

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Witnesses appearing before the  
Senate Appropriations Committee  
Subcommittee on Labor, Health and Human Services, Education, and Related  
Agencies

Hearing on  
Operation Warp Speed, vaccines, diagnostics, and therapeutics

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July 2, 2020

## **Introduction**

Chairman Blunt, Ranking Member Murray and distinguished members of this committee. It is an honor to appear before you today to discuss the Department of Health and Human Services' Operation Warp Speed efforts and the Department's efforts on vaccines, diagnostics, and therapeutics. We are grateful for this opportunity to address how each of our agencies and offices are harnessing innovation to prevent, diagnose, and treat the novel coronavirus SARS-CoV-2.

COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO), is caused by the SARS-CoV-2 virus. There are many types of human coronaviruses including some that commonly cause mild upper-respiratory tract illnesses. Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, coronaviruses that infect animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID-19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two other examples of coronaviruses that originated in animals and then spread to people.

The Department of Health and Human Services (HHS) is working closely with all of our government partners in this response. We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility. We thank Congress for your continual partnership that has allowed us to expedite this critical effort to respond to COVID-19.

To accelerate the development and subsequent production of a vaccine for COVID-19, in mid-May, President Trump announced Operation Warp Speed (OWS). OWS aims to deliver up to 300 million doses of a safe and effective vaccine for COVID-19 in early 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19

vaccines, therapeutics, and diagnostics (collectively known as countermeasures). OWS is a partnership among components of HHS, including CDC, FDA, NIH, and BARDA, and the Department of Defense (DoD), with the aim of a unified government approach to respond to the pandemic. OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. OWS coordinates with existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID).

To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support. Protocols for the demonstration of safety and efficacy are being aligned, which will allow the trials to proceed more quickly, and the protocols for the trials will be overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety, as happens normally. This increases the financial risk, but not the product risk.

We will be working constantly with the FDA, sending a constant stream of data to their scientists. Once the data are complete, FDA will perform the analysis they need to determine safety and efficacy as quickly as possible. The FDA will pursue its regulatory work in the standard manner, and by keeping the lines of communication open, they can produce ongoing guidance to support the clinical trials for the OWS candidates, as they often do for agency priorities.

To put it really simply, drug development is a series of boxes you have to check—very complicated boxes, but boxes nonetheless. You proceed through the different development phases, you need certification of your manufacturing processes, then you begin large scale manufacturing, and then you begin distribution. OWS requires checking each and every one of

those boxes just like we would for any other project, but we aren't going one by one down the list. We're aiming to check as many of them simultaneously as we can.

The following testimony will detail how the NIH, BARDA and CDC are contributing to OWS and overall vaccine, therapeutic, and diagnostic efforts.

### **National Institutes of Health**

NIH is the HHS agency leading the research response to COVID-19 and the novel coronavirus that causes the disease, SARS-CoV-2. Research to address the COVID-19 public health emergency is an NIH-wide effort.

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID-19 therapeutics and vaccines. The ACTIV public-private partnership brings together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. Other federal partners include BARDA, DoD, the Department of Veterans Affairs, CDC, and FDA. The ACTIV working groups are making rapid progress. For example, the Therapeutics Clinical Working Group developed and openly shared master protocols with agreed upon endpoints, sampling, and analysis for evaluating monoclonal antibody and vaccine candidates, in order to enhance trial efficiency.

#### *Developing Vaccines to Prevent SARS-CoV-2 Infection*

A safe and effective vaccine for SARS-CoV-2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks.

HHS NIAID is supporting development of several SARS-CoV-2 vaccine candidates, including vaccines based on platform technologies that have shown promise against the coronaviruses that cause SARS and MERS. As part of a longstanding collaboration, the NIAID Vaccine Research Center worked with the biotechnology company Moderna, Inc., to develop a vaccine candidate using a messenger RNA (mRNA) vaccine platform expressing the SARS-CoV-2 spike protein. On March 16, 2020, NIAID initiated a Phase 1 clinical trial of this

experimental vaccine at the Kaiser Permanente Washington Health Research Institute, and later added clinical sites at Emory University and the NIH Clinical Center. This trial was recently expanded to enroll older adults to better define the safety of and immune response to the vaccine across various age groups. On May 18, 2020, Moderna announced encouraging interim findings from the Phase 1 clinical trial and, on May 29, 2020, a Phase 2 clinical trial was initiated to further study safety and the immune response to the experimental mRNA vaccine. NIAID and BARDA are working with Moderna to launch a Phase 3 clinical trial as early as this month, pending positive results from this Phase 2 trial. The Coalition for Epidemic Preparedness Innovations funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA is supporting advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories in Hamilton, Montana have collaborated with University of Oxford researchers to develop a SARS-CoV-2 chimpanzee adenovirus-vectored vaccine candidate AZD1222, formerly known as ChAdOx1, now in a Phase 3 clinical trial in the United Kingdom, supported by the University of Oxford. BARDA recently announced plans to support advanced development and production of AZD1222 in the U.S. NIAID is working with additional academic and industry partners to develop several other vaccine concepts.

The rigorous clinical testing required to establish vaccine safety and efficacy means that it might take some time for a licensed SARS-CoV-2 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates may prove safe and effective by late 2020 or early 2021.

#### *Identifying Therapeutics to Treat COVID-19*

Effective therapeutics for COVID-19 are critically needed to treat patients who have been infected with SARS-CoV-2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID-19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of severe COVID-19 in hospitalized adults (ACTT-1). An analysis of preliminary data from ACTT-1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, although the

mortality data did not reach statistical significance. A mortality rate of 7.1 percent was observed for the group receiving remdesivir versus 11.9 percent for placebo. These initial findings were published on May 22, 2020, in the *New England Journal of Medicine*. Working as part of the ACTIV partnership, NIAID is developing and testing other novel and repurposed therapies. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib, which has been added to the next iteration of the study (ACTT-2), currently underway.

Another promising therapeutic is the use of monoclonal antibodies or mAbs. There are 21 companies developing mAbs and a number of them have started early clinical trials. As part of the ACTIV partnership, and in collaboration with other NIH Institutes, NIAID plans to launch a study to evaluate mAbs in outpatients with mild-to-moderate COVID-19 early this month. A separate trial will evaluate mAbs in inpatients. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin and mAbs for treatment of COVID-19 in hospitalized adults.

The National Heart, Lung, and Blood Institute (NHLBI) sponsored the addition of a U.S. site for a Canadian Institutes for Health Research-funded trial of colchicine—an anti-inflammatory drug commonly used to treat gout—for treating COVID-19 in the outpatient setting. Additionally, NHLBI is leveraging the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID-19, can help reduce the progression of COVID-19 in patients with mild symptoms. In the near future, NHLBI will begin a clinical trial on the use of anticoagulants, hoping to stem the life-threatening blood clots that COVID-19 causes in many patients.

The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection, a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS-CoV-2 therapeutics for further investigation. Other Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the development and testing of mAbs, antiviral, and anti-thrombotic drugs for potential treatment of COVID-19. NIAID, NCI, NHLBI, NCATS, the National Institute of Arthritis and

Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke (NINDS) are all engaged in this critical effort.

NIH also has convened the COVID-19 Treatment Guidelines Panel, comprised of representatives of NIH and five other federal agencies along with representatives of eight professional organizations, academic experts, and treating physicians including providers from high COVID-19 incidence areas. On April 21, 2020, the panel issued the first release of COVID-19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments currently available and address considerations for special populations, including pregnant women and children. On May 12, 2020, in response to the preliminary analysis of ACTT-1, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation. The guidelines are updated regularly as new evidence-based information emerges, including the recent report of benefit of the drug dexamethasone in hospitalized patients, based on results of a randomized trial in the United Kingdom.

#### *Enhancing Diagnosis and Understanding the Pathogenesis of COVID-19*

NIH is supporting an HHS-wide effort to promote the development and commercialization of diagnostic tests to detect current SARS-CoV-2 infection. On April 29, 2020, NIH announced the Rapid Acceleration of Diagnostics (RADx) initiative, which is working to identify, support, and make innovative strategies for COVID-19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. The RADx initiative has four focused programs to scale-up testing and enhance access to those most in need. The RADx Tech initiative is leveraging the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for the potential roll out of new products by fall 2020. NIH has received over 2,000 expressions of interest and over 500 complete applications for RADx Tech. Innovators will be matched with technical, clinical, regulatory, business, and manufacturing experts to increase the odds of success. So far, nine companies have products in Phase 1 testing and are close to commercialization. In addition, NIAID is using CARES Act funds to support diverse SARS-CoV-2 diagnostic platforms including RT-PCR and enzyme-linked immunosorbent assays, and facilitating development of

sensitive, specific, and rapid diagnostic tests by providing critical SARS-CoV-2 isolates and reagents to the developers of tests.

The RADx Underserved Populations (RADx-UP) initiative will augment the reach and power of technologies developed and enhanced through RADx by identifying and addressing implementation factors that present barriers to testing and follow-up in populations that need it the most. On June 12, 2020, NIH announced four new funding opportunities for community-engaged projects within RADx-UP. The goal of this is to understand factors that have led to disproportionate burden of the pandemic on vulnerable populations so that interventions can be implemented to decrease these disparities.

The National Cancer Institute is coordinating with FDA and NIAID to assess the sensitivity and specificity of certain SARS-CoV-2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV-2. NCI and NIAID also are working to establish a collaborative national network to increase national capacity for high-quality serological testing with return-of-results to subjects. In addition, they will conduct research to increase the understanding and application of those results and support related clinical efforts, including clinical trials of convalescent serum and the creation of registries of tested subjects for seroprotection studies.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the United States without a confirmed history of infection with SARS-CoV-2 have antibodies to the virus, indicating prior infection. In addition, NIH is supporting COVID-19 natural history studies to understand the incidence of infection in specific populations, including children and their household contacts, and aspects of the clinical course of infection, including incidents of thrombosis, strokes, heart attacks, and other sequelae of infection. Some of these studies will examine the quality and durability of the immune response to SARS-CoV-2 and evaluate whether unique immune responses may be associated with clinical disease trajectories; this information may be leveraged to develop SARS-CoV-2 therapeutics or vaccines. Natural history studies also will inform our understanding of COVID-19 pathogenesis, including factors that may predict disease progression and help to identify individuals or groups at high risk.

In order to improve understanding of neurological consequences of SARS-CoV-2 and inform potential treatment strategies, NINDS is supporting development of a database that would

collect data on the prevalence and spectrum of neurological symptoms observed in patients with SARS-CoV-2 infection. NHLBI and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development are leading a trans-NIH effort, with participation from NIAID, to coordinate research into the multisystem inflammatory syndrome in children (MIS-C), an extremely serious inflammatory condition that has been associated with SARS-CoV-2 infection in children and adolescents.

NIH continues to expand efforts to elucidate the viral biology and pathogenesis of SARS-CoV-2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIH is focused on developing and evaluating safe and effective COVID-19 vaccines and therapeutics, and sensitive, specific, and rapid point-of-care molecular diagnostic and serological tests. These efforts will improve our response to the current pandemic and bolster our preparedness for the next, inevitable emerging disease outbreak.

### **Centers for Disease Control and Prevention**

CDC has worked for decades with its state and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure, which will help ensure effective distribution can occur once a safe and effective COVID-19 vaccine is available.

CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS. Each year through the Vaccines for Children program and the section 317 immunization program and in partnership with state immunization programs, CDC safely distributes over 80 million doses of vaccines from every vaccine manufacturer to approximately 40,000 public and private health providers across the country. We have strong networks connecting public health departments, health care providers, community groups, and others that can be used to efficiently reach the population. From these sites, vaccine may be transported in small quantities to clinical sites for immediate use, while maintaining cold chain. During an emergency, this proven system has the capacity leveraged to manage and distribute many more doses of vaccine than in a typical year.

For decades, CDC's public-private partnerships have safely distributed tens of millions of doses of routinely recommended vaccines to thousands of provider sites each year. CDC's experience shows the importance of strategic engagement across public and private components of the vaccine enterprise in a collaborative effort to ensure appropriate planning and coordination from development and manufacturing, to distribution, administration, and tracking. Early engagement and planning can help ensure quick and efficient bi-directional exchange of information, so that everything needed to administer the vaccine, including personal protective equipment, is available where and when it is needed. And finally, the public must be well-informed, and misinformation must be addressed with timely, accurate, and trusted information.

CDC tracks and manages public vaccine inventory through its vaccine ordering system, allowing visibility into vaccine supply nationwide. CDC monitors vaccination coverage across the country providing national, regional, and local level data that can inform decision-making and outreach priorities. Vaccine coverage is monitored by jurisdictions through their Immunization Information Systems and CDC's National Immunization Surveys. Suspected adverse events are captured through the Vaccine Adverse Event Reporting System and evaluated through the Vaccine Safety Datalink. Together these systems help streamline the inventory management of federal vaccine assets; monitor national, regional, state, local vaccination coverage to guide targeted outreach and program priorities; inform vaccine program modifications based on vaccine safety findings; implement outreach and program activities; tailor communications and provider education; and coordinate data sharing across jurisdictions.

Building on lessons learned from the 2009 H1N1 pandemic and CDC's experience with routine domestic and global vaccine delivery, there are many critical components to consider in rapid implementation of a new vaccine during and in response to a pandemic. Many of these factors will be determined by the vaccine or vaccines that are licensed for use, and when and how much vaccine is available. Priority populations for receiving the initial supply of vaccine will need to be identified. This could be based on high-risk for exposure, high-risk for disease or other factors. In addition, critical plans will need to be developed for how the vaccine is allocated, distributed, and administered across the United States. These decisions have implications for both the public and private sectors, including who pays for the vaccine and administration fees, where and by whom vaccine is administered, and how to ensure equity and

avoid disparities in access. Monitoring supply, tracking who received vaccine, especially if more than one dose is needed, and assessing vaccination coverage are important. Critical to success of the nation's immunization program is ensuring vaccine safety, effectiveness, and ultimately confidence in the nation's immunization programs and policies.

COVID-19 is not the only health threat in our midst. The 2020-2021 influenza (flu) season is fast approaching, posing a risk of serious complications, hospitalization, or death, even among otherwise healthy children and adults. Pediatric outpatient visits and routine childhood vaccination have also declined substantially in recent months, leaving children and communities at risk for preventable disease outbreaks. Utilization of core preventive services has been disrupted by COVID-19. In order to ensure adequate hospital and medical care capacity, we must work aggressively to increase influenza and other routine childhood immunizations. Further, as we continue to fight the pandemic, it is important that Americans have confidence in all vaccines. CDC will leverage its immunization program to help maintain high coverage in routine childhood immunizations, to increase coverage for flu vaccinations, and prepare for a potential COVID-19 vaccine.

### *CDC's Immunization Program*

Vaccines are one of public health's greatest achievements. Investments in CDC's immunization program have improved the health of Americans. The immunization of children in the United States has saved millions of lives, contributed to longer life expectancy, reduced health disparities, improved quality of life, and saved trillions of dollars in societal costs. Immunizations have become a routine part of how we care for our children. Coverage for many childhood vaccinations are at, near, or above 90 percent, and reported cases for most vaccine preventable diseases have decreased by 90 percent or more in the United States with the introduction of vaccines. Adults need vaccines too. Every year thousands of adults in the U.S. become seriously ill and are hospitalized because of diseases that vaccines can help prevent. CDC's immunization program plays a fundamental role in achieving national immunization goals and sustaining high vaccination coverage rates to prevent death and disability. The signature pieces of this program include the Vaccines for Children (VFC) entitlement program and CDC's discretionary Section 317 Immunization Program.

VFC is one of the largest and most successful public-private partnerships, designed to ensure that eligible children do not contract vaccine-preventable diseases because of inability to pay. Approximately 50% of children from birth to 18 are eligible to receive free vaccine through VFC as part of routine care, supporting the reintegration of vaccination and primary care. CDC works with its 61 awardees to distribute vaccines directly to more than 40,000 public and private providers enrolled in the VFC program. VFC has been instrumental to achieving high childhood and adolescent vaccination coverage rates and reducing disparities.

The Section 317 Immunization Program is a national resource that will continue to fill critical public health needs, such as providing a safety net for adults with no health insurance and responding to outbreaks of vaccine preventable diseases (VPDs) and other urgent public health issues. The program supports the nation's ability to maintain public health preparedness for a response to a vaccine-preventable emergency, such as a pandemic or biological attack. To implement the program, CDC works collaboratively with 64 awardees comprised of the 50 states, six large cities including the District of Columbia, five territories, and three Pacific Freely Associated States.

CDC's support of national, state and local programs has dramatically improved access to vaccination for all children and put systems in place to detect and respond to outbreaks of VPDs and to monitor vaccine effectiveness and safety. However, we know from our surveys and data systems that COVID-19 interrupted access to routine medical services. CDC observed notable declines in pediatric outpatient visits and routine childhood vaccination since March, leaving some children and communities at risk for preventable disease and outbreaks. Corresponding declines were also observed in the number of measles-containing vaccine doses administered in eight U.S. health care organizations serving publicly and privately insured patients. On a positive note, however, we have started to see recovery in vaccine ordering data.

CDC is working with partners to catch up and restore the high levels of immunization. Fortunately, these efforts will provide opportunities to develop innovative systems and partnerships that will pave the way for COVID-19 vaccine distribution. For example, CDC is supporting providers in the safe administration of vaccines during the COVID-19 pandemic through development of guidance and support materials and helping to support catch-up vaccination for children who missed visits through the use of reminder/recall systems. CDC is

increasing communication efforts to remind parents, providers and partners of the importance of routine vaccinations during the COVID-19 pandemic and expanding outreach to provide information about the VFC program to families, especially those who may have recently lost insurance coverage. CDC is also working with partners to encourage back-to-school vaccination activities during the summer and influenza vaccination in the fall. Continued coordinated efforts between health care providers and public health officials at the local, state, and federal levels will be needed to restore and maintain routine pediatric vaccination services during the pandemic.

Another activity that is key to effective distribution and uptake of COVID-19 vaccine is ensuring people have accurate information to make decisions about getting the vaccine.

### *Preparing for COVID-19 Vaccines*

CDC is working closely with the interagency staff to determine a path forward on critical issues related to a COVID-19 vaccine program through OWS. CDC stands ready to use its expertise in public health preparedness and response along with its immunization infrastructure to support OWS in vaccine promotion, distribution, administration, and monitoring. Congress's recent investments through the Coronavirus Aid, Relief, and Economic Security Act have allowed CDC to provide its immunization awardees \$140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID-19 vaccine response work, awardee activities will include a specific focus on enhancing influenza coverage, especially in historically underserved populations, and enrolling and working with additional vaccinators (e.g., pharmacists, mass vaccinators).

Scientific-based vaccine policies are a foundation of the U.S. immunization system. In the U.S., the Advisory Committee on Immunization Practices (ACIP) advises the CDC Director on national vaccine policy for preventing infectious diseases in the civilian population. The immunization systems and expertise supported by CDC's immunization program make substantial contributions to the evidence base that informs immunization recommendations made by ACIP. The ACIP makes recommendations based upon data about the burden of disease,

safety and efficacy of vaccines, economic analyses, including cost-effectiveness data, and information about other factors such as how recommendations can be implemented by the health care system in conjunction with other recommended vaccines.

To prepare for potentially FDA-licensed COVID-19 vaccines, ACIP has established a workgroup that is evaluating safety and immunogenicity data of vaccine candidates, as well as the epidemiology of COVID-19 to target populations and priorities for vaccination. ACIP workgroups are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. While the ACIP workgroup does not have the authority to act on behalf of the advisory committee and they cannot vote on ACIP vaccine recommendations, workgroups review specific topics in detail and clarify issues in a way that helps ACIP voting members make informed and efficient decisions, with the best and most current information available. ACIP meets routinely approximately three times per year (February, June, October), but may meet more frequently as needed. An additional meeting to discuss COVID-19 vaccines is already being planned for August 2020. In addition, under exceptional circumstances, an emergency ACIP meeting may be called without prior notice. If COVID-19 vaccines became available, it is expected that an emergency meeting will be called for the vaccine to receive consideration.

Experience shows that, while vaccines are powerful tools, reaching every individual who would benefit from an immunization is not easy. For example, persistent racial and ethnic disparities exist among adult influenza vaccination rates with 9% and 12% lower coverage among black, non-Hispanics and Hispanics, respectively, as compared to the vaccination rate of whites<sup>1</sup>. To ensure that every American has access to the COVID-19 vaccine will require enhanced partnerships across sectors. This can build on and expand on existing partnerships that are in place for routine immunizations, and can also leverage other public health programs as well as the private sector. It is also important to recognize that the COVID-19 pandemic has affected the ways people engage with the health care system, and that a successful vaccine program will need to incorporate various sites and approaches for vaccine administration. For

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<sup>1</sup>CDC. Flu Vaccination Coverage, United States, 2018–19 Influenza Season. Available from: <https://www.cdc.gov/flu/fluview/coverage-1819estimates.htm>

example, worksites that have served as locations for adult immunization may be less accessible due to increased telework, so other complementary sites such as pharmacies and innovative locations that work for a given community may be more important during our response to this pandemic. Regardless of traditional or complementary vaccine provider site, it will be critical to ensure that all sites are linked to data monitoring systems.

A final public health consideration relates to the management of the vaccine itself—every vaccine has requirements regarding storage and handling that must be addressed in order for the vaccine to be effective when administered. Most vaccines require refrigeration, while others require being held at specific temperatures beyond the capacity of regular refrigerators. Ensuring that the cold chain is maintained from the point of manufacture until the time of use is a significant concern in any vaccination program. Improper storage can lead to vaccine being wasted, or more importantly, reduce its effectiveness. Careful consideration of all of these factors will be critical to ensuring that the investments that have been made in the development of a vaccine for COVID-19 achieve their intended purpose—protecting Americans from the threat of this novel coronavirus.

#### *Preparing for the 2020-2021 Influenza Season*

Unfortunately, COVID-19 is not the only public health threat we are facing. CDC is also working to increase vaccination coverage for the 2020-2021 flu season. This is an important public health goal in its own right, but also serves two important purposes related to COVID-19. First, increasing vaccine coverage this fall can reduce the strain on the health care system, which will be facing COVID-19 at the same time as seasonal influenza. Second, it is another opportunity to test the systems and infrastructure that will be leveraged to deliver a COVID-19 vaccine.

During the 2018-2019 flu season, only 49% of the US population received the flu vaccine. Still, flu vaccination helped to prevent 4.4 million flu illnesses, 58,000 flu-related hospitalizations, and 3,500 deaths. Any flu infection can carry a risk of serious complications, hospitalization or death, even among otherwise healthy children and adults. Increased flu vaccination coverage will protect more Americans from this seasonal health threat, while decreasing stress on the healthcare system.

CDC is committed to the goal of increasing flu vaccine uptake, especially in people at higher risk of serious flu and COVID-19 outcomes. We will continue to work with our public health and clinical partners to eliminate barriers to vaccination. The ongoing COVID-19 pandemic may affect where and how vaccines are given, and we are working with health departments to develop contingency plans. CDC is also looking at operational considerations such as access to vaccine with potential need for social distancing, and prolonging vaccine uptake throughout the flu season. CDC is making additional influenza vaccine available to state health departments for uninsured adults at higher risk for morbidity and mortality. To support this effort, we are enhancing communications to target audiences, including older Americans, persons with disabilities, people of any age with underlying health conditions, workers in long-term care facilities, other essential workers, African Americans, and Hispanics. Understanding that African American and Hispanic communities have lower rates of flu vaccination and a higher risk for COVID complications, we will enhance our education and communication efforts toward these key communities. We will be assessing the impacts the pandemic may have on vaccination, evaluating the quality of communications with patients regarding vaccinations, and focusing on influenza vaccination and African American and Hispanic patients.

We are taking many considerations into account in our efforts to expand flu vaccine coverage and focusing on specific efforts to address racial and ethnic disparities. Specifically, CDC will be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. We will be engaging in expert consultation to develop strategies for addressing racial and ethnic disparities in adult immunization, soliciting simultaneous individual expert opinion from 15 national leaders in health disparities, health equity, and social determinants of health.

On June 4, CDC awarded \$140 million from the CARES Act to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable state health departments to launch an initial scale up for influenza season, given the increased risk of COVID-19. Funds will begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for vulnerable populations.

There are many critical components to consider in implementation of a pandemic vaccine. Many of these factors will be determined by the availability and characteristics of licensed vaccines and the priority populations identified for receiving the vaccines. Critical to success of the vaccine program is ensuring vaccine safety, effectiveness, and ultimately vaccine confidence. COVID-19 is the most significant public health challenge to face our nation in more than a century. CDC is building upon our existing programs to provide the American public with the information and assistance it needs to address COVID-19 head on, while simultaneously working with our state and local public health partners to maintain routine childhood immunization coverage and prepare for the upcoming flu season. As we continue to work together to fight COVID-19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease.

**Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority**

*ASPR's Role in Response*

The Assistant Secretary for Preparedness and Response's (ASPR) mission is to save lives and protect Americans from 21st century health security threats. During previous public health emergencies, ASPR has led, on behalf of HHS, Emergency Support Function #8: Public Health and Medical Services, under the National Response Framework. This means ASPR serves as the primary coordinator for public health information and deployment of assets to support the health components of a response.

For the current COVID-19 pandemic response, ASPR. funding has been used to not only to accelerate development of medical countermeasures under BARDA but also to deploy trained medical teams to augment care in communities overwhelmed with COVID-19 cases, enter into contracts to resupply personal protective equipment and other critical components deployed from the Strategic National Stockpile (SNS) to aid in the treatment of persons with or suspected of having COVID-19 and provide grants to hospital associations and healthcare centers to aid in the ongoing response. We appreciate this Committee's support of our efforts and are utilizing the provided funds to ensure communities have the tools and resources to

detect and treat those diagnosed with or suspected of having COVID-19.

### *Vaccine Development Efforts*

Since late January, BARDA has collaborated with counterparts across the government to identify potential COVID-19 medical countermeasure candidates and accelerate their development. BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past successes include the 2009 H1N1 influenza pandemic, Ebola outbreaks in 2014-2016 in West Africa and in 2018 the Democratic Republic of the Congo, as well as the Zika outbreak in 2015. For these past response operations as well as the current response to COVID-19, Congress has provided emergency supplemental funding to support the urgent need for medical countermeasure development.

At the onset of the pandemic, BARDA reviewed investments, modified contracts, and began working with Regeneron, Janssen, and Sanofi Pasteur to initiate the development of vaccines and therapeutics for COVID-19. All three have successfully developed both prophylactic and therapeutic medical countermeasures for emerging infectious diseases in the recent past. BARDA's early leveraging of these existing partnerships and established platforms may help shave months off the development timelines for medical countermeasures and has been made possible by flexible authorities authorized and provided by Congress as well as prior investment into these platforms.

The BARDA portfolio now includes over 40 medical countermeasure projects including nine therapeutics, 26 diagnostics (12 of which have been granted Emergency Use Authorization by the FDA) and five vaccine candidates. Three of these five candidates are operating under OWS. On March 30, 2020, HHS announced \$456 million in funds for Janssen's (part of Johnson & Johnson) candidate vaccine, with Phase 1 clinical trials set to begin this summer. On April 16, 2020, HHS awarded \$483 million to support Moderna's candidate vaccine, which began Phase 1 trials on March 16 and received a fast-track designation from the FDA. Lastly, 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.

It is important to note that we are strictly adhering to and following all required regulatory and safety requirements required for vaccine development. We are not sacrificing the safety of the vaccine in order to expedite its development. We are instead supporting two steps at the same time. In addition to vaccine development, we are supporting manufacturing efforts to ensure we are positioned to produce and manufacture the vaccine quickly and effectively. Specifically, we are making investments in the necessary manufacturing capacity at federal risk, giving companies confidence that they can invest aggressively in development and allowing faster manufacturing and potential distribution of an eventual vaccine. Manufacturing capacity for selected candidates being advanced while vaccine candidates are still in development, rather than scaled up after approval or authorization. The May 21, April 16, and March 30, 2020, HHS agreements with AstraZeneca, Moderna, and Janssen/Johnson & Johnson respectively include product development and investments in large-scale manufacturing capabilities. Additionally, the June 1, 2020, HHS task order with Emergent BioSolutions to advance domestic manufacturing capabilities and capacity for a potential COVID-19 vaccine, as well as therapeutics, worth approximately \$628 million. Under the terms of the contracts for manufacturing capacity, reservations can be shifted as needed from one candidate vaccine to another more promising candidate based on the findings from clinical trials that are being conducted in parallel with manufacturing scale-up. OWS has also been working to address fill/finish capacity, to acquire needles and syringes, and to expand domestic capacity for manufacturing of needles, syringes, and vials.

BARDA is also working with and reviewing the capabilities and capacity of our Centers for Innovation in Advanced Development and Manufacturing (CIADMs). The CIADMs are government-sponsored facilities that were created as public-private partnerships to establish domestic manufacturing capacity and response capabilities in order to ensure the nation has adequate surge capacity for rapid medical countermeasure production to address pandemics or other biological threats. The two HHS CIADMs are Emergent BioSolutions in Baltimore, MD, and Texas A&M University System in College Station, TX. Currently, AstraZeneca and Janssen have reserved space at the Emergent facility to manufacture vaccines at scale. In addition, BARDA is engaged in active discussions to reserve and expand capacity at the Texas A&M University System CIADM. Through OWS, manufacturing capacity at the DoD ADM, Ology

Bioservices Inc. could also be utilized if necessary. I would be happy to keep the Committee updated on the progress of utilizing CIADMs as we move forward in this space.

Since its establishment in 2006, ASPR has proven its success in supporting past public health and medical emergencies. Whether the organization supported hurricanes, floods, influenza outbreaks, and other infectious diseases such as Pandemic Influenza, Ebola, Zika, or the current COVID-19 pandemic, we have utilized the authorities and resources provided by Congress to best support the nation in responding to the threat and mitigating the lasting impact. BARDA has successfully established over 300 industry partnerships and obtained 55 FDA approvals for medical countermeasures. Further, BARDA has worked with its partners to develop robust platform technologies that facilitate rapid development and manufacturing of medical countermeasures in the face of a newly emerging threat.

Thank you again for your support. Your partnership and support enable our mission accomplishment. I am confident that we can quickly develop and distribute a safe and effective vaccine to reduce the impact of COVID-19 to our nation.

### **Conclusion**

HHS appreciates the support and interest of Congress in our work related to Operation Warp Speed and the development of vaccines, therapeutics, and diagnostics. Considering the potential health, social, and economic benefits of getting a safe and effective vaccine faster, placing big financial bets on these vaccines is a fiscal investment for the nation. One economic analysis put the costs of nationwide stay-at-home orders at about \$20 billion a day—to say nothing of the lives that are being lost that we can save with faster progress toward a vaccine. We're putting billions of dollars on the line to solve a multi-trillion-dollar challenge.

We look forward to partnering with Congress and working together as the country continues to open safely again. Thank you for the opportunity to testify today and we look forward to your questions