

Congress of the United States  
Washington, DC 20510

January 14, 2021

Dr. Moncef Slaoui  
Chief Advisor, Operation Warp Speed  
1400 Defense Pentagon  
Washington, DC 20301

General Gustave Perna  
Chief Operating Officer, Operation Warp Speed  
1400 Defense Pentagon  
Washington, DC 20301

Dear Dr. Slaoui and General Perna:

We write regarding Operation Warp Speed's (OWS) efforts to secure an adequate supply of coronavirus disease 2019 (COVID-19) vaccines. Thousands of Americans are dying every day to COVID-19,<sup>1</sup> and although President Trump will soon be gone from office, it is imperative that the Trump administration take immediate steps to bolster the nation's vaccine supply and improve manufacturing capacity. To date, the Trump administration has failed to use the full authorities provided to it under the Defense Production Act (DPA) in order to do so, and we urge you to take immediate action accordingly.

Dr. Slaoui has stated that he believes OWS can vaccinate "70% to 80% of the U.S. population by May or June of 2021,"<sup>2</sup> and in recent weeks, Dr. Anthony Fauci has estimated that achieving herd immunity could require as high as 90% of the American people to get the COVID-19 vaccine.<sup>3</sup> So far, OWS has struck deals to procure 400 million vaccine doses from Moderna and Pfizer, enough to vaccinate 200 million Americans—less than two-thirds of those necessary to truly control the pandemic.<sup>4</sup> The remaining necessary doses are expected to come from other

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<sup>1</sup> Centers for Disease Control and Prevention, "CDC COVID Data Tracker," [https://covid.cdc.gov/covid-data-tracker/#cases\\_casesper100klast7days](https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days).

<sup>2</sup> CNBC, "We should be substantially back to normal' by summer 2021, says Operation Warp Speed's chief science advisor," Emily DeCiccio, November 25, 2020, <https://www.cnbc.com/2020/11/25/we-should-be-back-to-normal-by-summer-2021-says-operation-warp-speed-advisor.html>.

<sup>3</sup> Reuters, "Fauci says herd immunity could require nearly 90% to get coronavirus vaccine," Jonathan Allen, December 24, 2020, <https://www.reuters.com/article/health-coronavirus-usa/fauci-says-herd-immunity-could-require-nearly-90-to-get-coronavirus-vaccine-idUSL1N2J411V>.

<sup>4</sup> U.S. Department of Health and Human Services, "Trump Administration purchases additional 100 million doses of COVID-19 investigational vaccine from Moderna," press release, December 11, 2020, <https://www.hhs.gov/about/news/2020/12/11/trump-administration-purchases-additional-100-million-doses-covid-19-investigational-vaccine-moderna.html>; U.S. Department of Health and Human Services, "Trump Administration purchases additional 100 million doses of COVID-19 investigational vaccine from Pfizer," December 23, 2020, <https://www.hhs.gov/about/news/2020/12/23/trump-administration-purchases-additional-100-million-doses-covid-19-investigational-vaccine-pfizer.html>.

pharmaceutical companies' vaccines, which are still in the pipeline for development, but have yet to meet criteria necessary to receive an Emergency Use Authorization (EUA) from the Food and Drug Administration.<sup>5</sup> In addition, distribution of the existing vaccine supply has been delayed by logistical and supply chain challenges<sup>6</sup>—resulting in a continually slipping timeline for pharmaceutical companies' delivery and production.<sup>7</sup> Pfizer, for example, had pledged to deliver 40 million doses of its vaccine to the federal government by the end of 2020, but only was able to ship half that amount.<sup>8</sup> And Johnson & Johnson, one of the COVID-19 vaccine developers without an EUA, signed a federal contract promising 12 million doses of a vaccine by the end of February 2021 and 100 million doses by the end of June 2021, but “federal officials have been told that the company has fallen as much as two months behind the original production schedule.”<sup>9</sup>

The limited vaccine supply has contributed to confusion, miscommunication, and frustration between OWS, states, and vaccine manufacturing companies over the purchasing and distribution of COVID-19 vaccines—resulting in states receiving smaller shipments than expected and prompting alarm that the U.S. may face a “vaccine cliff” in the spring.<sup>10</sup> The Trump administration set a goal of distributing 20 million COVID-19 vaccines by the end of 2020, but only ten million people have received a dose of the vaccine so far.<sup>11</sup>

The federal government must use its existing authority to rapidly increase the vaccine supply. According to the White House, the Trump administration has “used the Defense Production Act 18 times in connection with Operation Warp Speed.”<sup>12</sup> But these efforts have been piecemeal and the past few weeks have illustrated that these isolated uses of the DPA are not enough to mitigate shortages of COVID-19 medical products. After almost one year of fighting the pandemic, the administration has not deployed the DPA to its fullest extent. The DPA can and should be used in at least the three ways described below.

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<sup>5</sup> Politico, “U.S. could face months of vaccine shortages amid global competition,” Sarah Owerhohle, December 8, 2020, <https://www.politico.com/news/2020/12/08/coronavirus-vaccine-shortage-443839>.

<sup>6</sup> New York Times, “Here’s Why Distribution of the Vaccine is Taking Longer Than Expected,” Rebecca Robbins, Frances Robles, and Tim Arango, December 31, 2020, <https://www.nytimes.com/2020/12/31/health/vaccine-distribution-delays.html>.

<sup>7</sup> STAT, “The timeline for Covid-19 vaccine distribution keeps slipping. Experts say it will change again,” Olivia Goldhill, December 11, 2020, <https://www.statnews.com/2020/12/11/covid19-vaccine-timeline-keeps-slipping-experts-say-it-will-change-again/>; Washington Post, “Trump’s Operation Warp Speed promised a flood of covid vaccines. Instead, states are expecting a trickle,” Christopher Rowland, Lena H. Sun, Isaac Stanley-Becker, and Carolyn Y. Johnson, December 5, 2020, <https://www.washingtonpost.com/business/2020/12/05/operation-warp-speed-coronavirus-vaccine-shortfall/>.

<sup>8</sup> New York Times, “Johnson & Johnson Expects Vaccine Results Soon but Lags in Production,” Carl Zimmer, Sharon LaFraniere, and Noah Weiland, January 13, 2021, <https://www.nytimes.com/2021/01/13/health/covid-vaccine-johnson-johnson.html>.

<sup>9</sup> *Id.*

<sup>10</sup> New York Times, “States Complain of Smaller Vaccine Shipments Than Expected,” Katie Thomas and Sharon LaFraniere, December 17, 2020, <https://www.nytimes.com/2020/12/17/health/pfizer-covid-vaccine-doses.html>; Politico, “U.S. could face months of vaccine shortages amid global competition,” Sarah Owerhohle, December 8, 2020, <https://www.politico.com/news/2020/12/08/coronavirus-vaccine-shortage-443839>.

<sup>11</sup> New York Times, “See How the Vaccine Rollout Is Going in Your State,” Updated January 13, 2021, <https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html>.

<sup>12</sup> White House, “Statement from the Press Secretary,” December 29, 2020, <https://www.whitehouse.gov/briefings-statements/statement-press-secretary-123020/>.

To start, OWS—in conjunction with the Trump administration—should be using the broad authorities provided in the DPA to require information disclosure from pharmaceutical companies about their capabilities and capacity. 50 U.S.C. 4555 makes clear that:

The President shall be entitled...to obtain such information from...any person as may be necessary or appropriate, in his discretion, to the enforcement or the administration of this chapter and the regulations or orders issued thereunder...The authority of the President under this section includes the authority to obtain information in order to perform industry studies assessing the capabilities of the United States industrial base to support the national defense.<sup>13</sup>

This broad authority must be used to allow OWS to fully understand American pharmaceutical companies' capabilities and capacity. Using the DPA in this manner would allow the federal government to finally understand the full capacity of American manufacturers to retool factories and production lines to produce vaccines. Some manufacturers have suggested a willingness to ramp up vaccine production, but a systematic survey is needed to obtain comprehensive information on needs and capacity.<sup>14</sup>

Second, OWS should use this broad information disclosure authority to require corporations that have developed and are producing the vaccine to share information and data needed to facilitate increased production. For example, while Moderna and Pfizer are both using similar technology, the Pfizer vaccine needs to be kept at a significantly lower temperature. Moderna believes the difference reflects the composition of its lipid nanoparticle and its experience with mRNA vaccines.<sup>15</sup> In exchange for reasonable compensation, Moderna should be required to share this information with mRNA vaccine developers, including Pfizer. This could save valuable time by allowing companies that are seeking to develop more thermostable formulations of mRNA vaccines, like Pfizer, to learn from a company that has already done so.<sup>16</sup>

Finally, in addition to requiring information sharing, the President should employ Title I of the DPA, which gives the President authority to require businesses to accept and prioritize contracts or orders and “allocate materials, services, and facilities to promote the national defense,” in order to compel other pharmaceutical companies' involvement in vaccine production if such

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<sup>13</sup> <https://www.law.cornell.edu/uscode/text/50/4555>.

<sup>14</sup> Reuters, “Sanofi says could help produce competitors' COVID-19 shots,” January 7, 2021, <https://finance.yahoo.com/news/sanofi-says-could-help-produce-173619207.html>.

<sup>15</sup> NPR, “Why Does Pfizer’s COVID-19 Vaccine Need to Be Kept Colder Than Antarctica?” Selena Simmons-Duffin, November 17, 2020, <https://www.npr.org/sections/health-shots/2020/11/17/935563377/why-does-pfizers-covid-19-vaccine-need-to-be-kept-colder-than-antarctica>; New Yorker, “Countdown to a Coronavirus Vaccine,” Carolyn Kormann, December 6, 2020, <https://www.newyorker.com/magazine/2020/12/14/countdown-to-a-coronavirus-vaccine>;

<sup>16</sup> NPR, “Why Does Pfizer’s COVID-19 Vaccine Need to Be Kept Colder Than Antarctica?” Selena Simmons-Duffin, November 17, 2020, <https://www.npr.org/sections/health-shots/2020/11/17/935563377/why-does-pfizers-covid-19-vaccine-need-to-be-kept-colder-than-antarctica>; New Yorker, “Countdown to a Coronavirus Vaccine,” Carolyn Kormann, December 6, 2020, <https://www.newyorker.com/magazine/2020/12/14/countdown-to-a-coronavirus-vaccine>;

companies will not voluntarily do so.<sup>17</sup> This information and technology transfer, organized and authorized at the federal level, would ensure the mobilization of capacity to scale-out manufacturing across production sites. For example, one month ago, the administration reportedly requested Pfizer to work with other corporations, like Merck, to produce the vaccine.<sup>18</sup> There have not been any further announcements. Technology transfer has already happened in a handful of instances during the COVID-19 pandemic, but the full power of this transfer has yet to be realized, meaning domestic manufacturing capacity may be sitting idle, as we lose thousands of Americans to COVID-19 every day.<sup>19</sup>

We are grateful to the scientists, public servants, and other essential workers who have labored tirelessly to develop life-saving vaccines and therapeutics at record-pace. It is incumbent upon the federal government to continue to do everything in its power to ensure that these vaccines are produced and put to use. In order to understand what the Trump administration has done and intends to do in its final days in office, we request answers to the following questions by no later than January 20, 2021:

1. Does OWS plan to use 50 U.S.C. 4555 to compel pharmaceutical companies to disclose information about manufacturing capacity with the federal government?
  - a. Has OWS obtained any information under 50 U.S.C. 4555 to date? If so, please provide a summary of this information.
  - b. If OWS intends to utilize this authority in the coming days, how will it be used and what is the anticipated timeline for when this authority will be utilized?
  - c. If OWS does not intend to utilize this authority, please explain why not.
2. Has OWS already, or does OWS plan to use 50 U.S.C. 4555, and other authorities under the DPA, to compel Moderna to share information that could help other manufacturers produce more thermostable mRNA vaccines?
  - a. If OWS has used this authority, please provide a summary of all information obtained to date.
  - b. If OWS intends to utilize this authority in the coming days, what is the anticipated timeline for when this authority will be utilized?
  - c. If OWS does not intend to utilize this authority, please explain why not.
3. Has OWS used, or does OWS plan to use Title I of the DPA, and other authorities under the DPA, to coordinate and facilitate technology transfer for increased vaccine production?
  - a. If OWS has used this authority, please provide a summary of all information obtained to date.

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<sup>17</sup> FEMA, “Defense Production Act Authorities,” June 23, 2020, <https://www.fema.gov/disasters/defense-production-act/dpa-authorities#:~:text=DPA%20Title%20I%20D%20Priorities%20and,to%20maximize%20domestic%20energy%20supplies>.

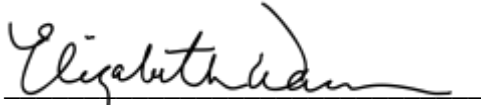
<sup>18</sup> U.S. and Pfizer Are Negotiating Deal for More Vaccine Doses Next Year, December 15, 2020, <https://www.nytimes.com/2020/12/15/us/politics/us-pfizer-vaccine-more-doses.html>.

<sup>19</sup> Public Citizen, “A Plan for the People’s Vaccine: How the Biden Administration Can Supply the World,” Zain Rizvi and Peter Maybarduk, December 9, 2020, <https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/A-Plan-for-the-Peoples-Vaccine-final.pdf>.

- b. If OWS intends to utilize this authority in the coming days, what is the anticipated timeline for when this authority will be utilized?
- c. If OWS does not intend to utilize this authority, please explain why not.


Thank you for your attention to this matter.

Sincerely,



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Elizabeth Warren  
United States Senator



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Katie Porter  
Member of Congress