

Congress of the United States
Washington, DC 20510

January 13, 2022

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

Jeffrey Zients
White House Coronavirus Response Coordinator
The White House
1600 Pennsylvania Avenue NW
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Dear Dr. Kessler and Mr. Zients:

We write to urge the Biden Administration to substantially increase the global supply of COVID-19 vaccines by invoking the full authority of the *Defense Production Act* (DPA) to facilitate mRNA vaccine technology transfer and by immediately standing up publicly-owned vaccine manufacturing facilities. We appreciate the Administration's efforts to expand vaccine access to date, including its negotiations with mRNA vaccine producers and its commitments to invest in domestic manufacturing capacity. But more is needed at this critical juncture. To boost vaccine production at home and abroad and to control this devastating pandemic, the Administration must mandate immediate transfer of mRNA vaccine technology and ensure public ownership of the country's new vaccine manufacturing capabilities.

The COVID-19 pandemic entered a new phase with the Omicron variant, highlighting the dangers that the United States and the world face from unchecked spread. Omicron is overwhelming America's hospital systems: as of January 3, 78% of ICU beds in the country were full,¹ and physicians across the country warned that staffing shortages could drastically impact patient care and lead to "collapsing" health care systems.² The Omicron variant has also caused widespread disruptions to schools, as staffing shortages, lack of adequate testing, and record case numbers among students and staff have closed at least 4,500 schools in the first week

¹ CNN, "Overwhelmed hospitals. Staffing shortages. Businesses closing. Here's how the Omicron wave is ravaging local communities," Dakin Andone, January 3, 2022, <https://www.cnn.com/2022/01/03/us/omicron-variant-covid-local-impacts/index.html>.

² Boston Globe, "R.I. health care system 'is currently collapsing,' emergency doctors warn," Brian Amaral, December 18, 2021, <https://www.bostonglobe.com/2021/12/18/metro/ri-health-care-system-is-currently-collapsing-emergency-doctors-warn>; Associated Press, "Kansas patients needing to be transferred stranded for days," Heather Hollingsworth, December 20, 2021, <https://apnews.com/article/coronavirus-pandemic-health-kansas-5ba0063b4c9fca95c043c9f5c03cb1cb>.

of January.³ And the latest COVID-19 wave threatens the economic progress that the Biden Administration has championed in its time in office, with air travel disruptions, cancelled public and private events, and further strain on the beleaguered restaurant industry pushing businesses across the country to the brink.⁴ Although the Omicron variant appears to be less deadly than the Delta or other variants of the virus, there is no guarantee that this will be true of any future mutations that may arise.⁵

This crisis is due, in part, to the failure of global efforts to vaccinate the world against COVID-19. Despite urgent warnings from epidemiologists that unequal vaccine distribution could create vaccine-resistant mutations and extend the pandemic by months or even years,⁶ COVID-19 vaccine distribution has remained stubbornly concentrated in wealthy countries. As of December 2021, low-income countries had received less than 2% of vaccinations administered globally from Western vaccine makers, and only 4% of people in low-income countries had received a primary series of vaccinations.⁷ While the Omicron variant may be more likely to escape the vaccines' protection against initial infection, vaccinations—including boosters—remain the best defense against hospitalization and death from COVID-19.⁸

Vaccine donations—the Administration's current strategy for closing the vaccine gap—have been and will continue to be insufficient to meet enormous global demand.⁹ Even without boosters, reaching President Biden's goal of a 70% global vaccination rate by September 2022 would require 11 billion COVID-19 vaccine doses, many more than the United States and other wealthy countries have committed to donate in that time.¹⁰ And as of January 2022, the United States had only delivered 336.4 million of its promised 1.1 billion doses.¹¹ Depending on

³ Vox, "America doesn't have enough teachers to keep schools open," Anna North, January 5, 2022, <https://www.vox.com/the-goods/22868641/chicago-school-closings-omicron-covid-remote-learning>.

⁴ Washington Post, "Mounting omicron infections force businesses to scramble, threatening economic recovery," David J. Lynch, January 6, 2022, <https://www.washingtonpost.com/business/2022/01/06/omicron-economy-worker-shortage/>.

⁵ Nature, "Beyond Omicron: what's next for COVID's viral evolution," Ewen Callaway, December 7, 2021, <https://www.nature.com/articles/d41586-021-03619-8>; New York Times, "Omicron: What We Know About the New Coronavirus Variant," Carl Zimmer and Andrew Jacobs, January 3, 2022, <https://www.nytimes.com/article/omicron-coronavirus-variant.html>.

⁶ Oxfam International, "Two-thirds of epidemiologists warn mutations could render current COVID vaccines ineffective in a year or less," press release, March 30, 2021, <https://www.oxfam.org/en/press-releases/two-thirds-epidemiologists-warn-mutations-could-render-current-covid-vaccines>.

⁷ Wall Street Journal, "More Covid-19 Vaccines Are Reaching Poorer Nations, But Slowly," Denise Roland and Felicia Schwartz, December 28, 2021, <https://next.wsj.com/articles/more-covid-19-vaccines-are-reaching-poorer-nations-but-slowly-11640692804>.

⁸ Reuters, "'Significant increase' in protection vs Omicron from mRNA boosters, study says," Nikolaj Skydsgaard, December 22, 2021, <https://www.reuters.com/business/healthcare-pharmaceuticals/significant-increase-protection-vs-omicron-mrna-boosters-study-says-2021-12-22>.

⁹ NBC News, "Covid omicron variant linked to vaccine inequality, experts say," Alexander Smith, November 30, 2021, <https://www.nbcnews.com/news/world/omicron-linked-global-vaccine-inequality-experts-rcna6916>.

¹⁰ Washington Post, "Biden's plan to vaccinate the world won't work. Here's a better one.," Lawrence Gostin, September 27, 2021, <https://www.washingtonpost.com/outlook/2021/09/27/biden-vaccines-globe-inequity-donations/>.

¹¹ Kaiser Family Foundation, "U.S. International COVID-19 Vaccine Donations Tracker – Updated as of January 10," January 10, 2022, <https://www.kff.org/coronavirus-covid-19/issue-brief/u-s-international-covid-19-vaccine-donations-tracker/>.

donations alone has led to a “fragmented patchwork that does not add up to a coordinated solution to the problem we’re all facing.”¹²

To its credit, the Biden Administration has taken several crucial steps to ensure that greater vaccine production is possible, including steps that many of us have long called for. In May 2021, the Biden Administration announced its support for a temporary waiver of intellectual property rights for COVID-19 vaccine technology under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹³ The Administration helped to facilitate a deal between Moderna and the African Union for the purchase of up to 110 million vaccines.¹⁴ And in November 2021, the Administration announced an investment of “billions of dollars” to expand domestic COVID-19 vaccine manufacturing capacity to produce at least one billion additional doses in 2022.¹⁵

But these efforts are simply not enough. Despite prolonged negotiations, the WTO has yet to make any progress towards approving a TRIPS waiver.¹⁶ And the Biden Administration has conceded that the growing demand for boosters in the United States and other wealthy nations may prevent the Administration from reaching its goal of vaccinating 70% of the world’s population by September 2022.¹⁷ In this race against a dangerous and rapidly mutating virus, the Administration must act aggressively to expand global vaccine access and can do so in two significant ways.

First, the Biden Administration should invoke the *Defense Production Act* to facilitate mRNA vaccine technology transfer. mRNA vaccines are highly effective at combatting COVID-19’s many variants, and manufacturers around the world stand ready to produce them.¹⁸ But Pfizer and Moderna—the two U.S. manufacturers of mRNA vaccines—have refused to share their vaccine technology, despite their reliance on years of publicly funded research, their use of billions of dollars in public funding through R&D and purchase contracts, and repeated requests

¹² Washington Post, “Biden’s plan to vaccinate the world won’t work. Here’s a better one.” Lawrence Gostin, September 27, 2021, <https://www.washingtonpost.com/outlook/2021/09/27/biden-vaccines-globe-inequity-donations/>.

¹³ Office of the United States Trade Representative, “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver,” press release, May 5, 2021, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

¹⁴ Reuters, “Exclusive: African Union to buy up to 110 million Moderna vaccines -officials,” Jeff Mason, October 26, 2021, <https://www.reuters.com/world/africa/exclusive-african-union-buy-up-110-million-moderna-covid-19-vaccines-officials-2021-10-26>.

¹⁵ New York Times, “White House Plans Major Expansion of Covid Vaccine Production,” Sheryl Gay Stolberg, November 17, 2021, <https://www.nytimes.com/2021/11/17/us/politics/biden-covid-vaccine-manufacturing.html>.

¹⁶ The Pulse, “Official expresses concern that pandemic will drag on until the world is vaccinated,” Austin Fisher, January 10, 2022, <https://pulse.ncpolicywatch.org/2022/01/10/official-expresses-concern-that-pandemic-will-drag-on-until-the-world-is-vaccinated>.

¹⁷ Politico, “Biden officials now fear booster programs will limit global vaccine supply,” Erin Banco, Adam Cancryn, and Sarah Owerhohle, December 31, 2021, <https://www.politico.com/news/2021/12/31/biden-novavax-production-covid-omicron-526283>.

¹⁸ Letter from Human Rights Watch and Doctors Without Borders/Médecins Sans Frontières USA to Acting Coordinator for Global COVID Response and Health Security Mary Beth Goodman, December 15, 2021, <https://www.hrw.org/news/2021/12/15/us-should-transfer-technology-covid-19-vaccines>.

by global health leaders and the Administration.¹⁹ Pfizer and Moderna’s refusal severely curtails the world’s ability to ramp up vaccine supply and end the pandemic as soon as possible. With the COVID-19 virus continuing to spread and mutate around the globe, the Biden Administration must mandate the transfer of mRNA vaccine technology now.

The federal government has the clear authority to require vaccine technology transfer under the *Defense Production Act*. In particular, the DPA empowers the President to (1) “allocate materials, services, and facilities” to promote the national defense²⁰—including for “emergency preparedness activities” (such as responding to a global pandemic)²¹—and (2) require the acceptance and performance of contracts to promote the national defense.²² The law defines “materials” to include “any technical information or services” related to products (such as vaccines).²³ As such, the Administration has two clear legal mechanisms to require Pfizer and Moderna to share their vaccine technology using a centralized hub—such as the Biomedical Advanced Research and Development Authority (BARDA)—to distribute the technology more widely: the government can directly allocate the vaccine technology to BARDA, or it can require Pfizer and Moderna to enter into contracts with the government to provide the technology to BARDA. In either case, Pfizer and Moderna could still receive reasonable compensation for their vaccine technology. We urge the Administration to promptly deploy its DPA authority, which can occur without obtaining the agreement of our trading partners, and simultaneously redouble its efforts to secure a TRIPS waiver.

Second, as the Biden Administration implements its plan to supercharge domestic mRNA vaccine manufacturing capacity, the Administration should prioritize contracts for public, government-owned, and contractor-operated manufacturing models. While we applaud the President’s commitment to expand domestic manufacturing capacity, recent experiences—including the federal government’s failed partnership with Emergent and the resulting millions of ruined COVID-19 vaccine doses²⁴—demonstrate that the public must have more control and oversight over massive investments in the pandemic response. The solution is simple. Rather than allowing private companies to direct the production of critical public-health resources and further pad their bottom lines, the federal government should own any new vaccine manufacturing facilities to ensure sufficient vaccine production, contracting with private companies to equip the facilities with appropriate mRNA vaccine technology and using the DPA to facilitate technology transfer as necessary.²⁵ These arrangements will further allow the federal

¹⁹ Health Affairs, “Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide.” Zain Rizvi, Jishian Ravinthiran, and Amy Kapczynski, August 6, 2021, <https://www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/full>.

²⁰ 50 U.S.C. § 4511(a).

²¹ 50 U.S.C. § 4552.

²² 50 U.S.C. § 4511(a).

²³ 50 U.S.C. § 4552.

²⁴ Washington Post, “U.S. Cancels Multimillion-Dollar Deal with Coronavirus Vaccine Maker Whose Plant Ruined Johnson & Johnson Doses,” Andrew Jeong, November 5, 2021, <https://www.washingtonpost.com/business/2021/11/05/coronavirus-vaccine-emergent-biosolutions-cancel/>.

²⁵ Letter from Partners In Health, PrEP4ALL, and Public Citizen to Chief Scientific Officer for the COVID-19 Response David Kessler and BARDA Director Gary Disbrow, December 13, 2021, https://www.citizen.org/wp-content/uploads/letter-calling-for-public-manufacturing-in-domestic-mRNA-plans-2021.12.13_final.pdf.


government to make vaccines available to low- and middle-income countries at reasonable prices, while fostering vaccine technology training and transfer.²⁶

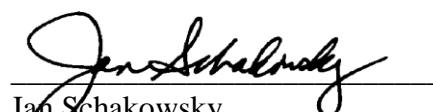
As the Omicron variant continues to disrupt lives and devastate communities across America and the globe, the federal government must use all tools at its disposal to save lives and hasten the end of the pandemic. Vaccine technology transfer and government-owned, contractor-operated vaccine manufacturing facilities are two critical tools in the fight against COVID-19, and we urge the Administration to invoke its authorities—including under the *Defense Production Act*—to expeditiously implement them. To better understand the Biden Administration’s strategy to expand global COVID-19 vaccine supply in this critical time, we ask that you answer the following questions and provide the following documents by January 27, 2022:

1. Does the Administration plan to invoke its authorities under the *Defense Production Act* to facilitate the transfer of mRNA vaccine technology? If so, when and how? If not, why not?
2. Has the Administration considered using public, government-owned, contractor-operated manufacturing models to fulfill its November 2021 commitment to drastically expand domestic COVID-19 vaccine manufacturing? If so, what is the status of the Administration’s vaccine manufacturing initiative? If not, why not?
3. What resources does the Administration have available to support a public, government-owned, contractor-operated manufacturing facility capable of meeting its stated target of producing one billion additional mRNA vaccine doses per year? Given the emergence of Omicron and the increased importance of mRNA vaccines, what additional resources would be required to scale this plan to produce billions more doses per year?
4. Please provide a list of the firms that have submitted responses to the Request for Information regarding domestic mRNA manufacturing capabilities dated November 17, 2021.

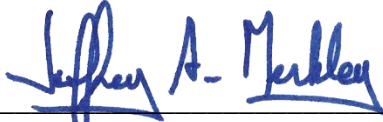
Thank you for your attention to this important matter.

Sincerely,

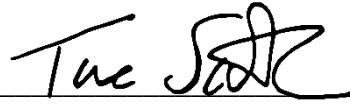

Elizabeth Warren
United States Senator


Jan Schakowsky
Member of Congress

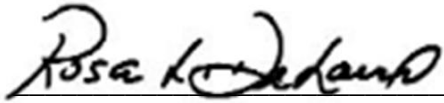
²⁶ *Id.*



Jeffrey A. Merkley
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