



MEMORANDUM

January 29, 2021

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “No Time to Lose: Solutions to Increase COVID-19 Vaccinations in the States”

On **Tuesday, February 2, 2021, at 11 a.m. (EST) via Cisco WebEx online video conferencing**, the Subcommittee on Oversight and Investigations will hold a hearing entitled, **“No Time to Lose: Solutions to Increase COVID-19 Vaccinations in the States.”** The hearing will examine the distribution and administration of the coronavirus disease of 2019 (COVID-19) vaccines in the United States.

I. BACKGROUND ON COVID-19 IN THE UNITED STATES

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) announced the first reported case of COVID-19 in the United States.¹ COVID-19 can be asymptomatic or cause a range of symptoms, which are typically more severe among older adults and people with underlying medical conditions, and has disproportionately affected people of color.² Former Secretary of Health and Human Services (HHS) Alex Azar declared the disease a public health emergency on January 31, 2020, and former President Trump declared the outbreak a national emergency on March 13, 2020.³ As of January 28, 2021, more than 25.5 million Americans have

¹ Centers for Disease Control and Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (press release).

² Centers for Disease Control and Prevention, *Things to Know about the COVID-19 Pandemic* (www.cdc.gov/coronavirus/2019-ncov/your-health/need-to-know.html) (accessed Jan. 22, 2020); Centers for Disease Control and Prevention, *COVID-19 Hospitalization and Death by Race/Ethnicity* (www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html) (accessed Jan. 22, 2021).

³ U.S. Department of Health and Human Services, *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020) (press release); Presidential Proclamation No. 9994, 85 Fed. Reg. 15337 (Mar. 18, 2020).

contracted COVID-19, leading to 427,626 deaths.⁴

II. FEDERAL GOVERNMENT ACTION TO PROMOTE COVID-19 VACCINES

A safe and effective COVID-19 vaccine is an essential tool to contain the pandemic.”⁵ Since the COVID-19 outbreak began in the United States, Congress has provided more than \$60 billion to facilitate the development, production, and distribution of COVID-19 medical countermeasures, including vaccines.⁶

On May 15, 2020, the Trump Administration announced the Operation Warp Speed (OWS) initiative, a partnership among HHS, the Department of Defense, private companies, and other federal agencies aimed at accelerating “the development, manufacturing, and distribution of COVID-19 vaccines” and other medical countermeasures.⁷ OWS initially aimed to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021, though OWS later reduced that goal to 20 million doses by the end of 2020.⁸ For additional information about OWS’s COVID-19 vaccine development and distribution planning efforts, please see the Subcommittee’s previous hearing memoranda from [July 16, 2020](#) and [September 25, 2020](#).

III. SUPPLY STATUS OF COVID-19 VACCINES

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer’s two-dose COVID-19 vaccine to be administered 21-days apart.⁹ A week later, FDA issued an EUA for Moderna’s two-dose vaccine to be administered 28-days apart.¹⁰ The federal government’s agreements with Pfizer and Moderna require each

⁴ Centers for Disease Control and Prevention, *United States COVID-19 Cases and Deaths by State* (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html) (accessed Jan. 28, 2020).

⁵ Centers for Disease Control and Prevention, *Benefits of Getting Vaccinated* (www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html) (accessed Jan. 22, 2021).

⁶ Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, Pub. L. 116-136; Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123; Consolidated Appropriations Act, 2021, Pub. L. 116-260.

⁷ U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for ‘Operation Warp Speed’* (May 15, 2020) (press release).

⁸ *Id.*, U.S. Department of Defense, *Operation Warp Speed Leaders Say 20 Million COVID-19 Vaccines May Be Available This Month* (Dec. 3, 2020) (press release).

⁹ U.S. Food and Drug Administration, *Pfizer-BioNTech COVID-19 Vaccine* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine) (accessed Jan. 21, 2021).

¹⁰ U.S. Food and Drug Administration, *Moderna COVID-19 Vaccine* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine) (accessed Jan. 21, 2021).

company to manufacture and deliver 200 million doses by the end of July 2021, with the first 100 million doses due from each by March 31, 2021.¹¹ As of January 4, 2021, Moderna had supplied the U.S. government with 18 million doses.¹² On January 15, 2021, Pfizer stated it had shipped more than 15 million doses across the country.¹³

Three additional vaccine candidates, developed by AstraZeneca, Johnson & Johnson, and NovaVax, are currently in Phase 3 U.S. clinical trials—the final phase of the clinical vaccine development process.¹⁴

IV. EQUITABLE ALLOCATION GUIDANCE AND STATES' PRIORITIZATION

In December 2020, the Advisory Committee on Immunization Practices (ACIP) developed a series of recommendations on COVID-19 vaccine allocation, beginning with health care workers and residents of long term care facilities (Phase 1a).¹⁵ CDC and HHS subsequently adopted these recommendation as official guidance.¹⁶ While most states followed ACIP's Phase 1a recommendations, because the guidance is nonbinding, many states have adapted criteria for subsequent phases to suit their state's population and vaccine supply.¹⁷ States continue to revise their prioritization groups as COVID-19 vaccination efforts continue.¹⁸

¹¹ Pfizer, Inc., *Pfizer and BioNTech to Supply the U.S. with 100 Million Additional Doses of COVID-19 Vaccine* (Dec. 23, 2020) (press release); Moderna, Inc., *U.S. Government Exercises 1st Option for Additional 100 Million Doses of Moderna's COVID-19 Vaccine Candidate* (Dec. 11, 2020) (press release).

¹² Moderna, Inc., *Moderna Provides COVID-19 Vaccine Supply Update* (Jan. 4, 2021) (press release).

¹³ *Pfizer says it has second doses of COVID-19 shot on hand, expects no U.S. supply problems*, Reuters (Jan. 15, 2021); *Pfizer says it has second doses of coronavirus vaccines for Americans, even if there's no stockpile*, CNN (Jan. 15, 2021).

¹⁴ *Coronavirus Vaccine Tracker*, New York Times (Jan. 19, 2021); Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020) (R46399).

¹⁵ Centers for Disease Control and Prevention, *COVID-19 ACIP Vaccine Recommendations* (www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html) (accessed Jan. 21, 2021); Centers for Disease Control and Prevention, *The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020* (Dec. 3, 2020) (69(49); 1857-1859).

¹⁶ *Id.*; Centers for Disease Control and Prevention, *The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020* (Jan. 1, 2021) (69(5152); 1657-1660).

¹⁷ KFF, *How are States Prioritizing Who Will Get the COVID-19 Vaccine First?* (Dec. 14, 2021).

¹⁸ KFF, *The COVID-19 Vaccine Priority Line Continues to Change as States Make Further Updates* (Jan. 21, 2021).

On January 12, 2021, former Secretary Azar announced changes to Trump Administration guidance, calling on states to expand vaccine eligibility to individuals over age 65 and those who are younger with high-risk medical conditions.¹⁹ President Biden has indicated he will encourage states to move through the priority groups more quickly, and expand access to all individuals age 65 and older and frontline essential workers.²⁰

V. VACCINATION PROGRESS AND CHALLENGES FACING STATES

According to CDC, as of January 28, 2021, the federal government had distributed 48.4 million vaccine doses to states, territories, and tribes.²¹ A total of 26.2 million doses have been administered, of which 4.3 million were second dose shots.²² Tracking indicates that approximately 56.4 percent of all doses distributed have been administered, ranging from 18.1 percent in Micronesia to 81.6 percent in West Virginia.²³ Projections suggest that the average daily pace would need to increase from the current average of more than 900,000 shots to 1.3 million doses per day to vaccinate all U.S. adults by the end of 2021.²⁴

OWS officials attributed the initially low rates of vaccine administration to a combination of anticipated implementation hurdles, along with shipping and scheduling challenges over the holidays.²⁵ Federal officials further caution that lengthy reporting lags may result in an undercount of states' actual progress administering the COVID-19 vaccines.²⁶ State leaders point to delayed funding to support vaccine programs, overburdened staff and hospital capacity, and limited notice of weekly dose allocations from the federal government to explain the slow pace of vaccination, as well as challenges with the rollout of the federal pharmacy partnership

¹⁹ *Id.*

²⁰ White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Jan. 21, 2021).

²¹ Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (<https://covid.cdc.gov/covid-data-tracker/#vaccinations>) (accessed Jan. 28, 2021).

²² *Id.*

²³ Bloomberg, *More Than 56.7 Million Shots Given: Covid-19 Vaccine Tracker* (www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/) (accessed Jan. 28, 2020).

²⁴ *This is how long it could take to vaccinate all the adults in the US against Covid-19*, CNN (Jan 21, 2021).

²⁵ *Shots are slow to reach arms as Trump administration leaves final steps of mass vaccination to beleaguered states*, Washington Post (Dec. 30, 2020); *Here's Why Distribution of the Vaccine Is Taking Longer Than Expected*, Washington Post (Jan. 11, 2021).

²⁶ *States' new vaccine worry: Not enough doses*, Politico (Jan. 20, 2021).

program which relies on retail pharmacies to vaccinate residents and staff of long-term care facilities.²⁷

In recent weeks, however, more than a dozen states caution that they are starting to run out of COVID-19 doses as demand for vaccination outpaces their supply, with some states having to cancel vaccination appointments after receiving fewer doses than expected.²⁸ The pressure on the availability of vaccines will likely continue as states increase their capability to administer vaccinations.

Finally, although public confidence in a COVID-19 vaccine increased in December 2020 after dramatic declines in the preceding months,²⁹ some hospital and nursing home staff are reportedly turning down vaccinations,³⁰ continuing to underscore the need for a public health education and communications campaign, as authorized by the fiscal year (FY) 2021 Omnibus and COVID Relief and Response Act, to build public confidence in COVID-19 vaccines.

VI. BIDEN ADMINISTRATION PROPOSALS AND ACTION

President Biden has promised to get 100 million COVID-19 vaccine doses administered in his first 100 days in office and believes 1.5 million shots per day can be administered across the country in the coming weeks.³¹ To achieve this goal, he has proposed \$20 billion for a national COVID-19 vaccine program to speed the distribution and administration of COVID-19 vaccines, including funding for distribution to underserved communities.³² On January 21, 2021, President Biden released a national COVID-19 strategy and issued ten executive orders calling for, among other COVID-19 response priorities, creating a public dashboard with real-time national and state-level COVID-19 data including on vaccinations.³³ The President also invoked the Defense Production Act in an effort to increase the supply of materials necessary for

²⁷ *Here's Why Distribution of the Vaccine Is Taking Longer Than Expected*, New York Times (Jan. 1, 2021); *CVS and Walgreens Under Fire for Slow Pace of Vaccination in Nursing Homes*, Kaiser Health News (January 15, 2021).

²⁸ *States' new vaccine worry: Not enough doses*, Politico (Jan. 20, 2021); *Thousands of Vaccine Appointments Canceled as Supply Lags*, New York Times (Jan. 21, 2021).

²⁹ KFF, *COVID-19 Vaccine Monitor: December 2020* (Jan. 15, 2021).

³⁰ *Despite having intimate knowledge of the pain and death caused by the coronavirus, a surprising number of US healthcare workers are refusing to get a COVID-19 vaccine*, Business Insider (Jan. 10, 2021).

³¹ *Biden ups vaccine goal to 1.5 million shots a day, says vaccine to be widely available by spring*, NBC News (Jan. 25, 2021).

³² *Joe Biden's Covid-19 Vaccine Plan: How He Intends to Speed Up Distribution*, Wall Street Journal (Jan. 21, 2021).

³³ *Biden Unveils National Strategy That Trump Resisted*, New York Times (Jan. 21, 2021); *Biden unveils national COVID strategy with slate of executive orders*, CBS News (Jan. 21, 2020).

COVID-19 vaccination, such as syringes that can maximize the amount of vaccine extracted from vials.³⁴ The Administration also announced plans to establish vaccine centers at large venues and mobilize federal personnel to assist with vaccinations.³⁵

Additionally, on January 26, 2021, the Biden Administration told governors it would begin projecting state allocations of vaccine doses three weeks ahead of shipment and that states' vaccine allocations would increase by 16 percent beginning the following week, totaling 10 million doses each week.³⁶ Further, President Biden announced that the federal government had purchased an additional 100 million doses each from Pfizer and Moderna, increasing the nation's total vaccine supply from 400 million doses to 600 million doses.³⁷ The additional 100 million doses of each vaccine are expected to be available later this summer.³⁸

VII. WITNESSES

The following witnesses have been invited to testify:

Dr. Ngozi Ezike, M.D.

Director
Illinois Department of Public Health

Dr. Joneigh S. Khaldun, M.D., M.P.H., F.A.C.E.P.

Chief Medical Executive and Chief Deputy Director
Michigan Department of Health and Human Services

Dr. Clay Marsh, M.D.

COVID-19/Coronavirus Czar
West Virginia

Dr. Courtney N. Phillips, Ph.D.

Secretary
Louisiana Department of Health

Jill Hunsaker Ryan, M.P.H.

Executive Director
Colorado Department of Public Health and Environment

³⁴ 'Wartime effort': Biden signs orders to fight the pandemic, Politico (Jan. 21, 2020).

³⁵ Biden unveils national COVID strategy with slate of executive orders, CBS News (Jan. 21, 2020).

³⁶ Biden announces purchase of 200M vaccine doses, CNN (Jan. 26, 2021).

³⁷ *Id.*

³⁸ See note 36.