

December 13, 2021

David Kessler, M.D.
Chief Scientific Officer for the COVID-19 Response
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Gary Disbrow, Ph.D.
Director
Biomedical Advanced Research and Development Authority
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Drs. Kessler and Disbrow,

For more than a year, our organizations have been calling for the United States Government to take leadership in rapidly scaling up mRNA production capacity to help put an end to severe global inequities in COVID-19 vaccine access, and we have published detailed plans for it to do so.^{1,2} We are encouraged by the Biden-Harris Administration's recent announcement of plans to invest billions of dollars from funds provided under the American Rescue Plan to help meet President Biden's pledge for the United States to be an "arsenal of vaccines" for the world, while disappointed the Administration did not pursue similar or more ambitious action sooner. We are concerned by the intimation from the White House that this new, critical American biosecurity infrastructure will simply be gifted to private companies such as Pfizer or Moderna to operate under their total ownership.³ However, for this investment to make the impact on supply and access that is needed, it is essential the U.S. government scales the ambition of this plan to produce billions more doses per year and retains ownership over any new domestic manufacturing capacity that is established.

Despite 8 billion doses of COVID-19 vaccine administered globally so far, only 6% of people in low-income countries have received even a single dose.⁴ The proportion of mRNA vaccine doses from Moderna and Pfizer that have reached low-income countries is even lower than from other manufacturers.⁵

Emergence of the Omicron variant, which experts fear may make current vaccines less effective, has provided a cruel reminder that the world does not have the time to wait. So long

¹ <https://www.citizen.org/news/report-how-biden-can-shore-up-global-u-s-production-of-covid-19-vaccines/>

² <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>

³ <https://www.nytimes.com/2021/11/17/us/politics/biden-covid-vaccine-manufacturing.html>

⁴ <https://ourworldindata.org/covid-vaccinations>

⁵ <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html>

as the United States and other high-income country governments allow the SARS-CoV2 virus to circulate unabated due to insufficient vaccine access, we risk the emergence of more variants.

Moderna and Pfizer are projecting cumulative sales in 2021 of more than \$50 billion for COVID-19 vaccines alone.⁶ Industry analysts project even greater windfalls in 2022, with Pfizer and Moderna revenues approaching \$100 billion.⁷ Despite these record-shattering revenues, arrangements Pfizer and Moderna have entered to provide doses to low- and middle-income countries have been grossly inadequate, providing far too few doses, far too slowly, and sometimes only under onerous terms.⁸ The two corporations so far have refused to share technology with willing and capable manufacturers, despite requests.⁹

Allowing Pfizer and Moderna total control over mRNA production and allocation has been disastrous for global vaccine access. To ensure newly established domestic manufacturing capacity provides the needed impact to fight COVID-19 and prepare us against future pandemic threats, the Biden-Harris Administration must pursue a public, government-owned, contractor-operated (GOCO) manufacturing model. To avoid pitfalls of past public-private biopharmaceutical manufacturing arrangements and to safeguard public interests, a well-designed GOCO vaccine manufacturing model would:

1) Preserve public control over the facility, giving the government the freedom to make critical decisions about operations, manufacturing partners and technology.

The United States experience with Centers for Innovation in Advanced Development and Manufacturing (CIADM) and specifically its relationship with Emergent and the Baltimore facility is a case in point of the need for the government to have control and oversight over operations.¹⁰ Government ownership would ensure that U.S. government scientists and manufacturing experts would be able to closely monitor facility activity, and would be able to replace a contractor failing to meet quality standards, should the need arise. If a different technology is needed to address public health needs, the United States would have the flexibility to retrofit the facility and shift which product is being manufactured with this capacity.

2) Enable transfer of technical know-how for mRNA vaccine production.

The United States Government holds vast technical expertise on vaccine production. Manufacturers throughout the world are eager to receive know-how and training that would enable them to locally produce mRNA vaccines. A GOCO facility could become a training center

⁶ <https://www.oxfam.org/en/press-releases/pfizer-biontech-and-moderna-making-1000-profit-every-second-while-worlds-poorest>

⁷ <https://www.fiercepharma.com/pharma/pfizer-moderna-will-rake-a-combined-93-billion-next-year-covid-19-sales-says-analytics-group>

⁸ <https://www.citizen.org/article/pfizers-power/>

⁹ <https://www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14/>

¹⁰ <https://www.fiercepharma.com/manufacturing/done-deal-emergent-says-covid-19-vaccine-production-contract-u-s-has-been-terminated>

for other manufacturers. For this pandemic or future pandemics, the United States could allow other manufacturers to visit the facility and learn about vaccine production, greatly expanding the impact of its investment. The United States could license technology and know-how developed at the facility for use in low- and middle-income countries.

3) Ensure fair pricing and global access.

Moderna and Pfizer revenues from COVID-19 vaccines have exceeded the gross domestic product of dozens of nation states, most of which do not have sufficient access to vaccines sold by Moderna and Pfizer nearly a year after regulatory authorization. Under a GOCO manufacturing arrangement, the United States Government would be able to ensure that LMICs and COVAX have access to the most efficacious vaccines at a reasonable price. Moderna and Pfizer, by contrast, have indicated intentions to raise vaccine prices at a future date.¹¹

Unless the U.S. government owns the manufacturing and exercises stewardship of the mRNA vaccine technology it helped pioneer, we risk repeating the cycle of the past year, in which manufacturer failures and corporate control compromise global vaccine access and slow efforts to end the pandemic. In addition to establishing domestic mRNA manufacturing capacity, the U.S. government should also support developing mRNA vaccine manufacturing capacity throughout the world where vaccines are needed, including in Africa. Goals of the U.S. government's mRNA production plan should include helping provide billions of doses of highly effective vaccines to the world as quickly as possible and equipping the world with adaptable manufacturing capacity. We call for domestic mRNA production to be publicly owned.

Sincerely,

Partners In Health
PrEP4All
Public Citizen

¹¹ <https://www.wsj.com/articles/boosters-pfizer-moderna-vaccine-sales-11629368306>