



MEMORANDUM

March 12, 2021

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations”

On Wednesday, March 17, 2021, at 10 a.m. (EDT) via Cisco WebEx online video conferencing, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations.” The hearing will examine the federal government’s response to the coronavirus disease of 2019 (COVID-19) pandemic and vaccination efforts in the United States.

I. BACKGROUND ON COVID-19 IN THE UNITED STATES

The Centers for Disease Control and Prevention (CDC) announced the first reported case of COVID-19 in the United States on January 21, 2020.¹ 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, 2020.² COVID-19 can be asymptomatic or cause a range of symptoms, typically more severe among older adults and people with underlying medical conditions, and has disproportionately affected people of color.³ More than 29 million Americans have contracted COVID-19, leading

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 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); Executive Office of the President, *Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*, 85 Fed. Reg. 15337 (Mar. 18, 2020) (Presidential Proclamation).

³ 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 Mar. 8, 2021); 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) (updated Feb. 18, 2021).

to more than 527,000 deaths.⁴ In the second week of March, there was a daily average of more than 68,000 new cases and more than 1,200 deaths a day in the United States.⁵

II. INITIAL FEDERAL ACTION TO PROMOTE COVID-19 VACCINE DEVELOPMENT

A safe and effective COVID-19 vaccine is one essential public health tool to help contain the pandemic.⁶ In 2020, Congress provided more than \$60 billion to facilitate the development, production, and distribution of COVID-19 medical countermeasures, including vaccines.⁷ On May 15, 2020, the former Administration announced the Operation Warp Speed (OWS) initiative, a public-private partnership aimed at accelerating “the development, manufacturing, and distribution of COVID-19 vaccines” and other medical countermeasures.⁸ 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 2020.⁹

III. STATUS OF COVID-19 VACCINE SUPPLY AND DISTRIBUTION

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer’s COVID-19 vaccine to be administered in two doses 21-days apart in individuals 16 years of age and older.¹⁰ A week later, FDA issued an EUA for Moderna’s vaccine to be administered in two doses 28-days apart in individuals 18 years and

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 Mar. 12, 2021).

⁵ *Id.*

⁶ Centers for Disease Control and Prevention, *Benefits of Getting Vaccinated* (www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html) (accessed Mar. 8, 2021).

⁷ 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.

⁸ U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for ‘Operation Warp Speed’* (May 15, 2020) (press release).

⁹ U.S. Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (web.archive.org/web/20200813010223/https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html) (accessed Mar. 10, 2021); 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).

¹⁰ 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 Mar. 8, 2021).

older.¹¹ The federal government's agreements with Pfizer and Moderna require each company to manufacture and deliver 300 million doses by the end of July 2021, with the first 100 million doses due from each company by March 31, 2021.¹² Pfizer and Moderna have each since committed to providing a total of 200 million doses by the end of May 2021.¹³

On February 27, 2021, FDA issued an EUA for Johnson & Johnson's single-dose vaccine for use in individuals 18 years and older.¹⁴ Johnson & Johnson expects to provide 20 million doses to the U.S. government by the end of March.¹⁵ On March 2, 2021, the Biden Administration announced that it had facilitated a collaboration between Johnson & Johnson and Merck that will allow approximately 100 million doses to be delivered by the end of May.¹⁶ On March 10, 2021, President Biden announced that the United States will purchase an additional 100 million doses of the Johnson & Johnson vaccine.¹⁷ Additional vaccine candidates, developed by AstraZeneca and Novavax, are currently in Phase 3 trials, the final phase of the clinical vaccine development process.¹⁸ As of March 12, 2021, the federal government had delivered over 131 million vaccine doses to states, territories, and tribes.¹⁹

¹¹ 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 Mar. 8, 2021).

¹² U.S. Department of Health and Human Services, *Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna* (Feb. 11, 2021) (press release).

¹³ House Committee on Energy and Commerce, Testimony of John Young, Chief Business Officer, Pfizer, and Testimony of Stephen Hoge, President, Moderna, *Hearing on Pathway to Protection: Expanding Availability of COVID-19 Vaccines*, 117th Cong. (Feb. 23, 2021).

¹⁴ U.S. Food and Drug Administration, *Janssen COVID-19 Vaccine* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine) (accessed Mar. 8, 2021).

¹⁵ House Committee on Energy and Commerce, Testimony of Richard Nettles, Vice President of Medical Affairs, Janssen Pharmaceutical Companies, Johnson & Johnson, *Hearing on Pathway to Protection: Expanding Availability of COVID-19 Vaccines*, 117th Cong. (Feb. 23, 2021).

¹⁶ U.S. Department of Health and Human Services, *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines* (Mar. 2, 2021) (press release).

¹⁷ *Biden to order 100 million more doses of Johnson & Johnson vaccine*, Politico (Mar. 10, 2021).

¹⁸ *Coronavirus Vaccine Tracker*, New York Times (Mar. 8, 2021); Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development and Deployment* (Nov. 25, 2020) (R46399).

¹⁹ Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (covid.cdc.gov/covid-data-tracker/#vaccinations) (accessed Mar. 12, 2021).

IV. COVID-19 VACCINE ADMINISTRATION AND EQUITY CHALLENGES

More than 98 million doses of COVID-19 vaccine have been administered in the United States, and over 35 million adults have been fully vaccinated.²⁰ Currently, more than two million doses per day are being administered, which is up from 900,000 doses per day in late January.²¹

COVID-19 vaccine administration rates in the initial months of the rollout fell short of expectations.²² Trump Administration officials attributed the slow pace of vaccination to a combination of anticipated implementation hurdles.²³ State leaders pointed to limited supply of doses, delayed funding to support vaccine programs, overburdened staff and hospital capacity, challenges with the federal pharmacy partnership program, and limited notice of weekly dose allocations from the federal government.²⁴ Although some of these challenges have been addressed, many eligible Americans continue to struggle to sign up for vaccine appointments due to fragmented health systems and technology barriers.²⁵

The anticipated limited vaccine supply necessitated a phased approach for vaccination.²⁶ Beginning in December 2020, the Advisory Committee on Immunization Practices (ACIP) developed a series of recommendations on COVID-19 vaccine allocation, which CDC and HHS adopted as official, though nonbinding, guidance.²⁷ ACIP recommended vaccinations for health

²⁰ *Id.*

²¹ *U.S. hits record daily Covid vaccinations but health officials warn against loosening restrictions*, CNBC (Mar. 7, 2021).

²² *Vaccine rollout falls short of expectations, raising questions about 2021 timeline*, ABC News (Dec. 31, 2020).

²³ *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*, New York Times (Jan. 1, 2021).

²⁴ *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); House Committee on Energy and Commerce, *Hearing on No Time to Lose: Solutions to Increase COVID-19 Vaccinations in the States*, 117th Cong. (Feb. 2, 2021).

²⁵ *'Vaccine angels' can only do so much: US struggles to make it easier to find COVID-19 vaccination appointments*, USA Today (Mar. 2, 2021).

²⁶ Centers for Disease Control and Prevention, *Interim Considerations for Phased Implementation of COVID-19 Vaccination and Sub-Prioritization Among Recommended Populations* (www.cdc.gov/vaccines/covid-19/phased-implementation.html) (accessed Mar. 12, 2021).

²⁷ *Id.*; Centers for Disease Control and Prevention, *The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United*

care workers and residents of long term care facilities in Phase 1a; people 75 years and older and frontline essential workers in Phase 1b; and individuals 65–74 years old, individuals 16–64 years old with high-risk medical conditions, and other essential workers as defined in each jurisdiction in Phase 1c.²⁸

Thirty states have followed ACIP’s Phase 1a recommendations, but most states have adapted ACIP’s criteria for Phases 1b and 1c and continue to revise their priority groups as COVID-19 vaccination efforts continue.²⁹ As of March 8, 2021, 38 states were in Phase 1b and 12 states and the District of Columbia were in Phase 1c.³⁰ President Biden has encouraged states to expand access to all individuals age 65 and older, frontline essential workers, and teachers and caregivers.³¹

Despite efforts to ensure an equitable vaccine rollout, equity challenges persist.³² Many Americans who are more vulnerable to COVID-19 may be less likely to have access to or seek COVID-19 vaccines. The limited data available show that Black and Hispanic people are being vaccinated against COVID-19 at lower rates than white people in the United States, despite facing significantly higher rates of infection, hospitalization, and death.³³ Public confidence in a COVID-19 vaccine also remains a challenge with as many as 40 percent of adults hesitant to get the vaccine, though some are open to learning more about vaccination.³⁴ Although vaccine confidence has increased since the end of 2020, persisting vaccine hesitancy underscores the

States, December 2020 (Jan. 1, 2021) (69(5152); 1657-1660); *Frontline Workers and People Over 74 Should Get Shots Next, C.D.C. Panel Says*, New York Times (Dec. 20, 2020).

²⁸ Centers for Disease Control and Prevention, *COVID-19 ACIP Vaccine Recommendations* (www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html) (accessed Mar. 10, 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).

²⁹ KFF, *State COVID-19 Vaccine Priority Populations* (www.kff.org/other/state-indicator/state-covid-19-vaccine-priority-populations) (accessed Mar. 10, 2021).

³⁰ KFF, *State COVID-19 Data and Policy Actions* (Mar. 8, 2021).

³¹ White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Jan. 21, 2021); White House, *Remarks by President Biden on the Administration’s COVID-19 Vaccination Efforts* (Mar. 2, 2021).

³² *Vaccine Distribution: An Equity Challenge*, NPR (Mar. 2, 2021).

³³ Centers for Disease Control and Prevention, *Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program — United States, December 14, 2020–January 14, 2021* (Feb. 5, 2021) (MMWR 70(5); 174-177); Centers for Disease Control and Prevention, *Race, Ethnicity, and Age Trends in Persons Who Died from COVID-19 — United States, May–August 2020* (Oct. 23, 2020) (MMWR 69(42); 1517–1521).

³⁴ Ad Council, *COVID-19 Vaccine Education* (www.adcouncil.org/campaign/vaccine-education) (accessed Mar. 10, 2021).

need for a public health education and communications campaign, as called for in President Biden's national strategy and as authorized by the Consolidated Appropriations Act of 2021.³⁵

V. RECENT ACTIONS BY THE BIDEN ADMINISTRATION AND CONGRESS TO ACCELERATE COVID-19 VACCINATIONS

President Biden has committed to administering 100 million COVID-19 vaccine doses in his first 100 days in office, and the Biden Administration has announced that there will be enough vaccine supply for all American adults by the end of May.³⁶ In his first week in office, the President released a national COVID-19 strategy, issued ten executive orders on COVID-19 response priorities, and proposed the American Rescue Plan to support the national COVID-19 pandemic response.³⁷ The American Rescue Plan provides relief for struggling families and invests in efforts to combat the pandemic, providing nearly \$130 billion to help schools safely reopen for in-person instruction, and provides more than \$20 billion for a national vaccine program to speed the distribution and equitable administration of COVID-19 vaccines.³⁸ Congress passed the American Rescue Plan Act of 2021 on March 10, and the President signed the bill into law on March 11.³⁹

President Biden also invoked the Defense Production Act to expedite production of vaccine doses and to increase the supply of materials, such as syringes, that are necessary for COVID-19 vaccine administration.⁴⁰ In February, the Biden Administration began establishing vaccine centers at large venues and mobilizing federal personnel, now including nearly 600

³⁵ White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Jan. 21, 2021); KFF, *COVID-19 Vaccine Monitor: February 2020* (Feb. 26, 2021); Consolidated Appropriations Act, 2021, Pub. L. 116-260.

³⁶ *100M shots in the first 100 days: Biden unveils Covid priorities, introduces health team*, NBC News (Dec. 8, 2020); *Biden ups vaccine goal to 1.5 million shots a day, says vaccine to be widely available by spring*, NBC News (Jan. 25, 2021); *Biden vows enough vaccine 'for every Adult in America' by end of May*, New York Times (Mar. 2, 2021).

³⁷ White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Jan. 21, 2021); *Biden unveils national COVID strategy with slate of executive orders*, CBS News (Jan. 21, 2021); White House, *President Biden Announces American Rescue Plan* (Jan. 20, 2021).

³⁸ American Rescue Plan Act of 2021, Pub. L. 117-2.

³⁹ *Senate approves Biden's \$1.9 trillion pandemic relief plan*, Politico (Mar. 6, 2021); *House passes \$1.9 trillion Covid relief bill, sends it to Biden to sign*, CNBC (Mar. 10, 2021); *Biden signs \$1.9T Covid relief bill*, Politico (Mar. 11, 2021).

⁴⁰ *Wartime effort?: Biden signs orders to fight the pandemic*, Politico (Jan. 21, 2021); U.S. Department of Health and Human Services, *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines* (Mar. 2, 2021) (press release).

centers with more than 6,000 active-duty service members.⁴¹ In addition, the Administration began notifying states, territories, and tribes of their projected vaccine dose allocations three weeks ahead of shipment.⁴² Vaccine shipments to states have increased to more than 20 million doses per week, up from 8.6 million doses per week when President Biden took office.⁴³

The Biden Administration has mobilized a federal partnership program with retail pharmacies (pharmacy partnership), including more than 20,000 locations across the country, which receive a separate allocation of more than two million doses per week.⁴⁴ Beginning the week of February 15, 2021, the Administration began shipping one million COVID-19 vaccine doses each week directly to community health centers (CHCs) in every state, targeting CHCs that serve a large proportion of disproportionately affected populations, including homeless individuals, public housing residents, and migrant or seasonal agricultural workers.⁴⁵ In addition, beginning the week of March 8, 2021, President Biden expanded access to COVID-19 vaccines through the pharmacy partnership for pre-K-12 teachers and school staff to help accelerate schools' reopening.⁴⁶ Further, the Administration launched a new initiative with health insurers which aims to expedite the vaccination of vulnerable seniors.⁴⁷

On March 11, 2021, President Biden announced that he will direct states to make all Americans eligible for vaccination by May 1.⁴⁸ In an address to the nation, the President

⁴¹ *Biden unveils national COVID strategy with slate of executive orders*, CBS News (Jan. 21, 2021); *Biden administration deploys more than 1,000 active-duty troops to aid vaccination efforts*, Politico (Feb. 5, 2021); White House, *FACT SHEET: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th* (Mar. 11, 2021) (press release).

⁴² *Biden announces purchase of 200M vaccine doses*, CNN (Jan. 26, 2021).

⁴³ White House, *Press Briefing by White House COVID-19 Response Team and Public Health Officials* (Mar. 10, 2021) (press briefing).

⁴⁴ White House, *FACT SHEET: President Biden Announces Increased Vaccine Supply, Initial Launch of the Federal Retail Pharmacy Program, and Expansion of FEMA Reimbursement to States* (Feb. 2, 2021) (press release); White House, *FACT SHEET: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th* (Mar. 11, 2021) (press release).

⁴⁵ White House, *FACT SHEET: President Biden Announces Community Health Centers Vaccination Program to Launch Next Week and Another Increase in States, Tribes, & Territories' Vaccine Supply* (Feb. 9, 2021).

⁴⁶ *President Joe Biden Urges States to Vaccinate Teachers, School Staff this Month*, CNBC (March 2, 2021).

⁴⁷ White House, *Press Briefing by White House COVID-19 Response Team and Public Health Officials* (Mar. 3, 2021) (press briefing).

⁴⁸ White House, *FACT SHEET: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th* (Mar. 11, 2021) (press release).

launched the next phase of the strategy to combat the pandemic consisting of increasing the number of vaccination sites and vaccinators, additional tools including a centralized website to help Americans access vaccines and expanding testing to help stop the spread of COVID-19.⁴⁹

According to CDC, more than one-in-five adults have had at least one dose of a COVID-19 vaccine.⁵⁰ On March 8, 2021, CDC released updated guidance on public health best practices for fully vaccinated adults.⁵¹ While some states have begun relaxing public health measures intended to prevent the spread of COVID-19, public health officials caution that prematurely lifting restrictions, such as mask-wearing and capacity limitations on businesses and restaurants, could lead to another surge of the disease, particularly as new variants emerge.⁵²

VI. WITNESSES

The following witnesses have been invited to testify:

Anthony S. Fauci, M.D.

Director

National Institute for Allergy and Infectious Diseases

National Institutes of Health

Peter Marks, M.D., Ph.D.

Director

Center for Biologics Evaluation and Research

U.S. Food and Drug Administration

Rochelle P. Walensky, M.D., M.P.H.

Director

Centers for Disease Control and Prevention

⁴⁹ *Id.*

⁵⁰ *See* note 19.

⁵¹ Centers for Disease Control and Prevention, *When You've Been Fully Vaccinated* (accessed Mar. 8, 2021) (www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html).

⁵² *See* note 21.