COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

January 29, 2021

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain"

On **Wednesday, February 3, 2021, at 11 a.m. (EDT), via Cisco Webex online video conferencing,** the Subcommittee on Health will hold a hearing entitled, "Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain."

I. THE TRUMP ADMINISTRATION'S RESPONSE TO COVID-19

Since the first case of the coronavirus disease of 2019 (COVID-19) in the United States was discovered on January 21, 2020,[1] the United States response efforts have failed to mitigate or reduce COVID-19 transmission in the country. As of January 26, 2021, more than 25 million Americans have been infected with COVID-19, and more than 419,000 people have died from the disease.[2] The COVID-19 response in the United States has faced many challenges, including availability of accessible and reliable tests, continued access to personal protective equipment (PPE) and medical supplies, and equitable distribution of vaccines.

A. Vaccines

On May 15, the Trump Administration announced Operation Warp Speed (OWS), a partnership led by the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD), along with private companies and other federal agencies. The partnership's goal was to facilitate and accelerate development, manufacturing, and distribution of COVID-19

[1] Centers for Disease Control and Prevention, *First Travel-related Case of 2019 novel Coronavirus Detected in United States* (Jan. 21, 2020) (www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html) (press release).

[2] Centers for Disease Control and Prevention, Unites States COVID-19 Cases and Deaths by State (covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days) (accessed Jan. 26, 2021).

vaccines, therapeutics, and diagnostics.[3] In order to speed the development of vaccines, OWS, which was led by Chief Operating Officer General Gustave F. Perna and Chief Advisor Dr. Moncef Slaoui, invested in manufacturing and development while vaccine candidates were under investigation and proceeding through clinical trials, thereby reducing financial risk and pressure on manufacturers.[4] As part of these investments, OWS contracted to purchase hundreds of millions of doses of vaccine candidates. For more information on early OWS vaccine development efforts, see Oversight and Investigations Subcommittee memoranda from July 16, 2020 and September 25, 2020.

Less than a year from when COVID-19 was first detected, the Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for Pfizer and BioNTech's COVID-19 vaccine on December 11, 2021, allowing it to be distributed and administered in the United States.[5] On December 18, 2020, FDA issued an EUA for a second vaccine manufactured by Moderna.[6] Under the Trump Administration, OWS contracted to purchase 100 million doses of each vaccine. The first 100 million of each are contracted to be delivered by the end of the first quarter of 2021, though due to a previously unforeseen ability to draw a sixth dose out of Pfizer vials with a particular type of syringe, Pfizer recently announced it will be able to deliver 120 million total doses by the end of the first quarter.[7] The ability to draw this additional dose will allow Pfizer to deliver a total of 200 million doses by May 31, 2021, two months ahead of its initial deadline.[8] Moderna will deliver a total of 200 million doses by June 30, 2021.[9] Government contracts include options to purchase additional doses of each

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[3] U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 5, 2020) (www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html) (press release).

[4] U.S. Department of Health and Human Services, Fact Sheet: Explaining Operation Warp Speed (www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html) (accessed Jan. 26, 2021).

[5] U.S. Food and Drug Administration, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020) (www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) (press release).

[6] U.S. Food and Drug Administration, *FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020) (www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid) (press release).

[7] *Pfizer to Deliver U.S. Vaccine Doses Faster Than Expected*, Bloomberg News (Jan. 26, 2021) (www.bloomberg.com/news/articles/2021-01-26/pfizer-to-deliver-u-s-vaccine-doses-faster-than-expected-ceo?srnd=prognosis).

[8] *Id.*

[9] U.S. Department of Health and Human Services, *Trump Administration purchases additional 100 million doses of COVID-19 investigational vaccine from Moderna* (Dec. 11,

vaccine.[10] Each of the currently authorized vaccines requires two doses. OWS also invested in several additional vaccine candidates currently in Phase 3 clinical trials in the United States, including those developed by the manufacturers Johnson & Johnson, Oxford-AstraZeneca, and NovaVax.[11] These manufacturers are expected to report results in the coming weeks and months.[12]

As promising clinical trial data from the first vaccine candidates became public, Dr. Slaoui stated in early December 2020, he was confident that 20 million Americans would be vaccinated by the end of the year.[13] However, by December 31, 2020, less than three million individuals had received even one dose of the vaccine, and total administered vaccine doses did not cross 20 million until January 23, 2021.[14] Supply chain experts attribute these delays in part to a decentralized distribution plan that relies heavily on underfunded state and local health entities whose resources have already been spread thin by the pandemic.[15] While CDC required states and other jurisdictions to begin planning to receive vaccines in October, which was before any COVID-19 vaccines were authorized, few resources were made available for states that cited hardships or distribution concerns in their plans.[16]

2020) (www.hhs.gov/about/news/2020/12/11/trump-administration-purchases-additional-100-million-doses-covid-19-investigational-vaccine-moderna.html) (press release).

[10] U.S. Department of Health and Human Services, *Trump Administration purchases additional 100 million doses of COVID-19 investigational vaccine from Moderna* (Dec. 11, 2020) (www.hhs.gov/about/news/2020/12/11/trump-administration-purchases-additional-100-million-doses-covid-19-investigational-vaccine-moderna.html) (press release); Pfizer, *PFIZER AND BIONTECH TO SUPPLY THE U.S. WITH 100 MILLION ADDITIONAL DOSES OF COVID-19 VACCINE* (Dec. 23, 2020) (www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-supply-us-100-million-additional-doses) (press release).

[11] *Coronavirus Vaccine Tracker*, New York Times (www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html) (accessed Jan. 24, 2021).

[12] *Id*.

[13] U.S. Department of Health and Human Services, *Briefing with Senior Officials on OWS and COVID-19 Vaccines* (Dec. 2, 2020) (www.youtube.com/watch?v=WBdDUIqXE3M).

[14] *U.S. CDC says 41.4 million doses of COVID-19 vaccines distributed, 20.5 million administered*, Reuters (Jan. 23, 2021) (www.reuters.com/article/us-health-coronavirus-usa-cdc-idUSKBN29S0NO).

[15] *U.S. Covid-19 Vaccination Plan Limits Speed of Rollout, Supply-Chain Experts Say*, Wall Street Journal (Jan. 11, 2021) (www.wsj.com/articles/u-s-covid-19-vaccination-plan-limits-speed-of-rollout-supply-chain-experts-say-11610283601).

[16] Kaiser Family Foundation, *States Are Getting Ready to Distribute COVID-19 Vaccines. What Do Their Plans Tell Us So Far?* (Nov. 18, 2020) (www.kff.org/coronavirus-covid-19/issue-brief/states-are-getting-ready-to-distribute-covid-19-vaccines-what-do-their-plans-tell-us-so-far/).

Since the rollout began, states have noted a myriad of distribution concerns. Most notably, states have cited miscommunication or a lack of communication from the federal government about the number of doses they can expect to receive.[17] Lacking sufficient clarity as to the number of doses they would receive, some states were forced to cancel appointments due to a lack of supply relative to the amount the state expected to receive, and other states have allowed vaccines to sit on shelves to ensure they would have an adequate supply to administer both required doses.[18] Many have also raised concerns about the speed with which the Trump Administration rolled out its partnership with pharmacies to administer vaccines to those living in nursing homes and other congregate living settings.[19] Additionally, states have also cited concerns with the complexity of administering a large number of vaccines in sparsely populated areas and following recommendations for equitable distribution from the Advisory Committee on Immunization Practices (ACIP) at CDC.[20] Other states, which have administered the vaccine more quickly, have noted ongoing challenges related to lack of vaccine supply.[21]

To speed administration of doses, on January 12, 2021, former HHS Secretary Alex Azar instructed states to begin vaccinating all Americans age 65 and older, as well as individuals at higher risk of COVID-19, such as those with certain medical conditions and frontline workers.[22] This was a divergence from ACIP guidelines, which recommended vaccines be administered to those age 75 and older, and frontline workers.[23] Former Secretary Azar also noted that some states had not ordered all vaccine doses they were eligible to receive, and suggested that future allocations to states might decline if they do not administer vaccines quickly enough, though this plan was not put into effect.[24]

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[17] '*Pixie dust': Why some vaccine sits on shelves while shortages intensify nationwide*, Washington Post (Jan. 21, 2021) (www.washingtonpost.com/health/2021/01/21/vaccine-rollout-states-shortages/).

[18] *Id.*

[19] *Frustrations Boil at Pace of Vaccinations at Long-Term Care Facilities*, New York Times (Jan. 16, 2021) (www.nytimes.com/2021/01/16/business/covid-vaccine-nursing-homes.html).

[20] *Pixie dust': Why some vaccine sits on shelves while shortages intensify nationwide*, Washington Post (Jan. 21, 2021) (www.washingtonpost.com/health/2021/01/21/vaccine-rollout-states-shortages/); Kaiser Family Foundation, *The COVID-19 Vaccine Priority Line Continues to Change as States Make Further Updates* (Jan. 21, 2021) (www.kff.org/policy-watch/the-covid-19-vaccine-priority-line-continues-to-change-as-states-make-further-updates/); Centers for Disease Control and Prevention, COVID-19, Advisory Committee on Immunization Practices (ACIP) (www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html) (accessed Jan. 26, 2021).

[21] *States' new vaccine worry: Not enough doses*, Politico (Jan. 20, 2021) (www.politico.com/news/2021/01/20/states-coronavirus-vaccine-shortages-460899).

[22] *States Told to Vaccinate Everyone 65 and Over as Deaths Surge*, New York Times (Jan. 12, 2021) (www.nytimes.com/2021/01/12/us/politics/vaccine-states.html).

[23] *Id.*

[24] *Id.*

B. Testing

Testing is a critical component of COVID-19 response efforts, including for use in identifying infected individuals and informing public health decisions such as reopening strategies. Widespread testing in the United States has faced many hurdles. Initial tests for COVID-19 in the United States were developed and produced by CDC, which first received an EUA from the FDA on February 4, 2020[25] and began shipping testing kits to public health laboratories on February 5.[26] Shortly after distribution of these tests, the reagent components were found to be contaminated, further slowing the rollout of reliable tests.[27] Following this discovery, CDC issued guidance to states on how to augment the faulty tests and released an updated test on February 28.[28] The first commercial test for COVID-19 was not authorized until March 12.[29]

While diagnostic testing is generally utilized to identify individuals suspected of infection, surveillance testing is often used to monitor for community or population occurrence.[30] Surveillance testing is an important tool for identifying a population outbreak and population trends in infection rates.[31] Public health experts have noted that the lack of surveillance testing in the United States has slowed our response compared to other global nations.[32]

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[25] Centers for Disease Control and Prevention, COVID-19, Diagnostic Testing (www.cdc.gov/coronavirus/2019-ncov/lab/testing.html) (accessed Jan. 26, 2021).

[26] Centers for Disease Control and Prevention, *Distribution of CDC Diagnostic Test Kits Will Expand Laboratory Capacity to Detect 2019-nCoV* (Feb. 6, 2021) (www.cdc.gov/media/releases/2020/p0206-coronavirus-diagnostic-test-kits.html). While most tests must typically go through an approval process at FDA before their use, during declared public health emergencies, tests may come to market after being authorized under an EUA. *See* 21 U.S.C. § 360bbb-3.

[27] *EXCLUSIVE: Internal HHS investigation finds CDC's early test kits were 'contaminated'*, KATU 2 ABC News (June 19, 2020) (katu.com/news/nation-world/exclusive-internal-hhs-investigation-finds-cdcs-early-test-kits-were-contaminated).

[28] *Amid testing concerns, US officials unveil new coronavirus test kits and streamline commercial development*, CNBC (Feb. 28, 2020) (www.cnbc.com/2020/02/28/amid-testing-capacity-concerns-cdc-unveils-new-coronavirus-test-kits.html).

[29] U.S. Food and Drug Administration, Emergency Use Authorization (www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization) (accessed May 29, 2020).

[30] Centers for Disease Control and Prevention, COVID-19, Pooling Procedures, (www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html) (accessed Jan. 26, 2021).

[31] *Id.*

[32] *'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response*, New York Times (March 10, 2020) (www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html).

The two primary types of tests for COVID-19 in the United States are viral tests and serology tests. Viral tests are used to help diagnose active infection, including molecular tests and antigen tests. Serology tests are used to help determine if a person was previously exposed to the virus via detection of antibodies in a blood sample. As of January 22, 2021, a total of 285,274,135 tests[33] (including both viral and serology tests as reported to CDC by most states) were performed in the United States. Further, the FDA has authorized 319 tests and sample collection devices, which includes 237 molecular tests, 69 antibody tests, and 13 antigen tests.[34] Currently 33 molecular tests can be used with home-collected samples, and three tests are available for at-home use.[35] Nine States or territories have authorized additional tests for use within their jurisdiction.[36]

While testing in the United States has expanded since the start of the pandemic, public health officials believe that the absence of robust COVID-19 testing has impacted the ability of the United States to contain the virus.[37] Today, the United States tests approximately 1.81 million people a day, less than what public health experts say is needed to suppress or contain COVID-19.[38] [39]

C. Medical Supply Chain

The Coronavirus Aid, Relief, and Economic Security Act, or "CARES" Act, requires the Government Accountability Office (GAO) to issue bi-monthly reports on the various impacts of COVID-19. As part of this ongoing work, GAO's November 2020 report included results from a

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[33] Centers for Disease Control and Prevention, COVID-19, United States Laboratory Testing (covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Ftesting-in-us.html#testing_positivity7day) (accessed on Jan. 26, 2021).

[34] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: January 22, 2021* (Jan. 22, 2021) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-january-22-2021) (press release).

[35] *Id.*

[36] U.S. Food and Drug Administration, Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2 (www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2) (accessed Jan. 26, 2021).

[37] *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, New York Times (March 28, 2020) (www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html).

[38] The COVID Tracking Project at The Atlantic, US Daily Tests (covidtracking.com/data/charts/us-daily-tests) (accessed Jan. 26, 2021).

[39] Harvard University Edmond J. Safra Center for Ethics, *Why We Must Test Million a Day* (Apr. 8, 2020) (ethics.harvard.edu/test-millions).

national survey to states and territories regarding ongoing shortages of certain testing-related and other medical supplies. Specifically, investigators found that 21 states reported shortages of testing reagents, 16 states reported shortages of testing instruments, and 24 states reported shortages of rapid point-of-care tests in the 30 days prior to the report's release; those same states predicted shortages would continue through the winter months.[40]

Beyond testing supplies, states have also experienced severe shortages in other critical medical supplies, such as exam gloves and other types of PPE.[41] Hospitals have reported shortages in oxygen cannisters and failing infrastructure as an impediment to delivering oxygen to hospitalized patients,[42] and while supply of vaccines is ramping up, there are looming shortages in total doses and the media to administer them.[43]

II. CONGRESSIONAL ACTION

To help support response efforts to COVID-19 in the United States, Congress has acted to pass several pieces of legislation.

On March 6, 2020, H.R. 6074, the Coronavirus Preparedness and Response Supplemental Appropriations Act, was signed into law.[44] This legislation invested $8.3 billion in critically needed funding as initial COVID-19 outbreaks spread across the country, including $3 billion for research and development of vaccines, therapeutics, and diagnostics, and $2.2 billion for public health activities at CDC.

On March 18, 2020, H.R. 6201, the Families First Coronavirus Response Act, was signed into law.[45] This legislation expanded access to free COVID-19 testing and required state and

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[40] *Nonpartisan report warns of COVID-19 testing shortages in over half US states, territories*, ABC News (Nov. 30, 2020) (abcnews.go.com/Politics/nonpartisan-report-warns-covid-19-testing-shortages-half/story?id=74469015).

[41] *Health Workers Still Face Shortages Of Critical Medical Supplies*, NPR (Jan. 26, 2021) (www.npr.org/2021/01/26/960631395/health-workers-still-face-shortages-of-critical-medical-supplies).

[42] *Oxygen supply shortages bedevil hospitals already overwhelmed by COVID-19 patients*, Los Angeles Times (Dec. 29, 2020) (www.latimes.com/california/story/2020-12-29/oxygen-supply-shortages-bedevil-hospitals-already-overwhelmed-by-covid-19-patients).

[43] *Warning of Shortages, Researchers Look to Stretch Vaccine Supply*, New York Times (Jan. 5, 2021) (www.nytimes.com/2021/01/05/us/politics/coronavirus-vaccine-supply.html?auth=login-email&login=email).

[44] Pub. L. No. 116-123 (2020).

[45] Pub. L. No. 116-127 (2020).

local governments to report aggregated testing data to the CDC.[46] It also included $1 billion in funding to reimburse providers for providing COVID-19 tests to uninsured individuals.[47]

On March 27, H.R. 748, the CARES Act, was signed into law.[48] This legislation included over $100 billion in funding for supply chain needs such as manufacturing, procurement, and distribution of vaccine, therapeutics, ancillary supplies, and replenishing the needs of the strategic national stockpile (SNS). Separate from the funding for materials, the CARES Act also included $1 billion for manufacturing activities utilizing the Defense Production Act. Additionally, the legislation included $100 billion in funding for eligible providers to provide diagnostic testing, and purchase PPE, tests, and testing supplies, as well as $27 billion for research, development, and procurement of vaccines, therapeutics, and diagnostics to prevent, treat, or detect COVID-19.[49]

On April 24, 2020, H.R. 266, the Paycheck Protection Program and Health Care Enhancement Act, was signed into law.[50] This legislation required, within 30 days, each state to submit to Congress a testing plan for containing the COVID-19 pandemic. This package included $25 billion for testing and contact tracing capacity, including $11 billion in funding for state, local, territorial, and tribal entities to be used for testing capacity procurement and distribution of tests, testing equipment, testing supplies, community-based testing sites and otherwise scale-up testing.[51]

On May 15, 2020, and again on October 1, 2020, the House passed the Heroes Act (H.R. 6800 and H.R. 8406), comprehensive COVID-19 legislation that included over $100 billion in federal investments in testing resources, vaccine and therapeutic research, development, distribution, administration, and promotion. These investments included largescale funding for the country's manufacturing, public health, laboratory, and testing infrastructure, including $500 million for domestic manufacturing, $450 million for public health data improvements, $1 billion for public health laboratory infrastructure, $6 billion for state, local, tribal and territorial health department infrastructure. Additionally, the legislation included $28 billion for procurement, distribution, and education campaigns for a safe and effective vaccine. The legislation also required the Administration to appoint a Medical Supplies Response Coordinator, develop a National Testing Strategy, and create a centralized testing information website. Also included was $75 billion for state, local, tribal, and territorial investments to execute the National Testing Strategy, including requirements for targeting testing in high-need, low-resource communities, and conducing contact tracing, surveillance, containment and mitigation activities.

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[46] *Id.*

[47] *Id.*

[48] Pub. L. No. 116-136 (2020).

[49] *Id.*

[50] Pub. L. No. 116-139 (2020).

[51] *Id.*

On December 27, 2020, H.R. 133, the Consolidated Appropriations Act and Coronavirus Response and Relief Supplemental Appropriations Act, was signed into law.[52] Along with discretionary appropriations for fiscal year (FY) 2021, and numerous health provisions, this legislation included investments to aid in COVID-19 relief. These investments included $8.75 billion for vaccine distribution, awareness, and promotion; $19.695 billion for manufacturing, production, and purchase of vaccines, therapeutics, and ancillary supplies; $22.4 billion for testing, contact tracing, surveillance, and mitigation; $3.25 billion for the SNS; among other investments.[53]

III. BIDEN ADMINISTRATION ACTIONS

On January 21, 2021, President Joseph Biden released his national strategy for COVID-19 response.[54] The plan would invest $20 billion to speed the distribution and administration of COVID-19 vaccines, including funding for distribution to underserved populations.[55] The plan would also invest $50 billion in testing, with investments for rapid tests, expanding lab capacity, and assisting states in implementing testing protocols.[56] In addition, since taking office, President Biden has issued ten executive orders to take action on COVID-19 response, including requiring the development of a public dashboard with real-time data on COVID-19 vaccinations, utilizing the Defense Production Act to accelerate the production of ancillary supplies necessary for speeding vaccine distribution, and clarifying that insurance plans are required to cover all COVID-19 testing.[57]

The Biden Administration has also taken immediate action to ramp up delivery of additional doses of COVID-19 vaccine while allowing states more time to plan vaccine administration. On January 26, 2021, the Biden Administration told states it would begin projecting state allocations of vaccine doses three weeks ahead of shipment, while shipping at least 10 million doses per week across the country, an increase of 16 percent.[58] The Administration also announced it would purchase an additional 100 million doses each of the

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[52] Pub. L. No. 116-260 (2020).

[53] *Id.*

[54] *Biden on ambitious Covid rescue plans: 'I will always be honest with you',* CNBC (Jan. 14, 2021) (www.cnbc.com/2021/01/14/biden-unveils-sweeping-plan-to-combat-the-covid-pandemic-in-the-us.html).

[55] *Joe Biden's Covid-19 Vaccine Plan: How He Intends to Speed Up Distribution*, Wall Street Journal (Jan. 21, 2021) (www.wsj.com/articles/joe-bidens-covid-19-vaccine-plan-how-he-intends-to-speed-up-distribution-11610794800).

[56] *Id.*

[57] The White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness* (Jan. 2021) (www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf).

[58] *Biden administration to buy 200 million more doses of Covid vaccine,* Politico (Jan. 26, 2021) (www.politico.com/news/2021/01/26/biden-covid-vaccine-purchase-462803).

Pfizer and Moderna vaccines, bringing the total federal purchase to 300 million doses of each of the currently authorized vaccines.[59] The additional 100 million doses of each vaccine are expected to be delivered later this summer.[60]

IV. WITNESSES

The following witnesses have been invited to testify:

Luciana Borio, M.D.
Vice President, In-Q-Tel
Former Acting Chief Scientist, FDA
Former Director for Medical and Biodefense Preparedness, National Security Council

Greg Burel
President and Principal Consultant, Hamilton Grace
Former Director, United States Strategic National Stockpile

The Honorable Michael O. Leavitt
Founder and Chair, Leavitt Partners
Former Secretary of Health and Human Services
Former Governor of Utah

Julie Morita, M.D.
Executive Vice President
Robert Wood Johnson Foundation

[59] *Id.*

[60] *Id.*