



**MEMORANDUM**

**September 25, 2020**

**To: Subcommittee on Oversight and Investigations Members and Staff**

**Fr: Committee on Energy and Commerce Staff**

**Re: Hearing on “Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”**

On Wednesday, September 30, 2020, at 11:30 a.m. (EDT) via Cisco Webex online video conferencing, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust.” The hearing will examine the safety and efficacy of, accessibility to, and the public’s trust in prospective coronavirus disease of 2019 (COVID-19) vaccines.

**I. BACKGROUND ON COVID-19 IN THE UNITED STATES**

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) announced the first reported case of COVID-19 in the United States.<sup>1</sup> COVID-19 can cause a range of mild to severe symptoms, with older adults and people with underlying medical conditions at higher risk of developing more severe complications, and people of color experiencing higher rates of infection and mortality.<sup>2</sup> On January 31, Secretary of Health and Human Services (HHS) Alex Azar declared the disease a U.S. public health emergency.<sup>3</sup> President Trump declared the outbreak a national emergency on March 13.<sup>4</sup>

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<sup>1</sup> Centers for Disease Control and Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (press release).

<sup>2</sup> Centers for Disease Control and Prevention, Symptoms of Coronavirus ([www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html](http://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)) (accessed Sept. 23, 2020); Centers for Disease Control and Prevention, *Disparities in Incidence of COVID-19 Among Underrepresented Racial/Ethnic Groups in Counties Identified as Hotspots During June 5–18, 2020 — 22 States, February–June 2020* (Aug. 14, 2020) (MMWR 66(33)) (early release).

<sup>3</sup> U.S. Department of Health and Human Services, Public Health Emergency Declarations ([www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx](http://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx)) (accessed Sept. 23, 2020). Secretary Azar renewed the public health emergency declaration for up to ninety days, effective July 25. *Id.*

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

As of September 24, there were more than 6.9 million reported COVID-19 cases and 201,000 COVID-19-related deaths in the United States.<sup>5</sup>

## II. THE VACCINE DEVELOPMENT PROCESS

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

To be approved for use in the United States, the Food and Drug Administration (FDA) must determine that a vaccine is safe and effective, based on data from laboratory studies and clinical trials.<sup>8</sup> In certain emergency situations, FDA may issue an emergency use authorization (EUA) for a vaccine before it is approved if several legal requirements are met, including a determination that a vaccine “may be effective” in preventing the disease and that its known and potential benefits outweigh the known and potential risks.<sup>9</sup>

The clinical vaccine development process traditionally takes ten to 15 years to complete and typically includes three phases of clinical trials intended to demonstrate a potential vaccine’s safety or effectiveness.<sup>10</sup> Generally, in the final phase of the clinical vaccine development

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<sup>5</sup> Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) Cases in the U.S. ([www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html](http://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html)) (accessed Sept. 24, 2020).

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

<sup>7</sup> U.S. Government Accountability Office, *Science & Tech Spotlight: Herd Immunity for COVID-19* (July 7, 2020) (GAO-20-646SP).

<sup>8</sup> 42 U.S.C. § 262(a)(2); 21 C.F.R. § 601.2 (2019).

<sup>9</sup> 21 U.S.C. § 360bbb-3.

<sup>10</sup> Seunghoon Han, *Clinical Vaccine Development*, Clinical and Experimental Vaccine Research (Jan. 30, 2015); Food and Drug Administration, Vaccine Product Approval Process ([www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process](http://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process)) (accessed Sept. 23, 2020).

process, known as Phase 3 trials, thousands of participants are enrolled in a study to evaluate a vaccine candidate's safety and efficacy across a wide range of patient categories.<sup>11</sup>

### III. FEDERAL GOVERNMENT ACTION TO PROMOTE COVID-19 VACCINES

Since the COVID-19 outbreak began in the United States, Congress has provided nearly \$10 billion to facilitate the promotion of COVID-19 medical countermeasures, including vaccines.<sup>12</sup> On May 15, 2020, the Trump Administration announced the Operation Warp Speed (OWS) initiative, a national program aimed at accelerating “the development, manufacturing, and distribution of COVID-19 vaccines” and other medical countermeasures.<sup>13</sup> OWS is a partnership between components of HHS, the Department of Defense, private firms, and other federal agencies.<sup>14</sup> OWS aims to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021, which would set a new record for a vaccine development timeline.<sup>15</sup>

Through OWS, the Federal Government has partnered or entered into purchase agreements with seven companies that have developed six COVID-19 vaccine candidates.<sup>16</sup> Four of these vaccine candidates, led by Moderna, Pfizer, AstraZeneca, and Johnson & Johnson, are currently in Phase 3 clinical trials in the United States,<sup>17</sup> although AstraZeneca's U.S. clinical trials are currently on pause due to an unexpected adverse event in a trial participant in the United Kingdom.<sup>18</sup> President Trump has said that a COVID-19 vaccine may be available in the

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<sup>11</sup> Congressional Research Service, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020).

<sup>12</sup> U.S. Department of Health and Human Services, Fact Sheet: Explaining Operation Warp Speed ([www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html](http://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html)) (accessed Sept. 23, 2020).

<sup>13</sup> U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020) (press release).

<sup>14</sup> *Id.*

<sup>15</sup> U.S. Department of Health and Human Services, Fact Sheet: Explaining Operation Warp Speed ([www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html](http://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html)) (accessed Sept. 23, 2020); U.S. Department of Defense, Coronavirus: Operation Warp Speed ([www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/](http://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/)) (accessed Sept. 23, 2020).

<sup>16</sup> U.S. Department of Health and Human Services, Fact Sheet: Explaining Operation Warp Speed ([www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html](http://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html)) (accessed Sept. 23, 2020).

<sup>17</sup> *Johnson & Johnson Begins Final-Stage Testing of Covid-19 Vaccine*, Wall Street Journal (Sept. 23, 2020).

<sup>18</sup> AstraZeneca, *Statement on AstraZeneca Oxford SARS-CoV-2 Vaccine, AZD1222, COVID-19 Vaccine Trials Temporary Pause* (Sept. 9, 2020) (press release).

United States by the end of October 2020.<sup>19</sup> However, certain public health experts, including CDC Director Robert Redfield and OWS Chief Scientific Adviser Dr. Moncef Slaoui, have indicated that the U.S. population may not be widely immunized to COVID-19 until the middle of 2021 at the earliest.<sup>20</sup>

On June 30, FDA issued guidance on the “Development and Licensure of Vaccines to Prevent COVID-19.”<sup>21</sup> According to the guidance and statements by FDA Commissioner Stephen Hahn, FDA may approve or authorize a COVID-19 vaccine only if it is demonstrated to be at least 50 percent more effective than a placebo in preventing the disease in a randomized controlled clinical trial.<sup>22</sup> On September 10, FDA’s Center for Biologics Evaluation and Research announced that it would be publishing additional guidance to provide recommendations regarding the data and information needed to support the issuance of an EUA for a COVID-19 vaccine.<sup>23</sup>

Earlier this month, nine pharmaceutical companies signed a pledge committing to submit a vaccine for approval or authorization only “after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.”<sup>24</sup> The four companies currently in Phase 3 trials in the United States have since released their respective vaccine trial protocols, which include details on the criteria researchers will use to determine their vaccine candidate’s safety and efficacy.<sup>25</sup>

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<sup>19</sup> *Trump Claims Vaccine Coming ‘Within a Matter of Weeks,’ Contradicting Health Officials*, Politico (Sept. 21, 2020).

<sup>20</sup> *When Will You Be Able to Get a Coronavirus Vaccine?*, New York Times (Sept. 17, 2020).

<sup>21</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines* (June 30, 2020) (press release).

<sup>22</sup> Food and Drug Administration, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (June 2020); Stephen M. Hahn, *FDA Commissioner: No Matter What, Only a Safe, Effective Vaccine will Get Our Approval*, Washington Post (Aug. 5, 2020).

<sup>23</sup> Food and Drug Administration, *Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2020* (Sept. 10, 2020).

<sup>24</sup> *Biopharma Leaders Unite to Stand with Science* (Sept. 8, 2020) (press release).

<sup>25</sup> *AstraZeneca, Under Fire for Vaccine Safety, Releases Trial Blueprints*, New York Times (Sept. 19, 2020); Johnson & Johnson, *Johnson & Johnson Initiates Pivotal Global Phase 3 Clinical Trial of Janssen’s COVID-19 Vaccine Candidate* (Sept. 23, 2020) (press release).

#### IV. DISTRIBUTION OF AND ACCESS TO A COVID-19 VACCINE

On September 16, 2020, the Trump Administration released a document outlining its strategy for distributing a COVID-19 vaccine to the public,<sup>26</sup> as well as 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.<sup>27</sup> According to the Administration, distribution of a COVID-19 vaccine would begin within 24 hours of FDA issuing an approval or EUA, and a vaccine rollout likely would involve a phased structure targeting specific populations.<sup>28</sup> The Administration's strategy also identifies the goal of "no upfront costs to providers and no out-of-pocket costs to the vaccine recipient."<sup>29</sup> The Administration engaged McKesson Corporation to serve as the Federal Government's central distributor for COVID-19 vaccines and related supplies.<sup>30</sup> CDC asked states to prepare for a "large-scale" distribution of a COVID-19 vaccine by November 1.<sup>31</sup>

Among the logistical challenges associated with the large-scale administration of any COVID-19 vaccine, individuals receiving the first available COVID-19 vaccines may need two doses of the same vaccine, spaced approximately 21 to 28 days apart, in order for the vaccine to be effective.<sup>32</sup> Additionally, certain vaccines may necessitate ultra-cold storage and handling requirements, potentially as low as negative 80 degrees Celsius.<sup>33</sup> While some ancillary supplies, such as needles, syringes, and limited personal protective equipment, will be automatically included with vaccine orders, CDC has indicated that state, tribal, territorial, and local health programs may be responsible for procuring certain other supplies, such as gloves, bandages, and sharps containers.<sup>34</sup> State, tribal, territorial, and local jurisdictions will also be

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<sup>26</sup> U.S. Department of Health and Human Services, *From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine* (Sept. 16, 2020).

<sup>27</sup> Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (Sept. 16, 2020).

<sup>28</sup> *Feds: COVID-19 Vaccine Will Begin Moving 24 Hours After the First One is Approved*, USA Today (Sept. 16, 2020); U.S. Department of Health and Human Services, *From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine* (Sept. 16, 2020).

<sup>29</sup> *Id.*

<sup>30</sup> U.S. Department of Health and Human Services, *Trump Administration Collaborates with McKesson for COVID-19 Vaccine Distribution* (Aug. 14, 2020) (press release).

<sup>31</sup> *CDC Tells States to Prepare for 'Large-Scale' Distribution of COVID-19 Vaccine by Nov. 1*, NBC News (Sept. 2, 2020).

<sup>32</sup> *U.S. Plans to Ship Free Covid-19 Vaccines Within 24 Hours of Authorization*, NBC News (Sept. 16, 2020).

<sup>33</sup> Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (Sept. 16, 2020).

<sup>34</sup> *Id.*

responsible for ensuring their immunization information system hardware and software are up-to-date and ready to track vaccinations and report data to CDC.<sup>35</sup>

To help inform future decisions regarding vaccine allocation, on September 1, a National Academies of Sciences, Engineering, and Medicine (NASEM) committee, established at the request of the National Institutes of Health and CDC, issued a study discussion draft outlining a phased approach to vaccine allocation and the rationale for prioritizing each group included in each phase.<sup>36</sup> NASEM intends to issue a final report early this fall.<sup>37</sup> Further, the Advisory Committee on Immunization Practices (ACIP)—a group of medical and public health experts who have historically developed recommendations on the use of vaccines to control disease in the United States—is also modelling allocation strategies for the initial supply of COVID-19 vaccines.<sup>38</sup> According to recent testimony from Director Redfield, CDC is preparing a vaccine distribution plan “that will be informed by a prioritization framework recommended by ACIP.”<sup>39</sup> On September 22, ACIP announced that it would vote on how to prioritize a COVID-19 vaccine only after FDA approval or authorization and an independent review of the late-stage clinical trial data by an internal working group.<sup>40</sup>

Public confidence in a COVID-19 vaccine has declined dramatically in recent months. Only 51 percent of U.S. adults report that they would get a vaccine if one were available today, down from 72 percent in May.<sup>41</sup> More than three-quarters of Americans think it is very or somewhat likely that a COVID-19 vaccine will be approved in the United States before its safety and effectiveness are fully understood.<sup>42</sup> During the hearing, the Committee will explore contributing factors to declining public confidence in COVID-19 vaccines and the ways in which the Federal Government may reverse this trend.

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<sup>35</sup> *Id.*

<sup>36</sup> National Academies of Sciences, Engineering, and Medicine, *National Academies Launch Study on Equitable Allocation of a COVID-19 Vaccine – First Meeting July 24* (July 21, 2020) (media advisory); National Academies of Sciences, Engineering, and Medicine, *National Academies Release Draft Framework for Equitable Allocation of a COVID-19 Vaccine, Seek Public Comment* (Sept. 1, 2020) (press release).

<sup>37</sup> *Id.*

<sup>38</sup> Advisory Committee on Immunization Practices, *Modelling Allocation Strategies for the Initial SARS-CoV-2 Vaccine Supply* (Aug. 26, 2020).

<sup>39</sup> Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Testimony of Robert R. Redfield, M.D., Director, Centers for Disease Control and Prevention, *Hearing on Review of Coronavirus Response Efforts*, 116<sup>th</sup> Cong. (Sept. 16, 2020).

<sup>40</sup> *Federal Panel Delays Vote on Initial COVID-19 Vaccine Distribution*, The Hill (Sept. 22, 2020).

<sup>41</sup> Pew Research Center, *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine* (Sept. 17, 2020).

<sup>42</sup> *Id.*

## **VII. WITNESSES**

The following witnesses have been invited to testify:

**Dr. Helene Gayle, M.D., MPH**

Co-Chair, Committee on Equitable Allocation of Vaccine for the Novel Coronavirus  
National Academies of Sciences, Engineering, and Medicine

**Dr. Ashish K. Jha, M.D., MPH**

Dean, School of Public Health  
Brown University

**Dr. Ali S. Khan, M.D., MPH, MBA**

Dean, College of Public Health  
University of Nebraska Medical Center

**Dr. Mark McClellan, M.D., Ph.D.**

Founding Director, Duke-Margolis Center for Health Policy  
Duke University

**Dr. Paul A. Offit, M.D.**

Director, Vaccine Education Center  
Children's Hospital of Philadelphia