

Congress of the United States
Washington, DC 20510

October 12, 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:

We write to seek information on the Biden administration's efforts to accelerate global vaccine manufacturing, expand access to COVID-19 vaccines around the world, and hasten the end of the pandemic. We appreciate the administration's attention to these issues, including President Biden's most recent commitment during the Global COVID-19 Summit to donate an additional 500 million doses of the Pfizer-BioNTech vaccine to low- and middle-income countries and to achieve full vaccination for 70 percent of the global population by the 2022 meeting of the United Nations General Assembly.¹ These are important steps; however, we remain concerned about the significant disparities in global vaccine supply and access.

Although more than six billion COVID-19 vaccine doses have been administered globally, the vast majority have been administered in higher-income countries, and less than one percent of doses have been administered in low-income countries.² As a result, under 10 percent of people living in poor nations have been fully vaccinated.³ Meanwhile, the virus continues to circulate, with an average of over 438,000 new cases reported daily, risking the evolution of new variants that have the potential to be even more infectious or deadly and, at worst, resistant to

¹ The White House, "FACT SHEET: Targets for Global COVID-19 Summit," press release, September 22, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/22/fact-sheet-targets-for-global-covid-19-summit/>; NPR, "The U.S. Is Donating More COVID Vaccines and Wants Other Rich Nations to Pitch in," Tamara Keith, September 22, 2021, <https://www.npr.org/2021/09/22/1039526862/the-u-s-is-buying-500-million-more-pfizer-vaccine-doses-to-donate-to-other-count>.

² The New York Times, "Tracking Coronavirus Vaccinations Around the World," Josh Holder, Accessed September 24, 2021, <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>.

³ The New York Times, "At Covid Summit, Biden Sets Ambitious Goals for Vaccinating the World," Sheryl Gay Stolberg, September 22, 2021, <https://www.nytimes.com/2021/09/22/us/politics/biden-covid-summit-vaccines.html>.

existing COVID-19 vaccines.⁴ That is why it is imperative for the administration to take bold steps to dramatically expand global vaccine access and manufacturing capabilities as quickly as possible.

Supporting manufacturing capacity across the world is important not only to make vaccine access more equitable during the COVID-19 pandemic, but also to prepare lower-income countries for future pandemics. In this way, such efforts are a smart investment for both the short and long-term.

The U.S. government has provided substantial financial support to pharmaceutical companies to accelerate the development of safe, effective COVID-19 vaccines. Moderna, which is the smallest of the three companies that produce vaccines authorized or approved by the FDA, has disproportionately benefited from this support. In addition to receiving significant federal resources to assist in vaccine development, the company also received nearly \$10 billion in federal government funding between April 16, 2020 and June 15, 2021 to boost its manufacturing capacity, execute large-scale clinical trials, and deliver vaccines.⁵ Prior to 2020, the company had neither successfully brought a product to market nor advanced a vaccine candidate to stage three clinical trials.⁶ The former scientific head of the COVID-19 vaccine response stated that the government “held Moderna by the hand on a daily basis.”⁷

Despite receiving huge sums of public funding from American taxpayers, Moderna has refused calls to share its technology, including from the U.S. government. According to reports:

The Biden administration has privately urged both Pfizer and Moderna to enter into joint ventures where they would license their technology to contract manufacturers with the aim of providing vaccines to low- and middle-income countries, according to a senior administration official.

4 The New York Times, “Coronavirus World Map: Tracking the Global Outbreak,” Updated October 4, 2021, <https://www.nytimes.com/interactive/2021/world/covid-cases.html>; Centers for Disease Control, “Understanding Variants,” Updated August 6, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/variants/understanding-variants.html>.

5 Pharmaceutical Technology, “Top Ten Pharma Companies in 2020,” Updated June 1, 2021, <https://www.pharmaceutical-technology.com/features/top-ten-pharma-companies-in-2020/>; Boston Globe, “The U.S. Government Has Now Paid Moderna \$6b for Vaccine Effort,” Jonathan Saltzman, April 29, 2021, <https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/>; U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, “COVID-19 Medical Countermeasure Portfolio,” Accessed October 4, 2021, <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine>.

6 CNN, “In quest for vaccine, US makes 'big bet' on company with unproven technology,” Robert Kuznia, Katie Polglase and Gianluca Mezzofiore, May 1, 2020, <https://www.cnn.com/2020/05/01/us/coronavirus-moderna-vaccine-invs/index.html>.

7 USA Today, “Deliver a safe, effective COVID-19 vaccine in less than a year? Impossible. Meet Moncef Slaoui,” Karen Weintraub, December 1, 2020, <https://www.usatoday.com/in-depth/news/health/2020/12/01/operation-warp-speeds-moncef-slaoui-guided-covid-19-vaccine-creation/6375043002/>.

Those talks led to an agreement with Pfizer, announced Wednesday morning, to sell the United States an additional 500 million doses of its vaccine at a not-for-profit price — rather than license its technology — to donate overseas. The discussions with Moderna have not been fruitful [...]

The World Health Organization has also had trouble getting Moderna to the negotiating table, according to Dr. Martin Friede, a W.H.O. official [...] “We would love to get a discussion with Moderna, about a license to their intellectual property — this would make life so much simpler, but for the moment all attempts have resulted in no reply,” Dr. Friede said.⁸

Moderna is projected to manufacture between 800 million and one billion doses of its COVID-19 vaccine in 2021.⁹ This production goal will still fall far short of the 11 billion doses experts estimate are needed to vaccinate 70 percent of the world’s population.¹⁰ Moderna’s recent announcement that it plans to open a new mRNA facility in Africa to produce up to 500 million vaccine doses per year is promising, but it does not solve the immediate problem.¹¹ This factory’s production will still not be sufficient to reach the Biden administration’s goal of ending the global pandemic by September 2022 because these doses will not be available for years.¹² The announcement further “does not answer calls from African leaders and activists to waive patent laws that would give more drugmakers access to details on how coronavirus vaccines are produced. It also does not address the continent’s immediate COVID-19 vaccine shortages.”¹³

Instead, to reach these targets as quickly as possible, it will be necessary to dramatically expand global vaccine manufacturing, and manufacturers around the world, including in South

8 The New York Times, “Pressure Grows on U.S. Companies to Share Covid Vaccine Technology,” Stephanie Nolen and Sheryl Gay Stolberg, September 22, 2021, <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>.

9 Moderna, “Moderna Announces Additional Investments to Increase Global Supply for COVID-19 Vaccine to up to 3 Billion Doses in 2022,” press release, April 29, 2021, <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-additional-investments-increase-global-supply>.

10 Nature, “COVID Vaccines to Reach Poorest Countries in 2023 – Despite Recent Pledges,” T.V. Padma, July 5, 2021, <https://www.nature.com/articles/d41586-021-01762-w>.

11 Moderna, “Moderna to Build State-of-the-Art mRNA Facility in Africa to Manufacture up to 500 Million Doses Per Year,” Press Release, October 7, 2021, <https://investors.modernatx.com/news-releases/news-release-details/moderna-build-state-art-mrna-facility-africa-manufacture-500>.

12 Politico, “Tensions grow between Moderna, White House over vaccine production,” Erin Banco, Adam Cancryn, and Sarah Owerhohle, October 7, 2021, <https://www.politico.com/news/2021/10/07/biden-admins-moderna-international-donations-515537>.

13 The New York Times, “Moderna says it will build a vaccine factory in Africa, but that will take time,” Lynsey Chutel, October 7, 2021, <https://www.nytimes.com/2021/10/07/world/africa/covid-moderna-africa.html>.

Korea and South Africa, stand ready to help.¹⁴ But without cooperation from Moderna, these facilities will be forced to spend precious time trying to replicate existing mRNA technology.¹⁵

Given the urgent need to ramp up global vaccine production, we appreciate the Biden-Harris administration's leadership in pushing for a waiver of international intellectual property protections for COVID-19 vaccines and its participation in negotiations at the World Trade Organization (WTO).¹⁶ However, we are concerned that an agreement on a waiver has not been reached, and we urge the administration to use all its resources to press the remaining opposing countries to reach an agreement.¹⁷ At the same time, the administration has other tools to increase global vaccine production that it can and should use.

The contract Moderna entered into with the Biomedical Advanced Research and Development Authority (BARDA) may give the federal government legal authority to access and share the ingredient list and manufacturing instructions for Moderna's COVID-19 vaccine.¹⁸ Specifically, the contract grants BARDA "unlimited rights to data funded under this contract pursuant to [the Federal Acquisition Regulations (FAR)] Clause 52.227-14."¹⁹ Under FAR, data is defined to include "recorded information, regardless of form or the media on which it may be recorded," as well as "technical data" – a broad definition that appears to include all key information needed to produce the vaccine.²⁰

Although portions of the BARDA-Moderna contract have been publicly released, large parts of it have been redacted, resulting in a lack of clarity about the government's full rights to information and data.²¹ To help us understand the scope of the government's rights under this contract, we request that you provide answers to the following questions by no later than October 26, 2021:

14 Financial Times, "Seoul Urges Biden to Break Vaccine IP Deadlock," Song Jung-a, Edward White, and Kiran Stacey, August 24, 2021, <https://www.ft.com/content/66adc278-7191-4b8b-a0fc-b33e915d4631>. See also: The New York Times, "Pressure Grows on U.S. Companies to Share Covid Vaccine Technology," Stephanie Nolen and Sheryl Gay Stolberg, September 22, 2021, <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>.

15 The New York Times, "Pressure Grows on U.S. Companies to Share Covid Vaccine Technology," Stephanie Nolen and Sheryl Gay Stolberg, September 22, 2021, <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>.

16 Office of the U.S. Trade Representative, "Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver," May 5, 2021, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

17 Roll Call, "Biden announces vaccine donations, but India and South Africa renew calls for IP waivers," Niels Lesniewski, September 22, 2021, <https://www.rollcall.com/2021/09/22/biden-announces-vaccine-donations-but-india-and-south-africa-renew-calls-for-ip-waivers/>.

18 U.S. Department of Health and Human Services, "Moderna-BARDA Contract, 75A50120C00034," April 16, 2020, <https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>; Public Citizen, "Sharing the NIH-Moderna Vaccine Recipe," Zain Rizvi, August 10, 2021, <https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/>.

19 U.S. Department of Health and Human Services, "Moderna-BARDA Contract, 75A50120C00034," April 16, 2020, <https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>.

20 48 CFR § 52.227-14.

21 U.S. Department of Health and Human Services, "Moderna-BARDA Contract, 75A50120C00034," April 16, 2020, <https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>.

1. What information is covered under the April 16, 2020 Moderna contract provision that grants BARDA “unlimited rights”? What information is covered under contract provisions that grant BARDA “limited” rights? Please provide a summary of all categories of information, and associated documents.
 - a. Does BARDA hold unlimited rights to Moderna’s commercial-scale processes, including but not limited to the master production records?
 - b. Does BARDA hold unlimited rights to manufacturing data and results, including but not limited to the batch records?
 - c. Does BARDA hold unlimited rights to clinical trial data?
 - d. Does BARDA hold unlimited rights to Moderna’s regulatory submissions to the Food and Drug Administration (FDA)?
 - e. Does BARDA hold unlimited rights to the final data submission packages submitted by Moderna? If so, what information is expected to be included in the packages?

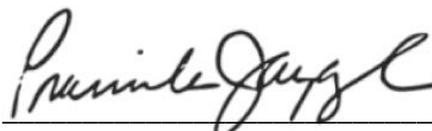
2. Are your offices in dialogue with the World Health Organization’s mRNA hub project, regarding sharing vaccine information to expand global COVID-19 vaccine manufacturing?²²
 - a. If so, please describe the collaboration, and whether the Biden administration will use its contractual authority to share vaccine information.
 - b. Are there any limiting factors – such as a shortage of knowledgeable production personnel or facilities – that would limit the benefits of vaccine information sharing?
 - c. If your offices are not in dialogue with the World Health Organization’s mRNA hub project, why aren’t they?

3. What other efforts has the Biden administration made to provide additional quantities of the Moderna vaccine to low- and middle-income countries? Has Moderna cooperated with these efforts?

Thank you for your urgent attention to this matter and for your efforts to bring a swift end to the COVID-19 pandemic around the globe.

Sincerely,

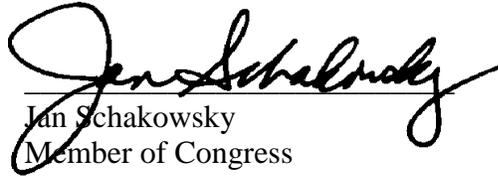

Elizabeth Warren
United States Senator


Pramila Jayapal
Member of Congress

²² World Health Organization, Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub to Scale Up Global Manufacturing,” April 16 2021, <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.



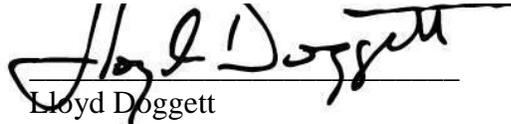
Jeffrey A. Merkley
United States Senator



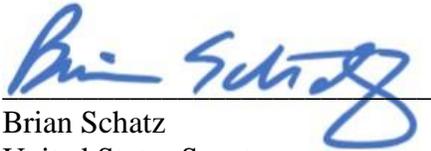
Jan Schakowsky
Member of Congress



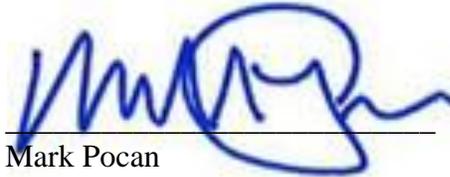
Tammy Baldwin
United States Senator



Lloyd Doggett
Member of Congress



Brian Schatz
United States Senator



Mark Pocan
Member of Congress



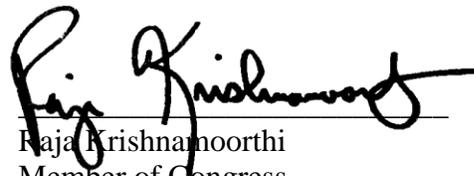
Tina Smith
United States Senator



Maxine Waters
Member of Congress



Sherrod Brown
United States Senator



Raja Krishnamoorthi
Member of Congress