandemic readiness.
- 3) Established a **R&D network** involving the spokes, their key academic partners and the South African Consortium to provide a collaborative platform aiming at facilitating and accelerating product development and access to novel mRNA vaccines in LMIC markets worldwide and by taking into consideration regional market coherence.