



September 25, 2020

TO: Members, Committee on Energy and Commerce

FROM: Committee Republican Staff

RE: Hearing entitled, “Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”

The Subcommittee on Oversight and Investigations will hold a virtual hearing on Wednesday, September 30, 2020, at 11:30 a.m., entitled “Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust.”

I. WITNESSES

- Helene Gayle, M.D., M.P.H., Co-Chair, Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, National Academies of Sciences, Engineering, and Medicine;
- Ashish K. Jha, Dean, M.D., M.P.H., Dean, School of Public Health, Brown University;
- Ali S. Kahn, M.D., M.P.H., M.B.A., Dean, College of Public Health, University of Nebraska Medical Center;
- Mark McClellan, M.D., Ph.D., Founding Director, Duke-Margolis Center for Health Policy, Duke University; and
- Paul A. Offit, M.D., Director, Vaccine Education Center, Children’s Hospital of Philadelphia.

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 Syndrome (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

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->

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-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 and July 17, 2020, the CDC made revisions to which medical conditions put individuals at any age at increased risk of severe illness, including cancer, 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 Further, children who have medical complexity; neurologic, genetic, or metabolic conditions; or congenital heart disease might be at increased risk for severe illness from COVID-19 compared to other children.⁷ According to the CDC, symptoms may appear 2 to 14 days after exposure.⁸

(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/>.

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 Sept. 21, 2020).

⁶ *Id.*

⁷ *Id.*

⁸ 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>.

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, 2020.⁹ 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 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.¹⁰ 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.¹¹ According to the WHO, this is the first pandemic caused by a coronavirus.

As of September 25, 2020, there are 188 countries/regions with a total of 32,345,456 confirmed COVID-19 cases and 984,590 deaths.¹² 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).¹³ While there are 60 jurisdictions reporting cases, different parts of the country are seeing different levels of COVID-19 activity. As of September 25, 2020, CDC reports that there are 6,958,632 cases and 202,329 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,

⁹ 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.

¹⁰ 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/>.

¹¹ 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>.

¹² 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 Sept. 25, 2020), available at <https://coronavirus.jhu.edu/map.html>.

¹³ 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.

¹⁴ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Cases in the US* (last updated September 25, 2020), available at <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html#accordion-1-collapse-2>; 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.

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

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 According to CDC, “[r]ecent data suggest that there can be transmission of COVID-19 through droplets of those with mild symptoms or those who do not feel ill. Current data do not support long range aerosol transmission of SARS-CoV-2, such as seen with measles or tuberculosis. Short-range inhalation of aerosols is a possibility for COVID-19, as with many respiratory pathogens.”¹⁹ 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.²⁰ According to the CDC, the virus is spreading more efficiently than influenza, but not as efficiently as measles.²¹

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.²²

¹⁵ *Id.*

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 Centers for Disease Control and Prevention, *COVID-19 Overview and Infection Prevention and Control Priorities in non-US Healthcare Settings*, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/overview/index.html#:~:text=Recent%20data%20suggest%20that%20there,seen%20with%20measles%20or%20tuberculosis> (last updated Aug. 12, 2020).

²⁰ 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.

²¹ *Id.*

²² 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>.

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 (OWS) on May 15, 2020, to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.²³ 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.²⁴

The three main areas where the effort will accelerate the timeframe for countermeasures to reach the American public include development, manufacturing, and distribution:²⁵

- *Development:* OWS 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.²⁶
- *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

²³ 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>.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

will be used, to the extent practicable, for whatever vaccine is successful, regardless of which companies have developed the capacity.²⁷

- *Distribution*: Before the countermeasures are approved or authorized, the program will build the necessary plans and infrastructure for distributing them; OWS 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.²⁸

Among other things, the goal of OWS is to have a significant amount—300 million doses—of safe and effective vaccine for COVID-19 available to Americans by January 2021.²⁹

For the development of vaccines, OWS selected the most promising candidates that could be scaled up and provide coordinated government support. Four criteria were developed in consultation with experts across the federal government for the selection of the vaccine candidates. This criteria included: (1) the candidates needed robust scientific data supporting them; (2) the candidates needed the potential to enter large-scale Phase 3 trials for efficacy by the summer or fall of 2020; (3) the candidates had to be based on vaccine technologies that permit rapid and effective manufacturing; and (4) the candidates had to use one of four vaccine platform technologies that were believed to be the most likely to yield a safe and effective vaccine against COVID-19.³⁰

As of May 15, 2020, OWS had chosen 14 promising vaccine candidates from the list of over 100 vaccine candidates currently in development. From there, eight vaccine candidates were 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 the candidates that are selected. Finally, additional non-clinical testing will be performed at the same time when possible.³¹ Of the eight candidates in OWS' portfolio, six have been announced, including Moderna, Pfizer/BioNTech, AstraZeneca, Janssen/Johnson & Johnson, Novavax, and Sanofi/GlaxoSmithKline.³² These six candidates, which are currently in clinical trials, represent three vaccine development platforms: messenger RNA (mRNA);

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

³¹ 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>.

³² Moncef Slaoui and Matthew Helpburn, *Developing Safe and Effective Covid Vaccines – Operation Warp Speed's Strategy and Approach*, THE NEW ENGLAND JOURNAL OF MEDICINE (Aug. 26, 2020), available at <https://www.nejm.org/doi/full/10.1056/NEJMp2027405>.

replication-defective live-vector; and recombinant subunit adjuvanted protein.³³ The remaining two candidates are expected to enter trials soon.³⁴

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 OWS. 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.³⁵

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 leading vaccine candidates will be enhanced while the vaccine candidates are still in development.³⁶ 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.³⁷ To date, the federal government has made more than \$10 billion in financial investments to support the candidates that have been selected in some combination of research and development, clinical trials, and industrial manufacturing.³⁸ In addition to financial investments, the federal government is providing significant technical and logistical support, allowing the companies to take several steps of the development process in parallel, without compromising the safety and efficacy of its vaccine.³⁹

For distribution of a COVID-19 vaccine, OWS 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.⁴⁰ This effort includes contract awards for supplies to administer vaccines,

³³ *Id.*

³⁴ *Id.*

³⁵ 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>.

³⁶ 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>.

³⁷ 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>.

³⁸ Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we’re developing a COVID-19 vaccine at ‘Warp Speed’: Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

³⁹ *Id.*

⁴⁰ 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>.

including injection devices, glass vials, and syringes.⁴¹ In addition, on August 14, 2020, CDC executed “an existing contract option with McKesson to support vaccine distribution.”⁴²

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.⁴³

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.⁴⁴ 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.⁴⁵

- *The Preclinical Working Group* is “charged to standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and

⁴¹ 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-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>.

⁴² U.S. Dept. of Health and Human Services, *Trump Administration Collaborates with McKesson for COVID-19 Vaccine Distribution* (Aug. 14, 2020), available at <https://www.hhs.gov/about/news/2020/08/14/trump-administration-collaborates-mckesson-covid-19-vaccine-distribution.html>.

⁴³ 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).

⁴⁴ 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>.

⁴⁵ 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=tf1&utm_term=051820.

vaccines to support entry into clinical trials.”⁴⁶ The goals of this working group are to increase access to animal models and identify informative assays.⁴⁷

- *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.”⁴⁸ The goals of this working group are to prioritize and test potential therapeutic agents and develop a master protocol for clinical trials.⁴⁹
- *The Clinical Trial Capacity Working Group* is “charged with assembling and coordinating existing networks of clinical trials to increase efficiency and build capacity.”⁵⁰ The goals of this working group are to develop survey instruments, develop inventory of clinical trial networks, and guide deployment of innovative solutions.⁵¹
- *The Vaccines Working Group* is “charged to accelerate evaluation of vaccine candidates to enable rapid authorization or approval.”⁵² 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.⁵³ 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.⁵⁴

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.⁵⁵ 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.⁵⁶ These

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ 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).

⁵⁶ 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 Sept. 25, 2020). This page is updated regularly but may not include all awards.

partnerships are focused on vaccines, diagnostics, therapeutics, rapidly deployable capabilities, and other items.⁵⁷

As of September 25, 2020, BARDA's COVID-19 Medical Countermeasure Portfolio with respect to vaccines includes: (1) ModernaTX, Inc. for SARS-CoV-2 mRNA-1273 vaccine; (2) Janssen Pharmaceutical Companies, for AD26.COVS - Viral Vector Vaccine for COVID-19; (3) Sanofi Pasteur and GSK for Recombinant SARS-CoV-2 Protein Antigen + AS03 Adjuvant; (4) Pfizer, Inc. for BNT162, a prototype COVID-19 mRNA vaccine; (5) Novavax Inc., for NVX-CoV-2373 Vaccine for SARS-CoV-2; (6) AstraZeneca for AZD1222 (formerly ChAdOx1 NCoV-19 vaccine); and (7) Merck and IAVI for rVSVΔG-CoV2.⁵⁸ BARDA has provided more than \$10 billion in funding for these efforts.⁵⁹

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.⁶⁰ 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."⁶¹ 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.⁶²

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."⁶³ Among other things, with respect to clinical trials, the guidance also states that:

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

⁶⁰ 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>.

⁶¹ 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).

⁶² 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>.

⁶³ *Id.* at 9.

- “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.”⁶⁴ The agency also “strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”⁶⁵
- “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.”⁶⁶ The several vaccine candidates developed under OWS will need 30,000 participants enrolled in Phase 3 clinical trials and must take place where outbreaks are occurring.⁶⁷
- “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.”⁶⁸

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.⁶⁹ The guidance also discusses the use of an Emergency Use Authorization (EUA) for a COVID-19 vaccine.⁷⁰

In addition to guidance for the clinical trials, for vaccine licensure, firms will need to show the vaccine can be stored and transported safely, by demonstrating the stability and expiry date of the vaccine in its final container, when maintained at the recommended storage temperature, using final containers from at least three final lots made from different vaccine bulks.

⁶⁴ *Id.* at 11.

⁶⁵ *Id.*

⁶⁶ *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).

⁶⁷ 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/>.

⁶⁸ 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).

⁶⁹ 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>.

⁷⁰ *Id.* at 19.

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.⁷¹

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."⁷²

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."⁷³ Further, Dr. Marks stated that he would resign if the FDA rubber-stamped an unproven COVID-19 vaccine.⁷⁴

b. Private Sector Efforts

According to WHO, there were 149 vaccine candidates in preclinical evaluation and 38 vaccine candidates in clinical evaluation as of September 22, 2020.⁷⁵ According to the Biotechnology Innovation Organization's (BIO) COVID-19 Therapeutic Development Tracker,

⁷¹ 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).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Dan Levine, Marisa Taylor, *Exclusive: Top FDA official says would resign if agency rubber-stamps an unproven COVID-19 vaccine*, REUTERS (Aug. 20, 2020), available at <https://www.reuters.com/article/us-health-coronavirus-vaccines-fda-exclu/exclusive-top-fda-official-says-would-resign-if-agency-rubber-stamps-an-unproven-covid-19-vaccine-idUSKBN25H03H>.

⁷⁵ World Health Organization, *DRAFT landscape of COVID-19 candidate vaccines* (Sept. 22, 2020), available at <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>.

U.S. institutions are working on the highest number of COVID-19 vaccine candidates, accounting for 85 vaccine candidates on the list as of September 21, 2020.⁷⁶

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 September 21, 2020, there are 75 COVID-19 vaccine candidates that are protein-based vaccines, 29 that are rViral-based vaccines, 25 that are RNA-based vaccines, 22 that are Viral-based vaccines, 16 that are DNA-based vaccines, 11 that are cell-based vaccines, 9 that are nanoparticle vaccines, and 1 that is antiviral (immune cell).⁷⁷

Below is the status of the six candidates in the U.S. that have been announced by OWS.

- **AstraZeneca:** AstraZeneca and Oxford University's ChAdOx replication-defective live-vector vaccine published findings from its phase 1/2 trial on August 15, 2020, which supported the company moving into phase 3 trials in the United Kingdom, Brazil, South Africa, in August. The U.S. phase 3 trial began September 1, 2020.⁷⁸ AstraZeneca recently paused enrollment in trials for the vaccine after a "suspected adverse event" in a person who received the vaccine in the UK. Trials have resumed in the UK, Brazil, and South Africa, but remain on hold in the U.S.
- **Janssen:** The Janssen Ad26 Covid-19 replication-defective live-vector vaccine demonstrated excellent protection in nonhuman primate models and began its U.S. phase 1 trial on July 27, 2020.⁷⁹ Positive interim results from the company's phase 1/2a clinical study demonstrated that the safety profile and immunogenicity after a single vaccination were supportive of further development.⁸⁰ On September 23, 2020, Johnson & Johnson announced the launch of its large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE) for its COVID-19 vaccine candidate.⁸¹

⁷⁶ 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 Sept. 25, 2020).

⁷⁷ *Id.*

⁷⁸ University of Minnesota, Center for Infectious Disease Research and Policy, *Third COVID vaccine candidate starts phase 3 trial in the US* (Sept. 1, 2020), available at <https://www.cidrap.umn.edu/news-perspective/2020/09/third-covid-vaccine-candidate-starts-phase-3-trial-us>.

⁷⁹ Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

⁸⁰ Johnson & Johnson, *Johnson & Johnson Initiates Pivotal Global Phase 3 Clinical Trial of Janssen's COVID-19 Vaccine Candidate* (Sept. 23, 2020), available at <https://www.jnj.com/johnson-johnson-initiates-pivotal-global-phase-3-clinical-trial-of-janssens-covid-19-vaccine-candidate>.

⁸¹ *Id.*

- **Moderna:** Moderna developed its RNA vaccine in collaboration with the NIAID and began its phase 1 trial in March.⁸² Moderna published encouraging safety and immunogenicity data in *The New England Journal of Medicine* on July 14, 2020, and entered phase 3 trials on July 27, 2020.⁸³
- **Novavax:** Novavax completed and published data from phase 1 trial of its recombinant-subunit-adjuvanted protein vaccine in *The New England Journal of Medicine* on September 2, 2020.⁸⁴ The Phase 2 portion of the Phase 1/2 clinical trial to evaluate the safety and immunogenicity of NVX-CoV2373 began in August in the U.S. and Australia.⁸⁵ Novavax is expected to enter phase 3 trials in the U.S. by the end of this month.⁸⁶
- **Pfizer/BioNTech:** Pfizer and BioNTech's RNA vaccine produced encouraging phase 1 results, which were published on July 1, 2020, and started its phase 3 trial on July 27, 2020.⁸⁷ Pfizer recently announced that it has reached its initial goal of 30,000 participants for the phase 3 trial of its coronavirus vaccine. However, Pfizer and BioNTech have submitted an amended protocol to the FDA to expand the enrollment of their Phase 3 trial to up to approximately 44,000 participants.⁸⁸

⁸² The Moderna vaccine candidate was dosed in its first human clinical trial participant within 63 days of sequencing the virus. By comparison, it took 20 months before a vaccine candidate for SARS could be tested in human trials. Shawn Radcliff, *How Long Will It Take to Develop a Vaccine for Coronavirus*, HEALTHLINE (Jan. 30, 2020), available at <https://www.healthline.com/health-news/how-long-will-it-take-to-develop-vaccine-for-coronavirus#Vaccinating-people-at-high-risk>.

⁸³ Lisa A. Jackson, M.D., M.P.H, Evan J. Anderson, M.D., et. al., *An mRNA Vaccine Against SARS-CoV-2 – Preliminary Report*, THE NEW ENGLAND JOURNAL OF MEDICINE (July 14, 2020), available at <https://www.nejm.org/doi/full/10.1056/NEJMoa2022483>; Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

⁸⁴ Cheryl Keech, M.D., Ph.D., Gary Albert, M.S., et al., *Phase 1-2 Trial of SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine*, THE NEW ENGLAND JOURNAL OF MEDICINE (Sept. 2, 2020), available at https://www.nejm.org/doi/full/10.1056/NEJMoa2026920?query=featured_coronavirus.

⁸⁵ Novavax, *Novavax Announces Publication of Phase 1 Data for COVID-19 Vaccine Candidate in The New England Journal of Medicine* (Sept. 2, 2020), available at <https://ir.novavax.com/news-releases/news-release-details/novavax-announces-publication-phase-1-data-covid-19-vaccine>.

⁸⁶ Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

⁸⁷ Mark J. Mulligan, Kirsten E. Lyke, et. al., *Phase 1/2 Study to Describe the Safety and Immunogenicity of a COVID-19 RNA Vaccine Candidate (BNT162b1) in Adults 18 to 55 Years of Age: Interim Report*, medRxiv (July 1, 2020), available at <https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1>; Sec. Alex M. Azar II, U.S. Dept. of Health and Human Services and Dr. Moncef Slaoui, *How we're developing a COVID-19 vaccine at 'Warp Speed': Alex Azar* (Sept. 2, 2020), available at <https://www.hhs.gov/about/leadership/secretary/op-eds/how-we-are-developing-a-covid-19-vaccine-at-warp-speed-alex-azar.html>.

⁸⁸ Pfizer, *Pfizer and BioNTech Propose Expansion of Pivotal COVID-19 Vaccine Trial* (Sept. 12, 2020), available at <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-propose-expansion-pivotal-covid-19>.

- **Sanofi/GlaxoSmithKline:** Sanofi and GSK announced on September 3, 2020, that they are launching a large Phase 1/2 clinical trial that will take place at 11 sites across the U.S. The trial, which is expected to be completed by early December, would pave the way for a Phase 3 efficacy trial to start the same month, if the experimental vaccine proves to be safe, tolerable, and appears to be generating enough of an immune response to proceed.⁸⁹

In addition to FDA's guidance, there are multiple safeguards in the clinical trial process to assure the safety and efficacy of the vaccine. First, there is a Data and Safety Monitoring Board (DSMB) for the phase 3 trials. The DSMB is an independent, multidisciplinary group, which include individuals who are experienced with clinical trials, biostatisticians, bioethicists, immunologists, vaccinologists, and virologists. According to NIAID, the purpose of DSMBs are "[t]o oversee and monitor clinical trials to ensure participant safety and the validity and integrity of the data."⁹⁰ The DSMB reviews the blinded data from the clinical trials "regularly to make sure that patients are not being endangered by side effects from the vaccine and that it's still ethical to give a placebo."⁹¹ The DSMB has pre-programmed times for review and have stopping rules that are defined ahead of time for both futility and for overwhelming efficacy.

Second, the private sector has taken steps to assure the public of their commitment to safety and efficacy. For example, on September 8, 2020, several companies who are developing a COVID-19 vaccine made a pledge to uphold the integrity of the scientific process as they work towards potential regulatory filings and approvals of the first COVID-19 vaccines.⁹² In addition, in an unprecedented action, some of the private sector companies have released documents that detail the clinical trial protocols, including how they are conducting late-stage trials of their coronavirus vaccines and how safety and efficacy will be determined. For example, Moderna, Pfizer, AstraZenca, and Janssen recently released their clinical study protocols for their coronavirus vaccines.⁹³ These protocols are more than 100 pages in length containing very

⁸⁹ Helen Branswell, *Sanofi and GSK move COVID-19 vaccine into human trials*, STAT NEWS (Sept. 3, 2020), available at <https://www.statnews.com/2020/09/03/sanofi-gsk-covid19-vaccine-human-trials/>.

⁹⁰ National Institute of Allergy and Infectious Diseases, *Data and Safety Monitoring Boards (DSMB) SOP*, available at <https://www.niaid.nih.gov/research/data-and-safety-monitoring-boards>.

⁹¹ Matthew Herper, *Experts see a chance for a Covid-19 vaccine approval this fall – if it's done right*, STAT News (Sept. 2, 2020), available at <https://www.statnews.com/2020/09/02/experts-see-a-chance-for-a-covid-19-vaccine-approval-this-fall-if-its-done-right/>.

⁹² Pfizer, *COVID-19 Vaccine Maker Pledge*, available at <https://www.pfizer.com/health/coronavirus/pledge>.

⁹³ Moderna, *Clinical Study Protocol, A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 and Older*, available at <https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf>; Pfizer, *A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate The Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals*, available at https://pfe-pfizercom-d8-prod.s3.amazonaws.com/2020-09/C4591001_Clinical_Protocol_0.pdf; AstraZeneca, *Clinical Study Protocol, A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19*, available at https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf; Janssen Vaccines & Prevention B.V., *A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-*

detailed study plans. Some observers have advocated that the companies publish their clinical protocols to enhance public confidence in the vaccine.

Thirdly, the COVID-19 vaccine candidates will submit data packages with information from clinical trials to the FDA Vaccines and Related Biological Products Advisory Committee. The Advisory Committee will review and evaluate data concerning the safety, effectiveness, and appropriate use of the vaccine.⁹⁴ Commissioner Hahn said any vaccine data released will be discussed publicly by an advisory committee of outside experts and Peter Marks, who runs the FDA division that oversees vaccine approvals, will ultimately make a recommendation.⁹⁵ Commissioner Hahn noted: “A discussion with this committee, made up of outside scientific and public health experts from around the country, will help ensure clear public understanding regarding clinical development of these vaccines indicated to prevent COVID-19 and the data needed to facilitate their authorization or licensure.”⁹⁶

Finally, the EUA review standard for COVID-19 vaccines will be rigorous. As observed by two former FDA commissioners: “To receive an authorization for emergency use, a developer must demonstrate that—based on the totality of scientific evidence—the product’s known or potential benefits outweigh the known and potential risks. Some worry that this is a lower standard for access that shouldn’t be applied to a vaccine, where the bar for safety needs to be high, as vaccines are given to the healthy. But the FDA has latitude to apply the standard appropriately to different settings—in particular, requiring more rigorous evidence for treatments used on healthier populations than for seriously ill hospitalized patients. It isn’t a lower standard for FDA approval. It’s a more tailored, flexible standard that helps protect those who need it most while developing the evidence needed to make the public confident about getting a Covid-19 vaccine.”⁹⁷

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. Several private partnerships and public-private partnerships have already been established to scale up

CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older, available at <https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol>.

⁹⁴ U.S. Food and Drug Administration, *Vaccines and Related Biological Products Advisory Committee* (Apr. 26, 2019), available at <https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee>.

⁹⁵ Berkeley Lovelace Jr, *FDA chief says he has ‘no intention’ of overruling career staff on coronavirus vaccine decision* (Sept. 10, 2020), available at <https://www.cnbc.com/2020/09/10/coronavirus-vaccine-fda-chief-says-he-has-no-intention-of-overruling-career-staff-on-decision.html>.

⁹⁶ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccines* (Aug. 28, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-covid-19-vaccines>.

⁹⁷ Scott Gottlieb and Mark McClellan, *How ‘Emergency Use’ Can Help Roll Out a Covid Vaccine*, THE WALL STREET JOURNAL (Sept. 13, 2020), available at <https://www.wsj.com/articles/how-emergency-use-can-help-roll-out-a-covid-vaccine-11600029175>.

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 financial risk.⁹⁸

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 than 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.”⁹⁹ 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.¹⁰⁰ 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 ancillary supplies, such as medical glass bottles oftentimes used to bottle vaccines. 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.¹⁰¹ In addition, there are several initiatives supporting OWS 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.¹⁰² On March 18, 2020, HHS 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.¹⁰³ 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.¹⁰⁴ In addition,

⁹⁸ 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>.

⁹⁹ 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>.

¹⁰⁰ *Id.*

¹⁰¹ *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>.

¹⁰² 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>.

¹⁰³ 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>.

¹⁰⁴ *Id.*

Becton, Dickinson and Company announced additional pandemic orders for needles and syringes from the U.S. in July, bringing the total U.S. orders from Becton, Dickinson and Company to 190 million devices.¹⁰⁵

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.¹⁰⁶ 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.¹⁰⁷ ACIP held a public meeting on vaccine recommendations on July 29, 2020.¹⁰⁸ The agenda included discussing COVID-19 vaccine safety considerations, among other things.¹⁰⁹ ACIP also held a meeting on September 22, 2020. The agenda included discussing enhanced vaccine safety surveillance, vaccine implementation, and an overview of vaccine equity and prioritization frameworks, among other things.¹¹⁰ However, ACIP put off voting on how to prioritize distribution of any COVID-19 vaccine and may wait until the FDA gives an EUA or approval to a vaccine.¹¹¹

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.¹¹² 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

¹⁰⁵ Becton, Dickinson and Company, *BD Receives Additional Orders For 177 Million Injection Devices For U.S., Canada COVID-19 Vaccine Preparations* (July 21, 2020), available at <https://www.prnewswire.com/news-releases/bd-receives-additional-orders-for-177-million-injection-devices-for-us-canada-covid-19-vaccine-preparations-301096584.html>.

¹⁰⁶ 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/>.

¹⁰⁷ 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/>.

¹⁰⁸ Centers for Disease Control and Prevention, *ACIP meeting information*, available at <https://www.cdc.gov/vaccines/acip/meetings/index.html> (last visited Sept. 2, 2020).

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ Peter Loftus, *CDC Advisory Panel to Delay Vote on Initial Covid-19 Vaccine Rollout*, THE WALL STREET JOURNAL (Sept. 22, 2020), available at <https://www.wsj.com/articles/cdc-advisory-panel-to-delay-vote-on-initial-covid-19-vaccine-roll-out-11600772401>.

¹¹² *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.”¹¹³

On September 16, 2020, HHS and DoD released two documents—developed in coordination with DoD and CDC—outlining the administration’s strategy to deliver safe and effective COVID-19 vaccine doses to the American people as quickly and reliably as possible.¹¹⁴ The documents “provide a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their respective jurisdictions.”¹¹⁵ Specifically, the overview lays out four tasks necessary for the COVID-19 vaccine program: (1) engage with state, tribal, territorial, and local partners, other stakeholders, and the public to communicate public health information around the vaccine and promote vaccine confidence and uptake; (2) distribute vaccines immediately upon granting of Emergency Use Authorization/Biologics License Application, using a transparently developed, phased allocation methodology and CDC has made vaccine recommendations; (3) ensure safe administration of the vaccine and availability of administration supplies; and (4) monitor necessary data from the vaccination program through an information technology system capable of supporting and tracking distribution, administration, and other necessary data.¹¹⁶

Since the vaccines are being manufactured concurrently with clinical trials, once the FDA approves an EUA or Biologics License Application (BLA), and CDC makes its recommendation for prioritization of the initial doses, the vaccines and associated ancillary kits (e.g. syringes, needles, and alcohol swabs) will be ready to be shipped.¹¹⁷ The vaccines will be shipped to states for distribution to administration sites including pharmacies, nursing homes, public clinics, hospitals, doctor’s offices and mobile clinics, and military treatment facilities.¹¹⁸ On September 23, 2020, HHS announced that the CDC will provide \$200 million to 64 jurisdictions through funding from the Coronavirus Aid, Relief, and Economic Security Act for COVID-19 vaccine preparedness.¹¹⁹

¹¹³ *Id.*

¹¹⁴ U.S. Dept. of Health and Human Services, *Trump Administration Releases COVID-19 Vaccine Distribution Strategy* (Sept. 16, 2020), available at <https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html>.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ U.S. Dept. of Health and Human Services, *Operation Warp Speed Vaccine Distribution Process* (Sept. 16, 2020), available at <https://media.defense.gov/2020/Sep/16/2002498504/-1/-1/1/OWS-VACCINE-DISTRIBUTION-GRAPHIC.pdf>.

¹¹⁸ *Id.*

¹¹⁹ U.S. Dept. of Health and Human Services, *Administration Announces \$200 million from CDC to Jurisdictions for COVID-19 Vaccine Preparedness* (Sept. 23, 2020), available at <https://www.hhs.gov/about/news/2020/09/23/administration-announces-200-million-from-cdc-jurisdictions-covid-19-vaccine-preparedness.html#:~:text=media%40hhs.gov-.Administration%20Announces%20%24200%20million%20from%20CDC%20to%20Jurisdictions%20for%20COVID,for%20COVID%2D19%20vaccine%20preparedness>.

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.¹²⁰ Among other provisions, Congress provided funding to multiple components within HHS for the development of COVID-19 vaccines, diagnostics, and therapeutics.¹²¹ 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.¹²²

On March 27, 2020, Congress passed, and President Trump subsequently signed into law, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act.¹²³ 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.¹²⁴ 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 additional protections for health care workers,¹²⁵ and the Paycheck Protection Program and Health Care Enhancement Act, which provided an additional \$484 billion in funding relief to

¹²⁰ Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123 (2020).

¹²¹ *Id.*

¹²² *Id.*

¹²³ Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. 116-136 (2020).

¹²⁴ *Id.*

¹²⁵ Families First Coronavirus Response Act, Pub. L. 116-127 (2020).

address the COVID-19 pandemic, including health related provisions and additional funding for the Paycheck Protection Program.¹²⁶

¹²⁶ 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/>.