U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

July 17, 2020

TO: Members, Committee on Energy and Commerce

FROM: Committee Republican Staff

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

The Subcommittee on Oversight and Investigations will hold a virtual hearing on Tuesday, July 21, 2020, at 10:00 a.m., entitled "Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine."

I. WITNESSES

- Sir Menelas N. Pangalos, Ph.D., Executive Vice President, BioPharmaceuticals R&D, AstraZeneca;
- Macaya Douoguih, M.D., M.P.H., Head of Clinical Development and Medical Affairs, Janssen Vaccines, Johnson & Johnson;
- Julie L. Gerberding, M.D., M.P.H., Executive Vice President and Chief Patient Officer, Merck;
- Stephen Hoge, M.D., President, Moderna; and
- John Young, MBA, Chief Business Officer, Pfizer.

II. BACKGROUND

a. History and Spread of COVID-19

Coronavirus (CoV) is a large family of viruses that causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory (MERS-CoV), which was first identified in Saudi Arabia in 2012, and Severe Acute Respiratory Syndrome (SARS-CoV), which was first identified in the Guangdong province of southern China in 2002.[1] Coronaviruses are zoonotic, meaning they are transmitted between animals and people, and several known coronaviruses are circulating in animals that have not yet infected humans. For example, SARS-

[1] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus; World Health Organization, Middle East respiratory syndrome coronavirus (MERS-CoV) (Dec. 20, 2019), *available at* https://www.who.int/news-room/q-a-detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov); World Health Organization, *International travel and health, SARS* (Severe Acute Respiratory Syndrome) (last visited Mar. 3, 2020), *available at* https://www.who.int/ith/diseases/sars/en/.

CoV was transmitted from civet cats to humans, and MERS-CoV was transmitted from dromedary camels to humans.[2] A novel coronavirus (nCoV), like the one that is currently being transmitted, is a new strain that has not been previously identified in humans. COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2, which was discovered as a result of the outbreak in Wuhan, China in late 2019.[3] Currently, the specific source of the COVID-19 outbreak is unknown.

Common signs of COVID-19 infection include respiratory symptoms, fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.[4] The Centers for Disease Control and Prevention's (CDC) website notes that this list does not include all possible symptoms and it will continue to update the list as they learn more about the virus. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. Anyone can have mild to severe symptoms, but older adults and people who have underlying medical conditions are at increased risk for developing more serious illness. On June 25, 2020, the CDC made revisions to which medical conditions put individuals at any age at increased risk of severe illness, including chronic kidney disease, chronic obstructive pulmonary disease, an immunocompromised state from solid organ transplant, obesity, serious heart conditions, sickle cell disease, and Type 2 diabetes mellitus.[5] In addition, individuals with medical conditions that might be at an increased risk for severe illness include moderate-to-severe asthma; cerebrovascular disease; cystic fibrosis; hypertension or high blood pressure; immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines; neurologic conditions, such as dementia; liver disease; pregnancy; pulmonary fibrosis; smoking; thalassemia; and Type 1 diabetes mellitus.[6] According to the CDC, symptoms may appear two to 14 days after exposure.[7]

While initial cases were reported in Wuhan, China and other countries starting in early December 2019, the first reported patient in the U.S. with confirmed COVID-19 was in Washington State on January 22, 2020.[8] On January 31, 2020, the U.S. Department of Health and Human Services (HHS) Secretary, Alex M. Azar II, declared a public health emergency for

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[2] World Health Organization, *Coronavirus* (last visited on Mar. 3, 2020), *available at* https://www.who.int/health-topics/coronavirus.
[3] World Health Organization, *Q&A on coronavirus* (COVID-19) (Feb. 23, 2020), *available at* https://www.who.int/news-room/q-a-detail/q-a-coronaviruses.
[4] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed May 13, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
[5] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), People with Certain Medical Conditions* (last updated June 25, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited July 13, 2020).
[6] *Id.*
[7] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Symptoms* (last reviewed Feb. 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html.
[8] Jennifer Harcourt, Azaibi Tamin, et. al., *Centers for Disease Control and Prevention, Emerging Infectious Diseases*, Vol. 26, Num. 6-June 2020, *Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States* (May 18, 2020), *available at* https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article.

the U.S. to aid the nation's health care community in responding to COVID-19, and announced travel restrictions and quarantines for individuals traveling from China, beginning on February 2, 2020, via a Presidential Proclamation issued by President Trump.[9] Additional travel restrictions for other countries have been issued since. During the week of February 23, 2020, CDC reported community spread of the virus in California, Oregon, and Washington. On March 11, 2020, the World Health Organization (WHO) announced that COVID-19 can be characterized as a pandemic.[10] According to the WHO, this is the first pandemic caused by a coronavirus.

As of July 17, 2020, there are 188 countries/regions with a total of 13,837,395 confirmed COVID-19 cases and 590,702 deaths.[11] Within the U.S. there are 60 U.S.-affiliated jurisdictions reporting cases of COVID-19, including all 50 states; the District of Columbia; New York City, the U.S. territories of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands; and three independent countries in compacts of free association with the U.S. (Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau).[12] While there are 60 jurisdictions reporting cases, different parts of the country are seeing different levels of COVID-19 activity. For example, of the U.S. jurisdictions reporting cases, there are 43 jurisdictions who have reported more than 10,000 cases of COVID-19.[13] As of July 16, 2020, CDC reports that there are 3,483,832 cases and 136,938 deaths from COVID-19 in the U.S.[14] However, CDC does not know the exact number of COVID-19 illnesses, hospitalizations, and deaths because the virus "can cause mild illness, symptoms might not appear immediately, there are delays in reporting and testing, not everyone who is infected gets tested or seeks medical care, and there may be differences in how jurisdictions confirm numbers."[15]

[9] Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus (Jan. 31, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-persons-pose-risk-transmitting-2019-novel-coronavirus/.

[10] World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020* (Mar. 11, 2020), *available at* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[11] Johns Hopkins University & Medicine, Coronavirus Resource Center, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (last visited July 17, 2020), *available at* https://coronavirus.jhu.edu/map.html.

[12] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), About CDC Data* (last updated July 13, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/about-us-cases-deaths.html; New York State's case and death counts do not include New York City's counts as they are separate jurisdictions.

[13] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Cases in the US* (last updated July 16, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html#accordion-1-collapse-2.

[14] *Id;* As of April 14, 2020, CDC case counts and death counts include both confirmed and probable cases and deaths. This change was made to reflect an interim COVID-19 position statement by the Council for State and Territorial Epidemiologists on April 5, 2020. The position statement included a case definition and made COVID-19 a nationally notifiable disease.

[15] *Id*.

b. Transmission of COVID-19

While we are still learning about how COVID-19 spreads, the virus is thought to spread mainly from person-to-person between people who are in close contact with one another (within six feet), through respiratory droplets produced when an infected person coughs, sneezes, or talks.[16] These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. In addition, COVID-19 may spread by people who are not showing symptoms, also known as someone who is asymptomatic or pre-symptomatic.[17] In addition to person-to-person spread, it may be possible to contract COVID-19 by touching a surface or object that has the virus on it and then touching your mouth, nose, and possibly eyes.[18] Further, while it appears the virus can spread from people to animals, at this time, the CDC believes that the risk of transmission from animals to people is low.[19] According to the CDC, the virus is spreading more efficiently than influenza, but not as efficiently as measles.[20]

There is currently no vaccine to prevent COVID-19. Therefore, the best way to prevent illness is to avoid being exposed to the virus. In addition, CDC has issued detailed recommendations on how everyone can help protect themselves from COVID-19 by wearing masks, thoroughly washing their hands, and avoiding close contact with people who are sick, among other things.[21]

III. EFFORTS TO DEVELOP COVID-19 VACCINES

a. Executive Branch Efforts

The U.S. government is supporting several initiatives to help accelerate the development of vaccines for COVID-19. Some of these initiatives include, but are not limited to, Operation Warp Speed and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

i. Operation Warp Speed

The Trump Administration established Operation Warp Speed on May 15, 2020, to accelerate the development, manufacturing, and distribution of COVID-19 vaccines,

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[16] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), How It Spreads* (last reviewed May 22, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprepare%2Ftransmission.html.
[17] *Id*.
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Protect Yourself* (last reviewed on Apr. 24, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

therapeutics, and diagnostics.[22] This public-private partnership aims to facilitate, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 countermeasures, among: (1) components of HHS, including the CDC, the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA); (2) the U.S. Department of Defense (DoD); (3) private firms; and (4) other federal agencies, including the U.S. Department of Agriculture, the U.S. Department of Energy, and the U.S. Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's ACTIV partnership for vaccine and therapeutic development, NIH's Rapid Acceleration of Diagnostics (RADx) initiative for diagnostic development, and work by BARDA.[23]

The three main areas where the effort will accelerate the timeframe for countermeasures to reach the American public include development, manufacturing, and distribution:[24]

- *Development*: Operation Warp Speed will select the most promising countermeasure candidates and provide coordinated government support throughout their development; align protocols for the demonstration of safety and efficacy, which will allow the trials to proceed more quickly; and protocols for the trials will be overseen and set by the federal government.[25]

- *Manufacturing*: The federal government is making investments in manufacturing and distribution at its own risk earlier than usual, giving companies confidence that they can invest in development; manufacturing capacity for selected candidates will be advanced while they are still in development; and manufacturing capacity developed will be used, to the extent practicable, for whatever vaccine is successful, regardless of which companies have developed the capacity.[26]

- *Distribution*: Before the countermeasures are approved or authorized, the program will build the necessary plans and infrastructure for distributing them; Operation Warp Speed will focus on expanding supplies of specialized materials and resources, such as cold-chain supplies, glass vials, and other materials, that can be necessary for distribution of countermeasures; and once a product is ready, DoD's involvement will enable faster distribution and administration.[27]

[22] U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020), *available at* https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] *Id*.
[27] *Id*.

Among other things, the goal of Operation Warp Speed is to have a significant amount—300 million doses—of safe and effective vaccine for COVID-19 available to Americans by January 2021.[28]

For the development of vaccines, Operation Warp Speed will select the most promising candidates that can be scaled up and provide coordinated government support. As of May 15, 2020, Operation Warp Speed had chosen 14 promising vaccine candidates from the list of over 100 vaccine candidates currently in development. From there, 8 vaccine candidates will be selected from the list of 14 to go through additional testing in early-stage small clinical trials. Then, large-scale randomized trials for the demonstration of safety and efficacy will proceed for 3 to 5 of the candidates. Finally, additional non-clinical testing will be performed at the same time when possible.[29] Select actions to support Operation Warp Speed vaccine development so far include:

- On March 30, 2020, "HHS announced $456 million in funds for Johnson & Johnson's candidate vaccine, with Phase 1 clinical trials set to begin this summer."[30]

- On April 16, 2020, "HHS made up to $483 million in support available for Moderna's candidate vaccine, which began Phase 1 trials on March 16 and received a fast-track designation from FDA."[31]

- On May 21, 2020, "HHS announced up to $1.2 billion in support for AstraZeneca's candidate vaccine, developed in conjunction with the University of Oxford. The agreement is to make available at least 300 million doses of the vaccine for the United States, with the first doses delivered as early as October 2020 and Phase 3 clinical studies beginning this summer with approximately 30,000 volunteers in the United States."[32]

- On July 7, 2020, HHS and DoD announced a $1.6 billion agreement with Novavax to demonstrate commercial-scale manufacturing of the company's COVID-19 investigational vaccine, and that "[b]y funding this manufacturing effort, the federal government will own the 100 million doses of investigational vaccine expected to result from the demonstration projects."[33] The announcement also stated that "[t]his manufacturing demonstration project will take place while clinical trials are underway."[34] Novavax announced that "A Phase 1/2 clinical trial of NVX-CoV2373

[28] *Id*.
[29] *Id*.
[30] U.S. Dept. of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (June 16, 2020), *available at* https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html.
[31] *Id*.
[32] *Id*.
[33] U.S. Department of Health and Human Services, *HHS, DOD Collaborate with Novavax to Produce Millions of COVID-19 Investigational Vaccine Doses in Commercial-Scale Manufacturing Demonstration Projects* (July 7, 2020), *available at* https://www.hhs.gov/about/news/2020/07/07/hhs-dod-collaborate-novavax-produce-millions-covid-19-investigational-vaccine-doses-commercial-scale-manufacturing-demonstration-projects.html.
[34] *Id*.

> in 130 healthy participants 18 to 59 years of age began in Australia in May. Preliminary immunogenicity and safety results are expected at the end of July, and the Phase 2 portion to assess immunity, safety, and COVID-19 disease reduction is expected to begin thereafter. The Phase 1/2 clinical trial is being supported by an up-to $388 million funding arrangement with the Coalition for Epidemic Preparedness Innovations (CEPI)."[35]

These four candidates represent three major vaccine development platforms: messenger RNA; adenovirus; and protein.

On July 8, 2020, NIH announced that it established the COVID-19 Prevention Trials Network (COVPN) by merging four existing clinical trials networks funded by the National Institute of Allergy and Infectious Diseases (NIAID). The COVPN is a unit of Operation Warp Speed. The network will use a harmonized vaccine protocol developed by the ACTIV public-private partnership, which will enable analysis of protection across multiple vaccine trials.[36]

For manufacturing of a COVID-19 vaccine, the federal government will make investments in manufacturing and distribution of top vaccine candidates at its own risk—the manufacturing and distribution capacity of the top 3 to 5 leading vaccine candidates will be enhanced while the vaccine candidates are still in development.[37] HHS' agreements with vaccine candidate manufacturers include investments in manufacturing capabilities. BARDA has also provided funding to Emergent BioSolutions to expand domestic manufacturing capacity for COVID-19 vaccine developers.[38]

For distribution of a COVID-19 vaccine, Operation Warp Speed is building the requisite plans and infrastructure to distribute a vaccine to hundreds of millions of Americans in a timely manner. Once a vaccine candidate is ready for distribution, the DoD will help distribute and administer the vaccine candidate.[39] This effort includes contract awards for supplies to administer vaccines, including injection devices, glass vials, and syringes.[40]

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[35] Novavax, *Novavax Announces $1.6 Billion Funding from Operation Warp Speed* (July 7, 2020), *available at* https://ir.novavax.com/news-releases/news-release-details/novavax-announces-16-billion-funding-operation-warp-speed .

[36] National Institutes of Health, *NIH launches clinical trials network to test COVID-19 vaccines and other prevention tools* (July 8, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-covid-19-vaccines-other-prevention-tools.

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

[38] Emergent BioSolutions, *Emergent BioSolutions Joins U.S. Government's Warp Speed Program in Landmark Public-Private CDMO Partnership for COVID-19 Vaccine Development and Manufacturing* (June 1, 2020), available at https://investors.emergentbiosolutions.com/node/19601/pdf.

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

[40] *See* U.S. Department of Defense, *DOD Awards $138 Million Contract, Enabling Prefilled Syringes for Future COVID-19 Vaccine* (May 12, 2020), available at https://www.defense.gov/Newsroom/Releases/Release/Article/2184808/dod-awards-138-million-contract-enabling-

ii. ACTIV Public-Private Partnership

On April 17, 2020, NIH announced the ACTIV public-private partnership to speed vaccine and treatment options. The ACTIV partnership is coordinated by the Foundation for the National Institutes of Health (FNIH) and brings together: (1) other divisions of HHS, including BARDA, CDC, and FDA; (2) other government agencies, including the DoD and the U.S. Department of Veterans Affairs; (3) the European Medicines Agency (EMA); and (4) representatives from academia, philanthropic organizations, and several biopharmaceutical companies.[41]

The ACTIV partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes, and/or leveraging assets among all partners to respond rapidly to the COVID-19 pandemic.[42] ACTIV has four working groups, each with one co-chair from NIH and one from industry: (1) The Preclinical Working Group; (2) The Therapeutics Clinical Working Group; (3) The Clinical Trial Capacity Working Group; and (4) The Vaccines Working Group.[43]

- *The Preclinical Working Group* is "charged to standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and vaccines to support entry into clinical trials."[44] The goals of this working group are to increase access to animal models and identify informative assays.[45]

- *The Therapeutics Clinical Working Group* is "charged to prioritize and accelerate clinical evaluation of a long list of therapeutic candidates for COVID-19 with near-term potential."[46] The goals of this working group are to prioritize and test potential therapeutic agents and develop master protocol for clinical trials.[47]

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prefilled-syringes-for-future-covid-19/source/GovDelivery/; SiO2 Materials Science, *SiO2 Materials Science Receives $143 Million Contract from U.S. Government to Accelerate Capacity Scale-Up of Advanced Primary Packaging Platform for COVID-19 Vaccines and Therapeutics*, BUSINESS WIRE (June 8, 2020), *available at* https://www.businesswire.com/news/home/20200608005120/en/SiO2-Materials-Science-Receives-143-Million-Contract; Corning, *Corning Valor Glass Selected to Help Accelerate Delivery of COVID-19 Vaccines and Drugs* (June 9, 2020), *available at* https://www.corning.com/worldwide/en/about-us/news-events/news-releases/2020/06/us-departments-of-defense-health-human-services-select-corning-valor-glass-packaging-to-accelerate-delivery-of-covid-19-vaccines.html.

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

[42] National Institutes of Health, *NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options* (Apr. 17, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options.

[43] Francis S. Collins, MD, PhD, Paul Stoffels, MD, *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), An Unprecedented Partnership for Unprecedented Times*, JAMA NETWORK (May 18, 2020), *available at* https://jamanetwork.com/journals/jama/fullarticle/2766371?guestAccessKey=5defc755-e585-47e5-b79a-fee2ec2dd42b&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=051820.

[44] *Id*.

[45] *Id*.

[46] *Id*.

[47] *Id*.

- *The Clinical Trial Capacity Working Group* is "charged with assembling and coordinating existing networks of clinical trials to increase efficiency and build capacity."[48] The goals of this working group are to develop survey instruments, develop inventory of clinical trial networks, and guide deployment of innovative solutions.[49]

- *The Vaccines Working Group* is "charged to accelerate evaluation of vaccine candidates to enable rapid authorization or approval."[50] The goals of this working group are to accelerate evaluation of vaccine candidates, identify biomarkers to speed approval, and provide evidence to address safety concerns.[51] Among other things, the ACTIV partnership's Vaccines Working Group is developing a harmonized master protocol for adaptive trails of multiple vaccine candidates, developing a trial network that potentially could enroll as many as 100,000 volunteers, and identify biomarkers to speed the authorization or approval of a vaccine candidate.[52]

iii. BARDA Funding for Vaccine Development

BARDA, which is part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to help protect the country from chemical, biological, radiological, and nuclear threats, and also from pandemic influenza and emerging infectious diseases.[53] To respond to the COVID-19 pandemic, BARDA is rapidly developing new partnerships and building a robust COVID-19 Medical Countermeasure Portfolio, among other things.[54] These partnerships are focused on vaccines, diagnostics, therapeutics, rapidly deployable capabilities, and other items.[55]

As of July 17, 2020, BARDA's COVID-19 Medical Countermeasure Portfolio with respect to vaccines includes: (1) ModernaTX, Inc. for SARS-CoV-2 mRNA-1273 vaccine; (2) AstraZeneca for AZD1222 (formerly ChAdOx1 NCoV-19 vaccine); (3) Janssen Research & Development, LLC, a Johnson & Johnson company, for Viral Vector Vaccine for COVID-19; (4) Merck and IAVI for rVSVΔG-CoV2; (5) Protein Sciences, a Sanofi company for Recombinant SARS-CoV-2 Protein Vaccine Candidate; and (6) Novavax Inc. for NVX-CoV-

[48] *Id*.
[49] *Id*.
[50] *Id*.
[51] *Id*.
[52] *Id*.
[53] U.S. Department of Health and Human Services, *Biomedical Advanced Research and Development Authority*, *available at* https://www.phe.gov/about/barda/Pages/default.aspx (last visited June 13, 2020).
[54] U.S. Department of Health and Human Services, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, *available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx (last visited July 13, 2020). This page is updated regularly but may not include all awards.
[55] *Id*.

2373 Vaccine for SARS-CoV-2.[56] BARDA has provided more than $3.8 billion in funding for these efforts.

iv. FDA Guidance for Vaccine Developers

On June 30, 2020, FDA's Center for Biologics Evaluation and Research (CBER) issued guidance for industry with recommendations for entities developing COVID-19 vaccines with the goal of licensing the vaccine candidate.[57] The guidance describes the "agency's current recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine."[58] Among other things, the guidance outlines key considerations to satisfy regulatory requirements for: (1) chemistry, manufacturing, and controls (CMC) for COVID-19 vaccines; (2) nonclinical data through development and licensure of COVID-19 vaccines; (3) clinical data through development and licensure of COVID-19 vaccines; (4) post-licensure safety evaluation of COVID-19 vaccines; and (5) additional considerations for COVID-19 vaccine development and licensure.[59]

For clinical trials, the guidance provides key considerations regarding trial populations, trial design, efficacy considerations, statistical considerations, and safety considerations. The guidance notes that, because the current understanding of COVID-19 immunology is limited and evolving, "the goal of development programs should be to pursue traditional approval via direct evidence of vaccine efficacy in protecting humans from SARS-CoV-2 infection and/or disease."[60] Among other things, with respect to clinical trials, the guidance also states that:

- "FDA encourages the inclusion of diverse populations in all phases of vaccine clinical development … [to help] ensure that vaccines are safe and effective for everyone in the indicated populations."[61] The agency also "strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities."[62]

- "Later phase trials, including efficacy trials, should be randomized, double-blinded, and placebo controlled," and the guidance "discusses the importance of ensuring that the sizes of clinical trials are large enough to demonstrate the safety and effectiveness of a vaccine."[63] The several vaccine candidates developed under Operation Warp

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[56] *Id*.
[57] U.S. Food and Drug Administration, *Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19* (June 2020), *available at* https://www.fda.gov/media/139638/download.
[58] Email from FDA Office of Legislation to Energy and Commerce Committee staff, *FDA Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (on file with Committee).
[59] U.S. Food and Drug Administration, *Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19*, at i (June 2020), *available at* https://www.fda.gov/media/139638/download.
[60] *Id*. at 9.
[61] *Id*. at 11.
[62] *Id*.
[63] *Id*. at 12; Email from FDA Office of Legislation to Energy and Commerce Committee staff, *FDA Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (on file with Committee).

Speed will need 30,000 participants enrolled in Phase 3 clinical trials and must take place where outbreaks are occurring.[64]

- "To ensure that a widely deployed COVID-19 vaccine is effective, the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%," thereby conveying that "FDA would expect that a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated."[65]

The guidance notes that, once there is a better understanding of COVID-19 immunology, accelerated approval of a COVID-19 vaccine may be available via FDA's Accelerated Approval pathway for vaccine licensure.[66] The guidance also discusses the use of an Emergency Use Authorization (EUA) for a COVID-19 vaccine.[67]

When the FDA issued guidance on June 30, 2020, on the development and licensure of vaccines to prevent COVID-19, both FDA Commissioner Dr. Stephen M. Hahn and FDA Director of CBER Dr. Peter Marks, released statements highlighting the importance of expediting vaccine development without sacrificing the FDA's standards for quality, safety, and efficacy.[68]

For example, Commissioner Hahn stated: "We recognize the urgent need to develop a safe and effective vaccine to prevent COVID-19 and continue to work collaboratively with industry, researchers, as well as federal, domestic, and international partners to accelerate these efforts. While the FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards. This is particularly important, as we know that some people are skeptical of vaccine development efforts. . . . We have not lost sight of our responsibility to the American people to maintain our regulatory independence and ensure our decisions related to all medical products, including COVID-19 vaccines, are based on science and the available data."[69]

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[64] Patrick Tucker, *White House 'Very Confident' on Coronavirus Vaccine By Year's End. But Supply Questions Remain*, DEFENSE ONE (July 14, 2020), *available at* https://www.defenseone.com/technology/2020/07/white-house-very-confident-coronavirus-vaccine-years-end-supply-questions-remain/166900/.

[65] U.S. Food and Drug Administration, *Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19*, at 14 (June 2020), *available at* https://www.fda.gov/media/139638/download; Email from FDA Office of Legislation to Energy and Commerce Committee staff, *FDA Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (on file with Committee).

[66] U.S. Food and Drug Administration, *Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19*, at 18 (June 2020), *available at* https://www.fda.gov/media/139638/download.

[67] *Id*. at 19.

[68] Email from FDA Office of Legislation to Energy and Commerce Committee staff, *FDA Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (on file with Committee).

[69] *Id*.

Similarly, Dr. Peter Marks stated: "In this particular crisis in which there is so much at stake, we need to help expedite vaccine development as much as we can without sacrificing our standards for quality, safety, and efficacy. We firmly believe that transparency regarding the FDA's current thinking about the scientific data needed to support approval of safe and effective COVID-19 vaccines will help build public confidence in the FDA's evaluation process, which will be critical in ensuring their use. . . . Right now, neither the FDA nor the scientific community can predict how quickly data will be generated from vaccine clinical trials. Once data are generated, the agency is committed to thoroughly and expeditiously evaluating it all. But make no mistake: the FDA will only approve or make available a COVID-19 vaccine if we determine that it meets the high standards that people have come to expect of the agency."[70]

b. Private Sector Efforts

According to WHO, there were 140 vaccine candidates in preclinical evaluation and 23 vaccine candidates in clinical evaluation as of July 15, 2020.[71] According to the Biotechnology Innovation Organization's (BIO) COVID-19 Therapeutic Development Tracker, U.S. institutions are working on the highest number of COVID-19 vaccine candidates, accounting for 72 vaccine candidates on the list as of July 13, 2020.[72] Many other vaccines in development are expected to begin clinical trials in 2020.

The COVID-19 vaccine candidates are being manufactured using a variety of different platforms, with some researchers and manufacturers using more traditional technologies while others are using more innovative, newer platforms such as DNA- and RNA- based platforms. According to BIO, as of July 13, 2020, there are 70 COVID-19 vaccine candidates that are protein-based vaccines, 21 that are viral-based vaccines, 25 that are rViral-based vaccines, 22 that are RNA-based vaccines, 16 that are DNA-based vaccines, 10 that are cell-based vaccines, and 5 that are nanoparticle vaccines.[73]

To help accelerate the development and manufacture of a vaccine for COVID-19, the U.S. government is supporting several different vaccine candidates. As of July 17, 2020, BARDA has provided more than $3.8 billion in funding for vaccine development.

Representatives of five companies developing COVID-19 vaccines will testify before the Subcommittee on Oversight and Investigations. Many other promising vaccine candidates are under development by other biopharmaceutical companies worldwide.

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[70] *Id*.
[71] World Health Organization, *DRAFT landscape of COVID-19 candidate vaccines* (July 15, 2020), *available at* https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.
[72] Biotechnology Innovation Organization (BIO), *BIO COVID-19 Therapeutic Development Tracker, available at* https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker (last visited June 29, 2020).
[73] Biotechnology Innovation Organization, *BIO COVID-19 Therapeutic Development Tracker, available at* https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker (last visited July 13, 2020).

i. AstraZeneca

On April 30, 2020, AstraZeneca and the University of Oxford partnered for the global development and distribution of the University of Oxford's potential COVID-19 vaccine candidate, AZD1222—formerly known as ChAdOx1 nCoV-19.[74] According to the WHO, the vaccine candidate is currently in Phase 3 clinical trials in some locations.[75]

The AstraZeneca/University of Oxford vaccine candidate "uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold (adenovirus) virus that causes infections in chimpanzees and contains the genetic material of SARS-CoV-2 spike protein."[76]

The University of Oxford began working on a COVID-19 vaccine on January 20, 2020.[77] On April 23, 2020, a Phase 1/2 clinical trial began for the vaccine candidate across multiple study sites in southern England.[78] On May 22, 2020, the University of Oxford announced that they had started recruiting to begin the Phase 2b/3 clinical trial at study sites across the U.K.[79]

AstraZeneca is responsible for the development, manufacturing, and distribution of the vaccine candidate under the agreement.[80] On May 21, 2020, AstraZeneca announced that it had received $1.2 billion from BARDA for the development, production, and delivery of the vaccine candidate, including 300 million doses.[81] The development program includes a Phase 3 clinical

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[74] AstraZeneca, *AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine* (Apr. 30, 2020), *available at* https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html#__prclt=8mfn5tcv.
[75] World Health Organization, *DRAFT landscape of COVID-19 candidate vaccines* (June 29, 2020), *available at* https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.
[76] AstraZeneca, *AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford's potential new vaccine* (May 21, 2020), *available at* https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html.
[77] *COVID-19 Oxford Vaccine Trial*, *available at* https://covid19vaccinetrial.co.uk/ (last visited June 11, 2020).
[78] AstraZeneca, *AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford's potential new vaccine* (May 21, 2020), *available at* https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html; University of Oxford, *Oxford COVID-19 vaccine begins human trial* stage (Apr. 23, 2020), *available at* http://www.ox.ac.uk/news/2020-04-23-oxford-covid-19-vaccine-begins-human-trial-stage.
[79] COVID-19 Oxford Vaccine Trial, *The Oxford Vaccine Centre COVID-19 Phase II/III Clinical Trial Explained* (May 22, 2020), *available at* https://covid19vaccinetrial.co.uk/phase-iiiii-trial-explained.
[80] AstraZeneca, *AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine* (Apr. 30, 2020), *available at* https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html#__prclt=8mfn5tcv.
[81] U.S. Department of Health and Human Services, Public Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, *available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx; AstraZeneca, *AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford's potential new vaccine* (May 21, 2020), *available at* https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html (last visited June 10, 2020).

trial with 30,000 participants and a pediatric trial.[82] Press reports indicate that U.S.-based Phase 3 clinical trials potentially will begin in August for the vaccine candidate.[83] AstraZeneca plans to have clinical trial results available in August, and, depending on whether the clinical trial results show the vaccine is safe and effective, the company potentially could begin delivering doses of the vaccine in the U.S. and U.K. in September and October of 2020.[84]

AstraZeneca has entered into agreements with entities such as the CEPI, Gavi the Vaccine Alliance, and the Serum Institute of India to support the manufacturing, procurement, and distribution of their COVID-19 vaccine candidate.[85] As of June 4, 2020, AstraZeneca had secured manufacturing capacity for two billion doses of the vaccine candidate.[86] On June 11, 2020, AstraZeneca announced a partnership valued at about $87 million with Emergent BioSolutions to provide development services, technology transfer, analytical testing, drug substance process and performance qualification and will reserve certain large-scale manufacturing capacity through 2020.[87]

ii. Johnson & Johnson

Johnson & Johnson is developing a COVID-19 vaccine candidate, Ad26.COV2-S, recombinant, through its Janssen Pharmaceutical Companies (Janssen), and the vaccine candidate is currently in the pre-clinical stages of development.

Johnson & Johnson began its efforts to develop a COVID-19 vaccine candidate as soon as the COVID-19 sequence became available in January 2020. After testing multiple vaccine candidates using Janssen's AdVac and PER.C6 technologies, Johnson & Johnson identified their lead COVID-19 vaccine, Ad26.COV2-S, recombinant, which uses a non-replicating viral vector platform.[88]

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[82] *Id*.
[83] Peter Loftus, *Coronavirus Vaccine Candidates' Pivotal U.S. Testing to Start This Summer*, THE WALL STREET JOURNAL (June 10, 2020), *available at* https://www.wsj.com/articles/coronavirus-vaccine-candidates-pivotal-u-s-testing-to-start-this-summer-11591781405.
[84] Peter Loftus and Joseph Walker, *AstraZeneca Signs More Coronavirus Vaccine Supply Deals*, THE WALL STREET JOURNAL (June 4, 2020), *available at* https://www.wsj.com/articles/astrazeneca-signs-more-coronavirus-vaccine-supplydeals-11591304979.
[85] AstraZeneca, *AstraZeneca takes next steps towards broad and equitable access to Oxford University's COVID-19 vaccine* (June 4, 2020), *available at* https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html.
[86] *Id*.
[87] Emergent BioSolutions, *Emergent BioSolutions Signs Agreement to be U.S. Manufacturing Partner for AstraZeneca's COVID-19 Vaccine Candidate* (June 11, 2020), *available at* https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-signs-agreement-be-us-manufacturing-0?field_nir_news_date_value[min]=.
[88] Johnson & Johnson, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health and Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic* Use (Mar. 30, 2020), *available at* https://www.jnj.com/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.

On March 30, 2020, Johnson & Johnson and BARDA announced a partnership to invest more than $1 billion together to co-fund research, development, and clinical testing of Johnson & Johnson's lead vaccine candidate.[89] BARDA has awarded Janssen, a subsidiary of Johnson & Johnson, $456 million to support development and licensure of the vaccine candidate.[90] Johnson & Johnson also has committed to expanding the company's global manufacturing capacity, including establishing new manufacturing capabilities in the U.S.[91]

On June 10, 2020, Johnson & Johnson announced that it expected to begin a Phase 1/2a clinical trial in the second half of July 2020.[92] Originally scheduled to begin in September, Johnson & Johnson explained that the clinical trial was accelerated "[b]ased on the strength of the preclinical data [Johnson & Johnson has] seen so far and interactions with the regulatory authorities."[93] Johnson & Johnson is in discussions with NIAID to try to start the Phase 3 clinical trial earlier than originally scheduled, pending the outcome of the Phase 1 studies and the approval of regulators.[94]

Johnson & Johnson has made several announcements regarding partnerships to manufacture the vaccine candidate. On April 23, 2020, Emergent BioSolutions announced that it signed an agreement with Johnson & Johnson to be a U.S. manufacturing partner for Johnson & Johnson's lead COVID-19 vaccine candidate.[95] Under the $135 million agreement, Emergent will provide Johnson & Johnson with drug substance manufacturing services and will reserve certain large-scale manufacturing capacity to manufacture up to 300 million doses of the vaccine candidate beginning in 2021.[96] On April 29, 2020, Catalent signed an agreement with Johnson & Johnson to help scale up manufacturing capacity for Johnson & Johnson's vaccine candidate. Catalent will hire about 300 additional employees at the program's site in Bloomington, Indiana starting in July 2020 to achieve operational readiness by January 2021.[97] In May 2020, Vibalogics—a global CDMO—announced that the company had entered into a partnership with

[89] *Id*.
[90] U.S. Department of Health and Human Services, Public Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, *available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx (last visited June 10, 2020).
[91] *Id*.
[92] Johnson & Johnson, *Johnson & Johnson Announces Acceleration of its COVID-19 Vaccine Candidate; Phase 1/2a Clinical Trial to Begin in Second Half of July* (June 10, 2020), *available at* https://www.jnj.com/johnson-johnson-announces-acceleration-of-its-covid-19-vaccine-candidate-phase-1-2a-clinical-trial-to-begin-in-second-half-of-july.
[93] *Id*.
[94] *Id*.
[95] Emergent BioSolutions, *Emergent BioSolutions Signs Agreement to be U.S. Manufacturing Partner for Johnson & Johnson's Lead Vaccine Candidate for COVID-19* (Apr. 23, 2020), *available at* https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-signs-agreement-be-us-manufacturing?field_nir_news_date_value[min]=.
[96] *Id*.
[97] Catalent, *Catalent Signs Agreement with Johnson & Johnson to be U.S. Manufacturing Partner for Lead COVID-19 Vaccine Candidate* (Apr. 29, 2020), *available at* https://www.catalent.com/catalent-news/catalent-signs-agreement-with-johnson-johnson-for-lead-covid-19-vaccine-candidate/.

Johnson & Johnson to manufacture additional clinical trial material for Johnson & Johnson's COVID-19 vaccine candidate.[98]

iii. Merck

On May 26, 2020, Merck and IAVI announced they were collaborating to develop a COVID-19 vaccine candidate, "[u]nder the agreement IAVI and Merck will work together to advance the development and global clinical evaluation of a SARS-CoV-2 vaccine candidate designed and engineered by IAVI scientists." [99]

The vaccine candidate is being developed using a recombinant vesicular stomatitis virus (rVSV) vaccine platform that uses an attenuated strain of vesicular stomatitis virus, "a common animal virus that has been modified to express proteins that stimulate an immune response."[100] The rVSV vaccine platform is the same viral backbone that is used in Merck's Ebola Zaire vaccine, ERVEBO, that was approved by FDA in December 2019.[101] This was the first rVSV vaccine approved for use in humans.[102]

IAVI started working on the vaccine at the end of January 2020. The vaccine candidate is currently in the pre-clinical stages of development and clinical studies are planned to start later in 2020.[103] In April, BARDA awarded Merck and IAVI about $38 million to assist with the development of the vaccine candidate, rVSVΔG-CoV2.[104]

In addition, Merck acquired Themis Bioscience, a company focused on vaccines and immune-modulation therapies for infectious diseases, including COVID-19.[105] Themis is

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[98] HospiMedica International staff writers, *Johnson & Johnson Partners with Vibalogics on Development of Lead COVID-19 Vaccine Candidate*, HOSPIMEDICA (May 20, 2020), *available at* https://www.hospimedica.com/covid-19/articles/294782493/johnson--johnson-partners-with-vibalogics-on-development-of-lead-covid-19-vaccine-candidate.html.

[99] Merck, *IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2* (May 26, 2020), *available at* https://investors.merck.com/news/press-release-details/2020/IAVI-and-Merck-Collaborate-to-Develop-Vaccine-Against-SARS-CoV-2/default.aspx.

[100] *Id*.

[101] IAVI, *Watch IAVI Experts Discuss Accelerating COVID-19 Vaccine Development with Merck* (June 3, 2020), *available at* https://www.iavi.org/newsroom/watch-iavi-experts-discuss-accelerating-covid-19-vaccine-development-with-merck.

[102] Merck, *IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2* (May 26, 2020), *available at* https://investors.merck.com/news/press-release-details/2020/IAVI-and-Merck-Collaborate-to-Develop-Vaccine-Against-SARS-CoV-2/default.aspx.

[103] Merck, *IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2* (May 26, 2020), *available at* https://investors.merck.com/news/press-release-details/2020/IAVI-and-Merck-Collaborate-to-Develop-Vaccine-Against-SARS-CoV-2/default.aspx; IAVI, *Watch IAVI Experts Discuss Accelerating COVId-19 Vaccine Development with Merck* (June 3, 2020), *available at* https://www.iavi.org/newsroom/watch-iavi-experts-discuss-accelerating-covid-19-vaccine-development-with-merck.

[104] U.S. Department of Health and Human Services, Public Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, *available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx (last visited July 13, 2020).

[105] Merck, *How Merck is Responding to the Global Pandemic, COVID-19, available at* https://www.merck.com/about/featured-stories/how-we-are-responding-to-the-global-pandemic-COVID-19.html

developing an experimental COVID-19 vaccine based on a measles vaccine that could begin human studies soon.[106]

iv. Moderna

ModernaTX, Inc. is developing a COVID-19 vaccine candidate, mRNA-1273, in collaboration with NIAID.[107] The vaccine candidate is currently in Phase 2 clinical trials.

The Moderna/NIAID vaccine candidate "is an mRNA [messenger RNA] vaccine against the novel coronavirus encoding for a prefusion stabilized form of the Spike (S) protein, which was designed by Moderna in collaboration with NIAID."[108] According to Moderna, developing a vaccine with an innovative mRNA vaccine technology "offers potential advantages in efficacy, speed of development, and production scalability and reliability."[109]

The first clinical batch of the vaccine candidate—which was funded by CEPI—was completed on February 7, 2020, and it was shipped to NIH on February 24, 2020, just 42 days from sequence selection.[110] NIAID and Moderna were able to develop the vaccine candidate so quickly because of prior research on related coronaviruses that cause SARS and MERS.[111]

The Moderna/NIAID vaccine candidate was the first vaccine candidate in the U.S. to enter clinical trials. The Phase 1 clinical trial began on March 16, 2020, at Kaiser Permanente Washington Health Research Institute in Seattle, Washington.[112] BARDA awarded Moderna $483 million on April 16, 2020, to fund the development of the mRNA-1273 vaccine candidate. The funding will also support manufacturing process scale up to enable large scale production in

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(last visited Jul. 13, 2020); *Merck Completes Acquisition of Themis, Milestone Reflects Merck's Commitment to Accelerate SARS-CoV-2 Vaccine Program*, BUSINESSWIRE (June 19, 2020), *available at* https://www.businesswire.com/news/home/20200619005217/en/Merck-Completes-Acquisition-Themis.

[106] Matthew Herper, *Merck leaps into Covid-19 vaccine race, aiming to test two different candidates this year*, STAT (May 26, 2020), *available at* https://www.statnews.com/2020/05/26/merck-aims-to-begin-human-tests-of-two-different-covid-19-vaccines-this-year/.

[107] Moderna, *Moderna Announced Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 18, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine.

[108] National Institutes of Health (NIH), *NIH clinical trial of investigational vaccine for COVID-19* (Mar. 16, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins; Moderna, *Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study* (Feb. 24, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-ships-mrna-vaccine-against-novel-coronavirus-mrna-1273.

[109] Moderna, *The Advantages of mRNA Vaccines*, *available at* https://www.modernatx.com/pipeline/therapeutic-areas/mrna-therapeutic-areas-infectious-diseases (last visited June 9, 2020).

[110] *Id*.; Moderna, *Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 12, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-receives-fda-fast-track-designation-mrna-vaccine-mrna.

[111] National Institutes of Health (NIH), *NIH clinical trial of investigational vaccine for COVID-19* (Mar. 16, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[112] *Id*.

2020.[113] On May 1, 2020, Moderna announced a worldwide strategic collaboration with Lonza to manufacture Moderna's vaccine candidate.[114] The companies plan to manufacture the vaccine candidate at Lonza's facilities in the U.S. and Switzerland, with the first batch of the vaccine candidate being manufactured at Lonza U.S. in July 2020.[115] Some of the funding Moderna received from BARDA under their contract will help fund the establishment of manufacturing operations at Lonza U.S.[116]

Moderna announced on May 12, 2020, that FDA granted Moderna's mRNA-1273 vaccine candidate Fast Track designation.[117] On May 18, 2020, Moderna announced positive interim Phase 1 data for its vaccine candidate, and stated that it planned to begin the Phase 3 trial in July.[118] Moderna announced on May 29, 2020, that it had begun the Phase 2 trial and that the first participants in each age cohort had received a dose of the vaccine candidate.[119] On June 11, 2020, Moderna announced that it had finalized plans to begin the Phase 3 clinical trial in July.[120] The Phase 3 study will have 30,000 participants.[121] Moderna also noted that Phase 1 of the clinical trial was still ongoing as of June 11, 2020, and that NIH would submit the Phase 1 data to a peer-reviewed clinical publication.[122] On July 14, 2020, Moderna announced the publication of an interim analysis of the open-label Phase 1 study of its mRNA-1273 vaccine candidate in *The New England Journal of Medicine,* which reaffirm the positive interim data assessment announced on May 18, 2020, and show that the vaccine candidate induced rapid and strong immune responses against SARS-CoV-2 and that it was generally safe and well tolerated, with no serious adverse events reported.[123]

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[113] 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), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million; U.S. Dep't of Health and Human Services, Public Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio, available at* https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx (last visited June 10, 2020).
[114] Moderna, *Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus* (May 1, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-and-lonza-announce-worldwide-strategic-collaboration.
[115] *Id*.
[116] *Id*.
[117] Moderna, *Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 12, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-receives-fda-fast-track-designation-mrna-vaccine-mrna.
[118] Moderna, *Moderna Announced Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 18, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine.
[119] Moderna, *Moderna Announced First Participants in Each Age Cohort Dosed in Phase 2 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (May 29, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-first-participants-each-age-cohort-dosed-phase.
[120] Moderna, *Moderna Advances Late-Stage Development of its Vaccine (mRNA-1273) Against COVID-19* (June 11, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-advances-late-stage-development-its-vaccine-mrna-1273.
[121] *Id*.
[122] *Id*.
[123] Moderna, *Moderna Announces Publication in The New England Journal of Medicine of Interim Results from Phase 1 Study of Its mRNA Vaccine Against COVID-19 (mRNA-1273)* (July 14, 2020), *available at*

On June 11, 2020, Moderna announced that the company is on track to be able to deliver about 500 million doses per year, and potentially up to 1 billion doses per year, beginning in 2021 from Moderna's U.S. manufacturing site and the partnership with Lonza.[124] On June 25, 2020, Moderna and Catalent announced an agreement for Catalent to provide fill-finish capacity for Moderna's COVID-19 vaccine candidate, including providing vial filling and packaging capacity, "additional staffing required for 24x7 manufacturing operations at the site to support production of an initial 100 million doses of the vaccine candidate intended to supply the U.S. market starting in the third quarter of 2020," and providing "clinical supply services from its facilities in Philadelphia, Pennsylvania, including packaging and labeling, as well as storage and distribution to support Moderna's Phase 3 clinical study."[125] The companies are also still discussing Catalent providing fill-finish capacity for hundreds of millions of additional doses.[126]

v. Pfizer

Pfizer and BioNTech have partnered to develop a COVID-19 vaccine candidate—known as BNT162 vaccine program. The companies are currently conducting Phase 1/2 clinical trials. There are four vaccine candidates being tested in the BNT162 vaccine program, each vaccine candidate is based on a different mRNA format and target antigen.[127]

On April 29, 2020, Pfizer and BioNTech announced the completion of dosing the first 12 study participants with the vaccine candidate in Germany for the Phase 1/2 clinical trial.[128] On May 5, 2020, Pfizer and BioNTech administered the first dose to participants in the U.S.[129] The Phase 1/2 study is designed to evaluate the safety, immunogenicity, and dose level of the four mRNA vaccine candidates.[130] On July 13, 2020, Pfizer and BioNTech announced that two of the companies' four investigational vaccine candidates, BNT162b1 and BNT162b2, received Fast

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https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-publication-new-england-journal-medicine.

[124] Moderna, *Moderna Advances Late-Stage Development of its Vaccine (mRNA-1273) Against COVID-19* (June 11, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/moderna-advances-late-stage-development-its-vaccine-mrna-1273.

[125] Catalent, *Moderna and Catalent Announce Collaboration for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate* (June 25, 2020), *available at* https://www.catalent.com/catalent-news/moderna-and-catalent-announce-collaboration-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-candidate/.

[126] *Id*.

[127] Pfizer, *Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program* (May 5, 2020), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_dose_first_participants_in_the_u_s_as_part_of_global_covid_19_mrna_vaccine_development_program.

[128] Pfizer, *BioNTech and Pfizer Announce Completion of Dosing for First Cohort of Phase 1/2 Trial of COVID-19 Vaccine Candidates in Germany* (Apr. 29, 2020), *available at* https://investors.pfizer.com/investor-news/press-release-details/2020/BioNTech-and-Pfizer-announce-completion-of-dosing-for-first-cohort-of-Phase-1-2-trial-of-COVID-19-vaccine-candidates-in-Germany/default.aspx.

[129] Pfizer, *Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program* (May 5, 2020), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_dose_first_participants_in_the_u_s_as_part_of_global_covid_19_mrna_vaccine_development_program.

[130] *Id*.

Track designation from the FDA.[131] According to the announcement, "[t]his designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies. The companies released early data from the ongoing U.S. Phase 1/2 study for the product candidate BNT162b1 on July 1, 2020. The manuscript is available on the online preprint server medRxiv and is concurrently undergoing scientific peer-review for potential publication. Early data from the German trial of BNT162b1 are expected to be released in July."[132]

Pfizer expects to start the Phase 3 clinical trial in July, and expects to have safety and efficacy data from the Phase 3 clinical trials by the fall, potentially as early as September.[133] The clinical trials sites will be around the world, especially where there are increases of COVID-19 cases, including in Florida, Arizona, and Texas.[134] Pfizer's goal is to submit data to the FDA for the vaccine candidate for an EUA by October.[135]

Pfizer and BioNTech are scaling-up manufacturing capacity at risk to increase global supply. Subject to the success of the development program and approval by the regulatory authorities, the companies are increasing production capacity to allow for the supply of hundreds of millions of vaccine doses by the end of 2020 and increasing to 1 billion by 2021.[136] Pfizer is investing $1 billion to develop and manufacture the vaccine candidate at risk.[137]

c. Supply Chain and Distribution Issues

In response to the COVID-19 pandemic, and the lack of requisite manufacturing capacity to produce enough vaccines for clinical trials and mass production, the federal government and the private sector have been working to ramp up manufacturing capacity.

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[131] *Pfizer and Biontech Granted FDA Fast Track Designation for Two Investigational MRNA-Based Vaccine Candidates Against SARS-CoV-2* (Jul. 13, 2020), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-fast-track-designation-two.
[132] *Id*.
[133] Beth Wang, *Pfizer CEO: COVID-19 Vaccine May be Ready for October Approval*, INSIDEHEALTHPOLICY (June 26, 2020), *available at* https://insidehealthpolicy.com/daily-news/pfizer-ceo-covid-19-vaccine-may-be-ready-october-approval.
[134] *Id*.
[135] Nathan Vardi, *The Race is On: Why Pfizer May be the Best Bet to Deliver a Vaccine by the Fall*, FORBES (May 20, 2020), *available at* https://www.forbes.com/sites/nathanvardi/2020/05/20/the-man-betting-1-billion-that-pfizer-can-deliver-a-vaccine-by-this-fall/#5389bf65382e.
[136] Pfizer, *Pfizer and BioNTech Dose First Participants in the U.S. as Part of Global COVID-19 mRNA Vaccine Development Program* (May 5, 2020), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_dose_first_participants_in_the_u_s_as_part_of_global_covid_19_mrna_vaccine_development_program; Beth Wang, *Pfizer CEO: COVID-19 Vaccine May be Ready for October Approval*, INSIDEHEALTHPOLICY (Jun. 26, 2020), *available at* https://insidehealthpolicy.com/daily-news/pfizer-ceo-covid-19-vaccine-may-be-ready-october-approval.
[137] Nathan Vardi, *The Race is On: Why Pfizer May be the Best Bet to Deliver a Vaccine by the Fall*, FORBES (May 20, 2020), *available at* https://www.forbes.com/sites/nathanvardi/2020/05/20/the-man-betting-1-billion-that-pfizer-can-deliver-a-vaccine-by-this-fall/#5389bf65382e.

Several private partnerships and public-private partnerships have already been established to scale up manufacturing capacity in parallel to the development of a vaccine candidate. Given that fewer than ten percent of vaccine candidates generally make it through clinical trials successfully, these efforts are done at risk.[138]

Recently, Dr. Fauci said that COVID-19 vaccine candidates will start being manufactured before they are approved or authorized for use in the U.S., thereby saving a significant amount of time that it would otherwise take to manufacture the vaccines after FDA approval or authorization. Dr. Fauci noted, "[s]omething that people need to understand is that we proceed at risk [with manufacturing the vaccine]. And at risk, doesn't mean at risk for the patient regarding safety and integrity of the science. The risk is to the financial investment."[139] Dr. Fauci further explained that manufacturing vaccines at-risk is "very risky from a financial situation," but it will potentially reduce the timeline to have a COVID-19 vaccine available to the public by months.[140] Thus, the accelerated timeline would be achieved through expediting manufacturing scale-up, and not through shortcuts in clinical trial requirements to determine safety and efficacy.

In addition, many private entities have raised concerns about a potential shortage of medical glass bottles oftentimes used to bottle vaccines. One of the biggest global medical glassmakers, Schott AG, indicated that the requests it has received for a billion vials are twice as much as the company can produce this year.[141] Vaccine manufacturers have requested about 1 billion glass vials from Schott, but Schott can only produce about 500 million vials for COVID-19 vaccines by the end of 2020.[142] CEPI recently said that there is a global glass shortage.[143] Some vaccine manufacturers are considering alternative forms of packaging to help reduce demand for medical glass vials, including multi-dose vials, multi-dose plastic bags, plastic vials, and plastic pre-filled syringes.[144]

There are several initiatives supporting Operation Warp Speed to help accelerate the delivery of COVID-19 vaccines and drugs, including an agreement with Corning to expand its domestic manufacturing capacity of Corning Valor glass vials for vaccines, an agreement with SiO2 Materials Science to scale-up the production of its primary packaging for COVID-19 vaccines and therapeutics, which includes vials and syringes, and an agreement with ApiJect to deliver prefilled syringes and increase manufacturing capacity.[145] On March 18, 2020, HHS

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[138] Bob Holmes, *The Time of Trials: Waiting for a Coronavirus Vaccine*, DISCOVER MAGAZINE (May 27, 2020), *available at* https://www.discovermagazine.com/health/the-time-of-trials-waiting-for-a-coronavirus-vaccine.
[139] Soo Kim, *Dr. Fauci Says Coronavirus Vaccine Doses Will be Manufactured 'Before We Even Know That the Vaccine Works*, NEWSWEEK (June 4, 2020), *available at* https://www.newsweek.com/dr-fauci-coronavirus-vaccine-manufactured-before-we-know-it-works-1508642.
[140] *Id*.
[141] Jared S. Hopkins and Drew Hinshaw, *Coronavirus Vaccine Makers Are Hunting for Vital Equipment: Glass Vials*, THE WALL STREET JOURNAL (June 16, 2020), *available at* https://www.wsj.com/articles/coronavirus-vaccine-makers-are-hunting-for-vital-equipment-glass-vials-11592317525.
[142] *Id*.
[143] *Id*.
[144] *Id*.; Alicia Wallace, *Finding a coronavirus vaccine is hard. Getting it to people is a whole other problem*, CNN (June 12, 2020), *available at* https://www.cnn.com/2020/06/11/business/vaccine-glass-vials-coronavirus/index.html.
[145] Corning, *Corning Valor Glass Selected to Help Accelerate Delivery of COVID-19 Vaccines and Drugs* (June 9, 2020), *available at* https://www.corning.com/worldwide/en/about-us/news-events/news-releases/2020/06/us-

announced a new public-private partnership to develop a U.S.-based, high-speed, high-volume emergency drug packaging solution using low-cost prefilled syringes.[146] HHS launched the new consortium for Rapid Aseptic Packaging of Injectable Drugs, or RAPID, to develop a surge capacity network of up to eight domestic facilities that can manufacture prefilled syringes using a process called Blow-Fill-Seal (BFS) aseptic plastics manufacturing technology.[147] HHS awarded the company leading RAPID, ApiJect Systems America, up to $456 million for this initiative.[148]

Finally, despite the extensive efforts to develop and produce COVID-19 vaccines, only limited doses of authorized or approved vaccines will initially be available. The CDC's Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts who are responsible for developing recommendations on the use of vaccines for Americans, including how a vaccine should be distributed, to whom, and when after FDA approval.[149] Given that it is likely when a vaccine is approved for COVID-19 there will not be a sufficient amount of vaccine available to immunize immediately all Americans, ACIP is already developing a plan on how to distribute available COVID-19 vaccine once one is approved or authorized for use by the FDA.[150] ACIP's most recent public meeting on vaccine recommendations was June 24, 2020.[151] The agenda included discussing "COVID-19 vaccine prioritization considerations," among other things.[152]

At a hearing held by the Committee on Energy and Commerce on June 23, 2020, Dr. Robert R. Redfield, the Director of the CDC, was asked about how a vaccine would be distributed to Americans if approved.[153] Dr. Redfield testified that "[i]t is a critical issue that is currently under discussion within the team to look at what the appropriate prioritization for distribution is" and that the decision "may be very dependent on what the product is" since

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departments-of-defense-health-human-services-select-corning-valor-glass-packaging-to-accelerate-delivery-of-covid-19-vaccines.html.

[146] U.S. Department of Health and Human Services, *HHS Announces New Public-Private Partnership to Develop U.S.-Based, High-Speed Emergency Drug Packaging Solutions* (Mar. 18, 2020), *available at* https://www.hhs.gov/about/news/2020/03/18/hhs-announces-new-public-private-partnership-to-develop-us-based-high-speed-emergency-drug-packaging-solutions.html.

[147] *Id*.

[148] *Id*.

[149] Centers for Disease Control and Prevention, *Advisory Committee on Immunization Practices (ACIP): General Committee – Related Information* (last updated Oct. 23, 2018), *available at* https://www.cdc.gov/vaccines/acip/committee/index.html; Elizabeth Weise, *When a coronavirus vaccine is developed, who will be first in line to get it? A CDC panel usually decides*, USA TODAY (May 18, 2020), *available at* https://www.usatoday.com/story/news/health/2020/05/18/coronavirus-vaccine-who-get-first-cdc-panel-usually-decides/5202932002/.

[150] Elizabeth Weise, *When a coronavirus vaccine is developed, who will be first in line to get it? A CDC panel usually decides*, USA TODAY (May 18, 2020), *available at* https://www.usatoday.com/story/news/health/2020/05/18/coronavirus-vaccine-who-get-first-cdc-panel-usually-decides/5202932002/.

[151] Centers for Disease Control and Prevention, *ACIP meeting information*, *available at* https://www.cdc.gov/vaccines/acip/meetings/index.html (last visited Jun. 22, 2020).

[152] *Id*.

[153] *Oversight of the Trump Administration's Response to the COVID-19 Pandemic: Hearing Before the H. Comm. On Energy and Commerce*, 116th Cong., Preliminary Transcript, at 64 (June 23, 2020).

"[e]ach of these vaccine products that are currently being developed may in fact have differential utilization for different populations."[154]

IV. CONGRESSIONAL RESPONSE

Congress has passed legislation in response to the COVID-19 pandemic, including historic levels of funding.

On March 5, 2020, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, and on March 6, 2020, President Trump signed the bill into law.[155] Among other provisions, Congress provided funding to multiple components within HHS for the development of COVID-19 vaccines, diagnostics, and therapeutics.[156] This includes, among other things, $3.1 billion in funding for the Public Health and Social Services Emergency Fund to prevent, prepare for, and respond to COVID-19, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, and the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, medical surge capacity, and related administrative activities.[157]

On March 27, 2020, Congress passed, and President Trump subsequently signed into law, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act.[158] Among other provisions, the CARES Act provided funding to multiple components within HHS for the development, manufacturing, and purchase of COVID-19 vaccines, diagnostics, and treatments.[159] This includes, among other things, $11 billion in funding for the Public Health and Social Services Emergency Fund to support the manufacturing, production, and purchase of vaccines, therapeutics, diagnostics, and other medical or preparedness needs. The CARES Act also expands coverage of COVID-19 diagnostics to include tests approved by state labs and developed by Clinical Laboratory Improvement Amendments (CLIA) labs before they get an EUA from FDA, and mandates timely commercial insurance coverage of COVID-19 vaccines or preventive treatments in commercial plan. Coverage is provided for any future vaccine under Medicare Part B exempt from the deductible and at no cost in the Medicaid program. The law also provides a state option to provide vaccine coverage for the uninsured through the Medicaid program.

In addition, Congress has passed, and President Trump subsequently signed into law, other significant pieces of legislation, including the Families First Coronavirus Response Act, which provided more than $2.5 billion in additional emergency relief for domestic efforts in responding to the COVID-19 outbreak by providing paid sick leave and free coronavirus testing, expanding food assistance and unemployment benefits, and requiring employers to provide

[154] *Id*.
[155] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).
[156] *Id*.
[157] *Id*.
[158] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. 116-136 (2020).
[159] *Id*.

additional protections for health care workers,[160] and the Paycheck Protection Program and Health Care Enhancement Act, which provided an additional $484 billion in funding relief to address the COVID-19 pandemic, including health related provisions and additional funding for the Paycheck Protection Program.[161]

[160] Families First Coronavirus Response Act, Pub. L. 116-127 (2020).
[161] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020); Kellie Moss, *The Paycheck Protection Program and Health Care Enhancement Act: Summary of Key Health Provisions*, KAISER FAMILY FOUNDATION (May 1, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/the-paycheck-protection-program-and-health-care-enhancement-act-summary-of-key-health-provisions/.