

United States Senate  
WASHINGTON, DC 20510

April 28, 2021

Stéphane Bancel  
Chief Executive Officer  
Moderna  
200 Technology Square  
Cambridge, MA 02139

Dear Mr. Bancel:

We write to you today regarding Moderna's plans to expand access to coronavirus disease 2019 (COVID-19) vaccines and vaccine manufacturing capacity globally, including in India. Increasing COVID-19 vaccinations in India is urgently needed to reduce human suffering and prevent unnecessary deaths. It could also help halt the spread of coronavirus variants that could prolong the pandemic across the globe.<sup>1</sup> To address our concerns about this matter, we are seeking information on the steps Moderna is taking to increase India's access to vaccines.

COVID-19 has infected over 148 million people and killed over three million globally, with hundreds of thousands of new cases and thousands of deaths being reported daily.<sup>2</sup> Though Pfizer, Moderna, Johnson & Johnson, and other companies have developed safe and effective COVID-19 vaccines, the uncontrolled spread of coronavirus poses significant risks to global vaccination efforts: as the virus proliferates, it evolves—increasing the risk of a variant developing that renders vaccinations ineffective.<sup>3</sup> Though wealthier countries, including the United States, have successfully secured vaccines and have made significant strides in vaccinating their populations, many middle- and lower-income nations have less access to vaccine doses.<sup>4</sup> A recent study estimates that unequal global vaccine distribution could result in a gross domestic product loss of \$1.2 trillion annually for the global economy.<sup>5</sup>

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<sup>1</sup> New York Times, "The U.S. will send vaccine materials and other supplies to India, officials say," Katie Rogers, April 25, 2021, <https://www.nytimes.com/2021/04/25/world/us-vaccines-india-covid.html>; World Health Organization, "The effects of virus variants on COVID-19 vaccines," March 1, 2021, <https://www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines>.

<sup>2</sup> Johns Hopkins University, Center for Systems Science and Engineering, "COVID-19 Dashboard," accessed April 27, 2021, <https://coronavirus.jhu.edu/map.html>.

<sup>3</sup> World Health Organization, "The effects of virus variants on COVID-19 vaccines," March 1, 2021, <https://www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines>.

<sup>4</sup> Kaiser Family Foundation, "Global COVID-19 Vaccine Access: A Snapshot of Inequality," Anna Rouw, Adam Wexler, Jennifer Kates, and Josh Michaud, March 17, 2021, <https://www.kff.org/policy-watch/global-covid-19-vaccine-access-snapshot-of-inequality/>.

<sup>5</sup> RAND Europe, "COVID-19 and the cost of vaccine nationalism," Marco Hafner, Erez Yerushalmi, Clement Fays, Eliane Dufresne, and Christian van Stolk, 2020, pg. v, [https://www.rand.org/content/dam/rand/pubs/research\\_reports/RRA700/RRA769-1/RAND\\_RRA769-1.pdf](https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA769-1/RAND_RRA769-1.pdf).

India is facing a humanitarian and public health crisis, with over 350,000 new COVID-19 cases reported in a single day earlier this week.<sup>6</sup> The country is a major producer of the Oxford/AstraZeneca COVID-19 vaccines and has exported over 66 million doses globally since January 2021.<sup>7</sup> In the midst of the recent surge of COVID-19 cases, India has paused exports of vaccines,<sup>8</sup> but it is still struggling to vaccinate people quickly enough to quell the outbreak. India's Serum Institute—the nation's largest vaccine manufacturer—can reportedly produce only 70 million AstraZeneca doses a month, and even when combining AstraZeneca shots with India's second approved vaccine, there are not enough doses to meet demand or need.<sup>9</sup> Currently, a little more than 1% of India's population is fully vaccinated<sup>10</sup>—allowing the contagious B.1.617 “double mutant” COVID-19 variant to spread widely.<sup>11</sup>

Addressing the spread of COVID-19 in India is critical, and there are of steps that Moderna could take to increase global vaccine access. For example, affirmative steps by Moderna to share technology, such as vaccine recipes and manufacturing information, with partner companies could drastically expand vaccine development and access. This technology transfer could take place voluntarily, underpinned by open, non-exclusive, and transparent agreements done in collaboration with the World Health Organization (WHO). For example, the WHO has set up multiple mechanisms through which technology transfer could occur, including through its “COVID-19 Technology Access Pool” (C-TAP)—which calls on “the global community to voluntarily share knowledge, intellectual property and data necessary for COVID-19”<sup>12</sup>—and its mRNA vaccine technology transfer hub—which seeks to “expand the capacity of low- and middle-income countries to produce COVID-19 vaccines and scale up manufacturing” by facilitating the transfer of technology and intellectual property to those countries.<sup>13</sup>

Experts have also called for the U.S. to support the temporary waiver of some Trade-Related Aspects of Intellectual Property Rights (TRIPS) rules proposed by India and South Africa at the World Trade Organization (WTO), which would temporarily lift certain intellectual property barriers and allow countries to locally manufacture COVID-19 diagnostics, treatments, and

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<sup>6</sup> CNBC, “Photos show the deadly toll of Covid in India as coronavirus cases top 17 million,” Vicky McKeever and Adam Jeffrey, April 26, 2021, <https://www.cnbc.com/2021/04/26/photos-show-the-deadly-toll-of-covid-in-india-as-coronavirus-cases-top-17-million.html>.

<sup>7</sup> Government of India, Ministry of External Affairs, “COVID-19 Updates,” <https://www.mea.gov.in/vaccine-supply.htm>.

<sup>8</sup> Quartz, “India exported millions of vaccine doses during its own Covid emergency,” Hasit Shah, April 26, 2021, <https://qz.com/2001534/why-did-india-export-millions-of-covid-vaccines/>.

<sup>9</sup> The Guardian, “India reportedly running out of vaccines amid Covid surge,” Hannah Ellis-Petersen, April 26, 2021, <https://www.theguardian.com/world/2021/apr/26/india-reportedly-running-out-of-vaccines-amid-covid-surge>.

<sup>10</sup> *Id.*

<sup>11</sup> NPR, “People Are Talking About A 'Double Mutant' Variant In India. What Does That Mean?” Michaeleen Doucleff, April 24, 2021, <https://www.npr.org/sections/goatsandsoda/2021/04/24/988744811/people-are-talking-about-a-double-mutant-variant-in-india-what-does-that-mean>.

<sup>12</sup> World Health Organization, “COVID-19 Technology Access Pool,” <https://www.who.int/initiatives/covid-19-technology-access-pool>.

<sup>13</sup> 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>.

vaccines—expediting global access to vaccines and treatment and facilitating a quicker end to the pandemic.<sup>14</sup>

To help us better understand what steps Moderna will take to expand global access to COVID-19 vaccines in India and elsewhere, we request answers to the following questions no later than May 11, 2021:

1. Has Moderna entered into voluntary licensing arrangements for the COVID-19 vaccine to expand supply around the world? Specifically:
  - a. Has Moderna voluntarily shared intellectual property, data, technology, or other knowledge with C-TAP? If not, why not?
  - b. If applicable, has Moderna voluntarily shared information with the WHO's mRNA technology transfer hub? If not, why not?
  - c. Is Moderna in conversations with, or does Moderna have plans to enter into conversations with, companies based in India for the purpose of manufacturing vaccine doses in India? If not, why not?
  - d. Is Moderna in conversations with, or does Moderna have plans to enter into conversations with, companies based abroad for the purpose of manufacturing vaccine doses in areas underserved by existing vaccine supply? If not, why not?
2. Is Moderna opposed to the TRIPS waiver? If so, has Moderna engaged in lobbying activities to convey its opposition to the USTR, WTO, members of Congress, or the White House? What alternative mechanisms, other than the waiver and entering into voluntarily licensing arrangements, has Moderna considered to rapidly expand global access to COVID-19 vaccines?
3. India has asked Pfizer, Moderna, and Johnson & Johnson to seek licenses to distribute their vaccines in the country as a means of expanding supply.<sup>15</sup> Does Moderna plan to apply for an emergency use license for its vaccines in India? If so, when?
4. What additional steps, if any, is Moderna taking to expand vaccine access globally?

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<sup>14</sup> Forbes, "Biden Facing Calls To Waive Covid Patents, Allowing Other Companies To Make Pfizer's And Moderna's Vaccines," Nicholas Reimann, April 8, 2021, <https://www.forbes.com/sites/nicholasreimann/2021/04/08/biden-facing-calls-to-waive-covid-patents-allowing-other-companies-to-make-pfizers-and-modernas-vaccines/?sh=13a08cf73ab3>; Public Citizen, "Presser: 400+ US Civil Society Organizations Call on Pres. Biden to Stop Blocking COVID-19 WTO Waiver to Boost Vaccines, Treatments Worldwide," February 26, 2021, <https://www.citizen.org/news/hundreds-of-prominent-us-civil-society-organizations-call-on-pres-biden-to-stop-blocking-covid-19-wto-waiver-to-boost-vaccines-treatments-worldwide/>.

<sup>15</sup> Reuters, "India wants Pfizer, Moderna, Johnson & Johnson to seek licence for COVID-19 vaccines soon - govt official," April 13, 2021, <https://www.reuters.com/world/india/india-wants-pfizer-moderna-johnson-johnson-seek-licence-covid-19-vaccines-soon-2021-04-13/>.

5. What current barriers are preventing expanded access to vaccines in India and the rest of the world?

Sincerely,

/s/

Elizabeth Warren  
United States Senator

/s/

Edward J. Markey  
United States Senator

/s/

Tammy Baldwin  
United States Senator

/s/

Jeffrey A. Merkley  
United States Senator

/s/

Christopher S. Murphy  
United States Senator