RE: U.S. Government Action Needed to Ensure Global Vaccine Access

Dr. Fauci, Dr. Walensky, Dr. Kessler, Dr. Murthy, & Dr. Nunez-Smith:

We are writing about the letter sent to you on 30 January 2020 by our South African colleagues regarding COVID-19 vaccine access in the Global South. Despite the severity of South Africa’s COVID-19 epidemic, the country has only succeeded in procuring enough vaccine doses to cover less than 50% of its population – even including the nation’s COVAX allotment. Alas, South Africa’s experience is
representative of the greater crisis in access to COVID-19 vaccines in lower- and middle-income countries.

Absent immediate intervention, vaccines will not be widely available in lower-income countries and many middle-income countries before 2023.\(^2\) This not only poses a risk to individuals and communities in those countries, but to all countries globally. Rapidly vaccinating the global population with highly effective vaccines is the surest and only way to reduce the risk of vaccine resistant viral variants.

**The U.S. government can and must take immediate action to increase the global availability and supply of COVID-19 vaccines.**

Although other vaccine candidates, multilateral agencies like GAVI, and other nations have an important role to play in global immunization, the lack of production scale up of the mRNA vaccine developed via a collaboration between the U.S. National Institute of Allergy and Infectious Diseases (NIAID) and Moderna is most concerning. The NIAID-Moderna vaccine represents a highly efficacious vaccine that reduces incidence of symptomatic COVID-19 by over 90\(^\%\)\(^3\) and can be stored in a normal freezer and a regular refrigerator for up to 30 days.\(^4\) Additionally, mRNA vaccines can be tweaked to address emerging variants more rapidly than other vaccine technologies.\(^5\) Currently, planned global production in 2021 for the NIAID-Moderna vaccine, in the best-case scenario, will only be enough for 500 million people – less than seven percent of the global population.\(^6\) The development of NIAID-Moderna vaccine was almost exclusively funded by the U.S. government, with over $2.5 billion spent so far.\(^7\) Furthermore, the NIAID-Moderna vaccine relies on intellectual property owned by the U.S. government.\(^8\)

The U.S. government has significant ability to both increase production and facilitate technology transfer to other nations. We therefore request:

1) **The U.S. government immediately scale up production of the NIAID-Moderna Vaccine and make it available to lower- and middle-income countries – including upper-middle-income countries facing dire need such as South Africa – at the cost of production.**

   Current global mRNA vaccine production capacity is insufficient to produce enough mRNA vaccine doses to ensure global access. Creating manufacturing capacity for enough mRNA vaccines to vaccinate the entire world for a single year would cost less than US$4 billion per year and would cost approximately US$2 a dose.\(^9\) Furthermore, the federal government has a unique role as owner of the intellectual property protecting the vaccine. There are multiple paths to scaled up production, including public production and global partnerships. As a holder of existing statutory powers (like the Defense Production Act and government patent use) the U.S. government has the power today to increase production of any vaccine for both domestic and global use.
2) The U.S. government should stop obstructing proposals that would enable global vaccine access and instead work to facilitate transfer of intellectual property and know-how for global production of COVID-19 vaccines.

A critical aspect of the global public health response to COVID-19 relies on LMIC’s ability to procure and manufacture vital diagnostics, drugs, and vaccines for responding to the COVID-19 pandemic. One component of this is allowing foreign governments to waive key intellectual property barriers and access know-how and proprietary information vital to the manufacture of these products. To do so, the U.S. government should support the request of India and South Africa for a temporary waiver of some aspects of Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding COVID-19 vaccines, diagnostics, and drugs, in advance of the WTO General Council Meeting March 1-2 and the TRIPS Council Meeting March 10-11. Furthermore, the U.S. government must pressure companies like Moderna to share know-how and intellectual property with the World Health Organization’s Coronavirus Technology Access Pool (C-TAP) and facilitate global tech-transfer to build manufacturing capacity abroad.

3) The U.S. government should commit to building mRNA production capacity not just in the U.S., but also abroad.

Any future global pandemic response requires establishing new production lines outside of the United States, including in lower- and middle-income countries, to avoid drug shortages. The U.S. should partner with other governments and companies to fund and facilitate tech transfer for new production lines outside of the U.S., such as an African Union hub or partnership with the Developing Countries Vaccine Manufacturers Network, based on an upfront commitment to equitable global access. Such expanded mRNA production capacity builds a more robust global supply chain better prepared to address future infectious disease outbreaks.

While important, alleviating the manufacturing shortages outlined above will do little without an implementation plan once mRNA vaccine supply can meet global demand. To address implementation, the WHO should act as a convener to determine (1) how to fund implementation worldwide, (2) a means of developing country-driven approaches to vaccine delivery, and (3) guidelines and best practices for vaccine delivery.

Sincerely,

Organizations:
PrEP4All
Public Citizen
Health GAP
Doctors for America
Initiative for Medicines, Access, & Knowledge
The Democracy Collaborative
Be A Hero
AVAC
Ibn Sina Academy of Medieval Medicine and Sciences, India
Progressive Doctors
Foundation for Integrative AIDS Research
Society for International Development
Latino Commission on AIDS
Hispanic Health Network
Foundation Eboko
Coal, Inc.
The Translatin@ Coalition
Hesperian Health Guides
SumOfUs
Women's Health in Women's Hands Community Health Centre
BARAC UK
Focus on the Global South
Southern and Eastern African Trade Information and Negotiations Institute

Individuals:

Wafaa El-Sadr, MD, MPH, Professor, Columbia University
Gregg Gonsalves, PhD, Assistant Professor, Yale School of Public Health
Jessica E. Justman, MD, Senior Technical Director, ICAP at Columbia, Mailman School of Public Health
Reshma Ramachandran, MD, MPP, Co-Chair, Drug Affordability Action Team, Doctors for America
Andrew Goldstein, MD, Founder, Progressive Doctors
Joseph Osmundson, PhD, Clinical Assistant Professor, New York University
Matthew Kavanagh, PhD, Director, Global Health Policy & Politics Initiative, Georgetown University
Jorge Bermudez, MD, DSc, Senior Professor, Fundação Oswaldo Cruz, Rio de Janeiro, Brazil
Mitchell Warren, Executive Director, AVAC
Asia Russell, Executive Director, Health GAP
George Carter, Founder & Director, Foundation for Integrative AIDS Research
Vanessa Mavila, President, Foundation Eboko
Zita Holbourne, National Chair, BARAC UK
Shalmali Guttal, Executive Director, Focus on the Global South
Peter Staley
David Barr
Nicoletta Dentico
Adina Gerver
Ben Cheng
Navya Dasari

2 Economist Intelligence Unit. “More than 85 poor countries will not have widespread access to coronavirus vaccines before 2023” (27 Jan 2021). URL: https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/