COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

July 16, 2020

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

On **Tuesday, July 21, 2020, at 10 a.m. (EDT) via Cisco Webex online video conferencing**, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine." The hearing will examine the current state of research, development, and manufacturing of potential vaccines for coronavirus disease of 2019 (COVID-19).

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 cause a range of mild to severe symptoms, with older adults and people with underlying medical conditions at higher risk of developing more severe complications, and people of color experiencing higher rates of infection and mortality.[2] On January 31, Secretary of Health and Human Services (HHS) Alex Azar declared the disease a U.S. public health emergency, a designation that will expire on July 25 if not extended.[3] President Trump declared the outbreak a national emergency on March 13.[4]

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[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, *Symptoms of Coronavirus* (www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html) (accessed July 14, 2020); Kaiser Family Foundation, *Growing Data Underscore that Communities of Color are Being Harder Hit by COVID-19* (Apr. 21, 2020).

[3] U.S. Department of Health and Human Services, *Public Health Emergency Declarations* (www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx) (accessed July 14, 2020); *HHS Will Renew Public Health Emergency*, Modern Healthcare (June 29, 2020).

[4] White House, *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak* (Mar. 13, 2020).

As of July 15, there were more than 3.3 million reported COVID-19 cases and 135,991 COVID-19-related deaths in the United States.[5]

II. THE VACCINE DEVELOPMENT PROCESS

Leading U.S. public health experts believe that a safe and effective COVID-19 vaccine "will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks."[6] Typically, between 70 percent and 90 percent of a population needs to develop immunity to achieve "herd immunity," which provides indirect protection to those who are not immune to the disease.[7]

Vaccines are developed to prevent diseases and generally work by introducing pathogens to the body to trigger an immune response to the disease.[8] To be approved for use in the United States, the Food and Drug Administration (FDA) must determine that a vaccine is safe and effective, based on data from laboratory studies and clinical trials.[9] In certain emergency situations, FDA may issue an emergency use authorization (EUA) for a vaccine before it is approved if several legal requirements are met, including a determination that a vaccine "may be effective" in preventing the disease and that its known and potential benefits outweigh the known and potential risks.[10]

Clinical trials intended to demonstrate a potential vaccine's safety or effectiveness for purposes of FDA approval generally proceed in three successive phases.[11] In Phase 1, a vaccine candidate is first introduced in a relatively small number of human subjects and is typically

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[5] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19) Cases in the U.S.* (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html) (accessed July 15, 2020).

[6] House Committee on Energy and Commerce, Testimony of Robert R. Redfield, M.D., Director, Centers for Disease Control and Prevention; Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases; Admiral Brett P. Giroir, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services; and Stephen M. Hahn, M.D., Commissioner, Food and Drug Administration, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (June 23, 2020).

[7] U.S. Government Accountability Office, *Science & Tech Spotlight: Herd Immunity for COVID-19* (July 2020).

[8] Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020).

[9] 42 U.S.C. § 262(a)(2); 21 C.F.R. § 601.2 (2019).

[10] 21 U.S.C. § 360bbb-3.

[11] Food and Drug Administration, *Vaccine Product Approval Process* (www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process) (accessed July 14, 2020).

evaluated for its initial safety profile and ability to provoke an immune response.[12] In Phase 2, the testing involves a larger group of participants, usually no more than a few hundred, and an evaluation generally of the vaccine candidate's safety, efficacy, common side effects, and optimal dosage.[13] Finally, in Phase 3, thousands of participants are typically enrolled in the study to evaluate the vaccine candidate for safety and efficacy across a wide range of patient categories.[14] To accelerate the vaccine development timeline, the phases of clinical trials may be combined in various ways in certain circumstances.[15]

The clinical vaccine development process typically takes ten to 15 years to complete.[16] Studies have found that only six percent of vaccine candidates in pre-clinical development reach the market historically,[17] and that approximately 33 percent of infectious-disease vaccines in clinical trials ultimately secure approval.[18]

III. FEDERAL GOVERNMENT ACTION TO PROMOTE COVID-19 VACCINES

Since the COVID-19 outbreak began in the United States, the Federal Government has taken steps designed to facilitate the promotion of COVID-19 vaccines. On April 17, 2020, the National Institutes of Health (NIH) announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership "to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines."[19] Through ACTIV, NIH is collaborating with government agencies, academia, nonprofit organizations, and biopharmaceutical companies to prioritize the most promising vaccine candidates and move them into clinical trials safely and efficiently.[20]

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[12] Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020).

[13] *Id.*

[14] *Id.*

[15] *Coronavirus Vaccine Tracker*, New York Times (www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html) (accessed July 15, 2020).

[16] Seunghoon Han, *Clinical Vaccine Development*, Clinical and Experimental Vaccine Research (Jan. 30, 2015).

[17] Esther S. Pronker et al., *Risk in Vaccine Research and Development Quantified*, PLOS One (Mar. 20, 2013).

[18] Chi Heem Wong et al., *Estimation of Clinical Trial Success Rates and Related Parameters*, Biostatistics (Jan. 31, 2018).

[19] National Institutes of Health, *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)* (https://www.nih.gov/research-training/medical-research-initiatives/activ) (accessed July 14, 2020).

[20] *Id.*

Additionally, on May 15 the Trump Administration announced the Operation Warp Speed (OWS) initiative, a national program aimed at accelerating "the development, manufacturing, and distribution" of COVID-19 countermeasures, including vaccines.[21] OWS is a partnership between components HHS, the Department of Defense, private firms, and other federal agencies.[22] OWS aims to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021, which would set a new record for a vaccine development timeline.[23] According to Secretary of Defense Mark Esper, OWS will deliver "a vaccine at scale to treat the American people and our partners abroad" by the end of 2020.[24]

To accelerate development of COVID-19 vaccines, OWS initially selected 14 vaccine candidates to receive coordinated government support, with the goal of launching large-scale randomized trials for three to five candidates.[25] Through OWS, the Federal Government is assuming financial risk by investing in manufacturing capacity while selected vaccine candidates are still in development, rather than scaling up after approval or authorization.[26] According to HHS, OWS is also building a distribution infrastructure for eventual COVID-19 vaccines before any are approved or authorized.[27] To date, Congress has directed nearly $10 billion to vaccine and treatment development through the Coronavirus Aid, Relief, and Economic Security (CARES) Act and other supplemental funding.[28]

Additionally, on June 30, 2020, FDA issued guidance on the "Development and Licensure of Vaccines to Prevent COVID-19."[29] The guidance advises that later phase trials for COVID-19 vaccine candidates should be randomized, double-blinded, and placebo controlled, and states that late phase trials "will likely need to enroll many thousands of participants,

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[21] U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020) (press release).

[22] *Id.*

[23] U.S. Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020); *Can a Vaccine for Covid-19 Be Developed in Record Time?*, New York Times (June 9, 2020).

[24] White House, *Remarks by President Trump on Vaccine Development* (May 15, 2020).

[25] U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020) (press release).

[26] U.S. Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020).

[27] *Id.*

[28] *Id.*

[29] Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (press release).

including many with comorbidities."[30] The guidance also notes that clinical development programs for COVID-19 vaccines may be expedited in certain circumstances to allow for more rapid progression through the usual phases of clinical development.[31] According to the guidance, FDA may approve or authorize a COVID-19 vaccine only if it is demonstrated to be at least 50 percent more effective than a placebo in preventing the disease.[32] In recent testimony before the Committee, FDA Commissioner Dr. Stephen Hahn stated that, when determining whether to approve a potential COVID-19 vaccine, FDA "will use the science and data that come to us, and we will use our high standards to assess the safety and efficacy of a vaccine."[33]

IV. COMPANIES INVOLVED IN COVID-19 VACCINE DEVELOPMENT TESTIFYING AT THE SUBCOMMITTEE HEARING

As of July 15, 2020, at least 140 COVID-19 vaccine candidates are in preclinical evaluation and at least 23 candidates are in clinical evaluation worldwide.[34] Some of these efforts are using a traditional approach to vaccine development, in which a dead or weakened virus is used to elicit a protective immune response in patients.[35] Other efforts are using newer technologies through which genetic code instructs cells in a person's body to make specific proteins that produce an immune response.[36] Additionally, several research teams are using an adenovirus or other viruses to deliver genes into cells to confer immunities, while other researchers are utilizing different methods.[37]

Multiple companies are currently developing COVID-19 vaccines for use in the United States. The Committee has invited five of these companies to testify—AstraZeneca, Johnson & Johnson, Merck, Moderna, and Pfizer—all of which are reportedly involved in OWS.[38]

A. AstraZeneca

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[30] Food and Drug Administration, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (June 2020).

[31] *Id.*

[32] *Id.*

[33] House Committee on Energy and Commerce, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (June 23, 2020).

[34] World Health Organization, *Draft Landscape of COVID-19 Candidate Vaccines* (July 15, 2020).

[35] *Different Approaches to a Coronavirus Vaccine*, New York Times (May 20, 2020).

[36] *Id.*

[37] *Id.*

[38] *Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists*, New York Times (June 3, 2020); *White House Works with Seven Drugmakers in 'Warp Speed' Push*, Bloomberg (June 3, 2020).

AstraZeneca is a biopharmaceutical company based in the United Kingdom focused on developing medicines to treat oncology, cardiovascular, renal and metabolism, and respiratory and immunology diseases.[39] On April 30, 2020, AstraZeneca announced an agreement with the University of Oxford for the global development and distribution of the University's potential recombinant adenovirus vaccine for COVID-19.[40] The Trump Administration announced a collaboration with AstraZeneca on May 21 to produce at least 300 million doses of this vaccine in the United States beginning as early as October.[41] Through OWS, AstraZeneca will receive up to $1.2 billion from the Biomedical Advanced Research and Development Authority (BARDA) to support development and production of this vaccine candidate.[42] Oxford University started a Phase 2/3 trial in the United Kingdom in May,[43] and a Phase 3 trial involving approximately 30,000 participants is expected to begin later this summer in the United States.[44] In a press release, AstraZeneca announced it had agreed to supply one billion doses of its vaccine for low-and-middle-income countries, including 400 million doses before the end of 2020.[45]

B. Johnson & Johnson

Johnson & Johnson is an American multinational corporation headquartered in New Brunswick, New Jersey, that develops medical devices, pharmaceuticals, and consumer packaged goods.[46] On March 30, 2020, Janssen Pharmaceutical Companies, a subsidiary of Johnson & Johnson, announced the selection of a lead COVID-19 vaccine candidate, which uses a modified adenovirus, along with two back-ups.[47] As part of OWS, BARDA awarded the

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[39] AstraZeneca, *AstraZeneca and Oxford University Announce Landmark Agreement for COVID-19 Vaccine* (Apr. 30, 2020) (press release).

[40] *Id.*

[41] U.S. Department of Health and Human Services, *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to Be Available Beginning in October* (May 21, 2020) (press release).

[42] *Id.*

[43] AstraZeneca, *AstraZeneca to Supply Europe with Up to 400 Million Doses of Oxford University's Vaccine at No Profit* (June 13, 2020) (press release).

[44] U.S. Department of Health and Human Services, *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to be Available Beginning in October* (May 21, 2020) (press release).

[45] AstraZeneca, *AstraZeneca Takes Next Steps Towards Broad and Equitable Access To Oxford University's Potential COVID-19 Vaccine* (June 4, 2020) (press release).

[46] *Johnson & Johnson Profile*, Market Watch (www.marketwatch.com/investing/stock/jnj/profile) (accessed July 14, 2020).

[47] Johnson & Johnson, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use* (Mar. 30,

company $456 million to support development of the lead vaccine candidate.[48] Johnson & Johnson expects to initiate Phase 1/2a trials of its lead candidate in the second half of July, with the first batches of the vaccine potentially available for emergency use in early 2021.[49] The company's stated goal is to supply more than one billion doses of its vaccine globally through the course of 2021, and it has committed to bringing a vaccine to the public on a not-for-profit basis for emergency pandemic use.[50]

C. Merck

Merck is a biopharmaceutical company based in Kenilworth, New Jersey, focused on developing medicines and vaccines for diseases such as cancer, HIV, and Ebola.[51] On May 26, 2020, Merck announced it would develop a recombinant virus vaccine platform for COVID-19 in partnership with the International AIDS and Vaccine Initiative (IAVI), using the same approach the company used to develop its approved Ebola vaccine.[52] According to a company press release, Merck's vaccine candidate was in preclinical development in May, with clinical studies planned for later this year.[53] Under OWS, Merck and IAVI received $38 million from BARDA to develop this vaccine,[54] which Merck has stated will be accessible and affordable globally, if approved.[55] Merck has also acquired biotechnology firm Themis, which is developing a vaccine for COVID-19 using a measles virus vector platform, with clinical studies planned later in 2020.[56]

D. Moderna

2020) (press release); *Johnson & Johnson To Begin Human Trials for Coronavirus Vaccine in Late July, Earlier than Expected*, CNBC (June 10, 2020).

[48] U.S. Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020).

[49] Johnson & Johnson, *Scientific Progress Toward Treatment and Prevention Measures for COVID-19* (https://www.jnj.com/coronavirus/prevention-and-treatment) (accessed July 14, 2020).

[50] *Id.*

[51] Merck, *IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2* (May 26, 2020) (press release).

[52] *Id.*

[53] *Id.*

[54] U.S. Department of Health and Human Services, *COVID-19 Medical Countermeasure Portfolio* (medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx) (accessed July 14, 2020).

[55] Merck, *IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2* (May 26, 2020) (press release).

[56] Merck, *Merck to Acquire Themis* (May 26, 2020) (press release).

Moderna is a clinical stage biotechnology company based in Cambridge, Massachusetts, working on messenger RNA (mRNA) therapeutics and vaccines, including the first COVID-19 vaccine candidate to enter clinical trials in the United States.[57] Phase 1 trials for Moderna's COVID-19 vaccine candidate were announced on March 16, 2020, and conducted by NIH.[58] The results of Moderna's Phase 1 trials were published in the *New England Journal of Medicine* on July 14.[59] Through OWS, BARDA awarded Moderna up to $483 million in April and another $53 million in May to accelerate development of and increase manufacturing capacity for the company's vaccine candidate,[60] which received fast track designation by FDA on May 12.[61] Moderna intends to begin a Phase 3 trial consisting of approximately 30,000 participants in July, in collaboration with NIH. According to a company press release, Moderna expects to supply between 500 million and one billion doses of its vaccine per year, beginning in 2021.[62]

E. Pfizer

Pfizer is a global biopharmaceutical company headquartered in New York, New York.[63] On March 16, 2020, Pfizer announced it had reached a letter of intent with German biotechnology firm BioNTech regarding the co-development and distribution of a potential mRNA-based COVID-19 vaccine.[64] On May 5, Pfizer announced that Phase 1/2 clinical trials for four vaccine candidates in the companies' mRNA vaccine program were underway in the

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[57] Moderna, *Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (Mar. 16, 2020) (press release); *First Patient Dosed in Moderna's COVID-19 Vaccine Trial*, Bio Space (Mar. 16, 2020).

[58] Moderna, *Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (Mar. 16, 2020) (press release).

[59] Lisa A. Jackson et al., *An mRNA Vaccine Against SARS-COV-2–Preliminary Report*, New England Journal of Medicine (July 14, 2020).

[60] Moderna, *Moderna Announces Award from U.S. Government Agency BARDA for Up to $483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (Apr. 16, 2020) (press release); U.S. Department of Health and Human Services, *COVID-19 Medical Countermeasure Portfolio* (https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx) (accessed July 14, 2020).

[61] Moderna, *Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 12, 2020) (press release).

[62] Moderna, *Moderna Completes Enrollment of Phase 2 Study of its mRNA Vaccine Against COVID-19 (mRNA-1273)* (July 8, 2020) (press release).

[63] Pfizer, SEC Form 10-K (Feb. 27, 2020).

[64] Pfizer, *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine* (Mar. 16, 2020) (press release).

United States.[65] In a press release, Pfizer stated it plans to test at least one of these candidates in a Phase 2b/3 trial involving up to 30,000 participants starting in late July.[66] On July 13, the company announced that two of its four vaccine candidates received fast track designation by FDA.[67] If a vaccine candidate receives approval, Pfizer expects to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses by the end of 2021.[68] According to the company's chief business officer, Pfizer has decided not to seek federal funding for development of its COVID-19 vaccine candidates.[69]

VII. WITNESSES

The following witnesses have been invited to testify:

Dr. Mene Pangalos
Executive Vice President, BioPharmaceuticals R&D
AstraZeneca

Dr. Macaya Douoguih
Head of Clinical Development and Medical Affairs, Janssen Vaccines
Johnson & Johnson

Dr. Julie Gerberding
Executive Vice President and Chief Patient Officer
Merck

Dr. Stephen Hoge
President
Moderna

Mr. John Young
Chief Business Officer
Pfizer

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[65] Pfizer, *Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program* (May 5, 2020) (press release).

[66] Pfizer, *Pfizer and BioNTech Announce Early Positive Data from an Ongoing Phase 1/2 Study of mRNA-Based Vaccine Candidate Against SARS-CoV-2* (July 1, 2020) (press release).

[67] Pfizer, *Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-Based Vaccine Candidates Against SARS-CoV-2* (July 13, 2020) (press release).

[68] *Id.*

[69] *BIO: What's the ROI on a COVID-19 Vaccine? We Have No Idea, Says Pfizer*, Fierce Pharma (June 11, 2020).