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Senate Committee on Health, Education, Labor, and Pension

Hearing
COVID-19: Update on Progress Toward Safely Getting Back to Work
and Back to School

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Introduction

Chairman Alexander, 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' ongoing response to the COVID-19 pandemic. We are grateful for this opportunity to address how each of our agencies and office 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. Within HHS, the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID), the Assistant Secretary for Health, and the Food and Drug Administration (FDA), along with additional components not represented today, play critical roles in the response to this public health emergency as discussed below.

Centers for Disease Control and Prevention

CDC is America's health protection agency, and works 24/7 to save lives and protect America from health, safety and security threats, both abroad and in the United States. CDC has a key role in preparedness and response, and addressing infectious diseases like COVID-19 is central to our mission. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and the H1N1 pandemic influenza, to meet new challenges presented by COVID-19. These challenges are many, and they are historic. Every single American is affected by this pandemic, and CDC is leaning into this public health crisis with every applicable asset we have. CDC is drawing on its emergency response capacity and its relationships with state, tribal, local, and territorial (STLT), global, and private sector partners; and is leveraging our workforce's strengths in public health surveillance, prevention, and laboratory capacity, to develop and provide the nation with the science-backed information and analysis needed to address this public health emergency. CDC has developed and continues to update guidance for healthcare professionals and the public to encourage safer practices, improve health outcomes, and save lives. CDC is also working with partners to develop guidance and decision tools to assist state and local officials and other stakeholders in adjusting mitigation strategies. Importantly, CDC is collaborating to prepare the nation's public health system and the private sector to disseminate rapidly a vaccine to the American people when one is available. Abroad, CDC is leveraging investments in global health security, pandemic influenza preparedness and public health infrastructures and capacities built through presidential initiatives, including the President's Emergency Plan for AIDS Relief to support countries in mitigating and containing COVID-19. In addition, CDC has staff in over 60 countries, who work very closely with host governments. Since the beginning of the outbreak, they have been providing technical assistance, and now programmatic funding, to help countries mitigate the effects of COVID-19 and stop the disease from spreading. The emergence and rapid spread of COVID-19 confirms that an infectious disease threat anywhere is a threat to Americans everywhere, including here at home.

When, in late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered in Wuhan, China, CDC began monitoring the outbreak. At the beginning of January, CDC began developing regular situation reports, including input from

our respiratory disease experts in the CDC Country Office in China, which were shared with HHS, and reaching out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response structure to facilitate staffing and communications. On January 21, 2020, CDC officially activated its Emergency Operations Center for COVID-19. Using the IM structure, CDC immediately set up task forces to address key needs, reach out to our state and local partners, and deploy staff where needed to support state and local screening and investigation efforts. CDC is an integral part of the COVID-19 response and coordinates with other agencies through the Joint Coordination Center (JCC) led by Secretary Azar. Addressing COVID-19 is an all-of-government effort.

Congress has addressed the urgent need to respond to this pandemic at home and abroad and has allocated substantial resources for CDC's COVID-19 activities through the statutes mentioned above. This funding supports a federally guided, state managed, and locally implemented response to COVID-19 in the United States. With support provided by Congress for global disease detection and emergency response through COVID-19 appropriations, CDC is supporting prevention, preparedness, and response efforts in partnership with public health agencies, health ministry counterparts, and multilateral and non-governmental agencies worldwide. Here in the United States, CDC is working with STLT partners to focus use of these resources to establish and enhance case identification; conduct contact tracing; implement appropriate containment and community mitigation measures; improve public health surveillance; enhance testing capacity; control COVID-19 in high-risk settings; protect vulnerable and high-risk populations; and work with healthcare systems to manage and monitor capacity. As of June 22, 2020, CDC has announced or obligated \$12.1 billion in direct awards to jurisdictions across America from the funds provided by Congress, including \$10.25 billion from the Paycheck Protection Program and Health Care Enhancement Act.

CDC is providing direct technical assistance and support to STLT partners as they consider approaches to mitigate and contain COVID-19. CDC has deployed 149 teams at the request of state, tribal, local, and territorial partners to provide infection prevention and control consultation and epidemiological expertise in support of those on the front lines of this battle. The White House, and federal partners including CDC, have convened calls with all 50 states,

Puerto Rico and the District of Columbia to identify state capacities and needs. The federal government has committed to ensuring that states can meet testing objectives for the month of June, as identified by each state. Through these calls and other outreach efforts, CDC has worked with jurisdictions to identify needs and develop plans to enhance testing capacity, state surveillance, contact tracing, and surge staffing. These discussions and plans for action will emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

In addition, CDC has launched a multifaceted approach to enhance and complement STLT efforts and expand support to communities during the current public health emergency, including deploying over 1,500 individuals to over 100 locations across the United States. These support staff will augment health department teams and engage in core public health functions including contact tracing, testing, infection prevention and control, call center activities, COVID-19 education, and public health surveillance.

CDC relies on timely and accurate public health surveillance data to guide public health action and inform the nationwide response to COVID-19. This crisis has highlighted the need to continue efforts to modernize the public health data systems that CDC and states rely on for accurate data. Public health data surveillance and analytical infrastructure modernization efforts started in FY 2020 using funds provided by Congress, which have been augmented by \$500 million provided for these efforts under the CARES Act. Timely and accurate data are essential as CDC and the nation work to understand the impact of COVID-19 on all Americans, particularly for populations at greater risk for severe illness, such as older Americans, those with chronic medical conditions, and some racial and ethnic minorities.

CDC is working with and providing support to STLT partners as they develop plans to conduct contact tracing. Contact tracing is a core disease control strategy that involves case and contact investigation followed by the implementation of an intervention (for example, isolation and quarantine) that interrupts disease transmission. Case investigation and contact tracer staff have been employed as local and state health department personnel for decades to address other infectious diseases, and contact tracing is a key strategy for preventing further spread of COVID-19 as well as a key component of state plans to reopen. As of June 5, 2020, CDC has posted 12 different guidance documents including case investigation guidelines, checklists for developing a

case investigation and contact tracing plan, digital contact tracing tools, and a Contact Tracing Communications Toolkit for Health Departments.

CDC is also working to understand the impact of COVID-19 on healthcare workers, first responders, and other essential workers. Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is capitalizing on multiple existing surveillance systems run in collaboration with STLT partners, including influenza and viral respiratory disease systems. In collaboration with STLT partners, CDC is committed to making data available to the public, while protecting individual privacy. CDC's population-based COVID-NET system monitors COVID-19 associated hospitalizations that have a confirmed positive test in greater than 250 acute care hospitals in 99 counties in 14 states. Data gathered are used to estimate age-specific hospitalization rates on a weekly basis and describe characteristics of persons hospitalized with COVID-19 illness. CDC also is augmenting the existing National Healthcare Safety Network to monitor and analyze the capacity of the healthcare system daily—including hospitals and nursing homes—so that federal, state, and local officials can adjust their response and mitigation efforts as needed.

CDC is using these data to monitor hospitalizations by race, ethnicity, underlying condition, age, and gender, and is now including this information in CDC's weekly COVIDView summary. CDC is now receiving more granular data on deaths by state and locality, allowing us to identify and work with individual jurisdictions to address where there may be racial and ethnic disparities in morbidity and mortality. CDC is leveraging all available surveillance systems to monitor COVID-19 and protect vulnerable communities. CDC is using diverse systems to define a more complete picture of the outbreak, including race/ethnicity data and is working with communities of color to protect communities at risk. CDC has recently updated the COVID-19 Case Report Form (CRF) to allow for better collection of data on populations that have previously been under-represented in reporting. The initial CRF included questions for sex, age, race and ethnicity and whether the case is part of a recognized outbreak. The revised form includes additional variables for populations that may be at higher risk for severe illness (e.g., tribes) and risk factors (e.g. homelessness, disabilities, and other factors). States have improved the completeness of their CRF reporting in the past two months; in particular, the percentage of reports that include race/ethnicity data has increased from 18 percent in April to 43 percent in

early June. While progress has been made, CDC will continue to work with states to improve completeness of the data. Additionally, new reporting requirements that accompanied more than \$10 billion in funding for states from the Paycheck Protection Program and Healthcare Enhancement Act require states to report race, ethnicity and other important demographic information with test results providing information on those impacted. Furthermore, race and ethnicity data for hospitalizations captured in CDC's COVIDNET has increased to more than 80 percent providing a much stronger picture of the different levels hospitalizations from COVID.

Regarding laboratory support, from the outset, CDC laboratories have been applying sequencing technologies to SARS-CoV-2 and have made the data available through domestic and global databases. CDC is leading the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES), a new national genomics consortium to coordinate SARS-CoV-2 sequencing across the United States to do large-scale, rapid genomic sequencing of the virus. These advanced molecular detection and sequencing activities are being ramped up at the state and local levels to give us a clearer picture of how the virus outbreak is evolving and how cases are connected. CDC is engaged with the National Institutes of Health (NIH), the FDA, and the Biomedical Advanced Research and Development Authority (BARDA) to evaluate serology tests, and CDC is supporting serological surveys to help determine how laboratory testing can contribute to decisions about enabling Americans to return to work.

CDC has developed a new serologic laboratory test to assist with efforts to determine how much of the U.S. population has been infected with SARS-CoV-2, the virus that causes COVID-19. The serology test looks for the presence of antibodies, which are specific proteins made in response to infections. It typically takes one to three weeks after someone becomes sick with COVID-19 for their body to make antibodies; some people may take longer to develop antibodies. The antibodies detected by this test indicate that a person has had an immune response to SARS-CoV-2, regardless of whether symptoms developed from infection or the infection was asymptomatic. However, it is important to point out that, at this point, we do not know whether the presence of antibodies provides immunity to the virus. Currently, CDC's serologic test is designed and validated exclusively for broad-based surveillance and research that is giving us information needed to guide the response to the pandemic and protect the

public's health. The test is currently not designed to test individuals who want to know if they have been previously infected with COVID-19.

During the week of March 30, CDC and public health partners began the first stage of antibody studies of community transmission of SARS-CoV-2. These initial studies use serum samples collected in the state of Washington and New York City. In April, the second stage expanded to include serologic testing in more areas with high numbers of people with diagnosed infections. It also includes studies of households in some states. By using seroprevalence surveys, CDC can learn about people who have been infected, including those infections that might have been missed due to lack of symptoms or testing not being performed for other reasons. These surveys can also track how infections progress through the population over time. This is done by taking "snap shots" of the percentage of people from the same area who have antibodies against SARS-CoV-2 (also called the seroprevalence) at different time points.

On April 27, 2020, CDC updated testing prioritization and focused testing guidelines for those who may have or who are at risk for active SARS-CoV-2 infection. Clinicians considering testing of persons with possible COVID-19 should use commercial or hospital clinical laboratory viral tests for COVID-19 that have been issued an Emergency Use Authorization (EUA) by FDA or are being offered as outlined in FDA's policy regarding COVID-19 tests or continue to coordinate testing through public health laboratories and work with their local and state health departments. Increasing testing capacity will allow clinicians to consider the medical necessity of COVID-19 testing for a wider group of symptomatic patients and persons without symptoms in certain situations. CDC recommends that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing) but some people may present with other symptoms as well.

CDC has developed a new laboratory test that checks for three viruses at the same time, two types of influenza viruses (A and B) and SARS-CoV-2, the virus that causes COVID-19. Testing for all three viruses simultaneously will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find co-infections of influenza and SARS-CoV-2, which is important for doctors to diagnose and treat people properly. CDC requested emergency use authorization (EUA) for this combined laboratory test from the U.S. Food and Drug Administration (FDA) on June 18, 2020. CDC expects that private sector laboratory test developers may be creating similar multiplex assays to meet clinician needs during influenza season. The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID-19. CDC develops and disseminates guidance for a range of audiences, individuals and communities, including business, schools, and healthcare professionals. These recommendations include actions that every American should take, such as following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. CDC guidance is available here <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick-prevention.html>.

CDC released consideration documents to help businesses and community organizations operate as safely as possible during the COVID-19 pandemic, including K-12 schools and universities. These documents complement other CDC resources, including interim guidance documents that are posted online and the decision tools that help communities make decisions about resuming and gradually scaling up operations. These decision tree tools quickly walk through some key questions that should be answered in preparation for phased opening of schools, businesses, mass transit, and other settings. These suggestions are updated as we learn more about COVID-19 and as state and local leaders continue to decide how to adjust mitigation strategies in their communities. School administrators and officials can consult with state and local health officials to determine how to put these considerations into place. In addition, schools may need to make adjustments to meet their unique needs and circumstances.

First responder and healthcare guidance documents cover a range of topics - from addressing potential work-related exposures, implementing infection prevention and control measures in health facilities, and optimizing the supply of personal protective equipment to clinical evaluation, testing, and clinical care. CDC is providing these recommendations to support communities' efforts, while recognizing that each sector and community is unique and will need to consider these in the context of their community-level data and circumstances. CDC teams on the ground and those aiding from Atlanta are and will continue working with state and local officials to integrate these recommendations into COVID-19 plans. CDC offers a framework for providing non-COVID-19 clinical care that outlines key considerations for healthcare systems and health care providers. Key considerations include monitoring trends in local cases and deaths, consulting with state or local health departments for region-specific information and recommendations, following recommended infection control practices, screening all patients for COVID-19 symptoms and expanding services gradually.

Mitigation and containment of COVID-19 are the key to public health strategies, and CDC is committed to using our expertise and partnering with others on the frontlines. While surveillance, testing, contact tracing, and community mitigation interventions are the best tools we have right now, looking to the future, CDC continues to work to prepare our nation's public and private health systems to deliver effectively a COVID-19 vaccine once it is available. This includes working with CDC's 64 immunization grant recipients to help ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking.

While it remains unclear how long the pandemic will last, COVID-19 activity will likely continue for some time. It is also unclear what impact the ongoing COVID-19 pandemic will have on health care and public health systems during the upcoming influenza season. If there is COVID-19 and flu activity at the same time, this could place a tremendous burden on the health care system related to bed occupancy, laboratory testing needs, personal protective equipment and health care worker safety. In the context of likely ongoing COVID-19 activity, getting a flu vaccine is more important now than ever. Getting a flu vaccine will help keep you and your loved ones out of a doctor's offices and hospitals and help conserve scarce medical resources to care for COVID-19 patients.

CDC works with public health and clinical partners each year to increase the number of people who get the flu vaccine and eliminate barriers to vaccination. Ongoing COVID-19 activity may affect where and how flu vaccines are given. CDC is working with manufacturers to maximize flu vaccine supply and with providers and health departments to develop contingency plans so that people can be vaccinated in a safe environment.

In addition, on June 4, CDC awarded \$140 million 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, among other activities, begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for these vulnerable populations. Due to the risk of COVID-19, the goal is to increase flu coverage for vulnerable populations during the 2020-21 flu season, ensure Americans are aware of the importance of getting vaccinated this flu season, and increase access to flu vaccines for uninsured, high-risk adults.

COVID-19 is the most significant public health challenge to face our nation in more than a century. CDC is providing the American public with the information and assistance it needs to address COVID-19 head on. As we work together to fight COVID-19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease threats and to save lives.

National Institute of Allergy and Infectious Diseases

NIH is the HHS agency leading the research response to COVID-19 and the novel coronavirus that causes the disease, SARS-CoV-2. Within NIH, NIAID is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19.

NIAID responds rapidly to threats of emerging infectious diseases, by accelerating fundamental basic research efforts, engaging a domestic and international basic and clinical research infrastructure that can be quickly mobilized, and leveraging collaborative and highly productive partnerships with industry. NIAID also provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research on emerging and re-emerging infectious diseases. These research resources help bridge gaps in

the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by product developers and incentivizing companies to partner with us in developing safe and effective countermeasures including vaccines, therapeutics, and diagnostics.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has enhanced our fundamental understanding of coronaviruses in general and provides a strong foundation for our accelerated efforts to address the specific challenge of COVID-19 by developing vaccines, therapeutics, and diagnostics.

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. 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 July 2020, pending positive results from this Phase 2 trial. The Coalition for Epidemic Preparedness Innovations (CEPI) 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 (RML) in Hamilton, Montana, are collaborating 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 2/3 clinical trial supported by the University of Oxford. BARDA recently announced plans to support advanced development and production of AZD1222. RML investigators also have partnered with University of Washington scientists to investigate another mRNA vaccine candidate against SARS-CoV-2. 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. The COVID-19 response currently is focused on the proven public health practices of containment and mitigation.

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). The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib, which was recently added to the next iteration of the study (ACTT-2). An analysis of preliminary data from 1,063 patients enrolled in the 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*. NIAID is developing and testing other novel and repurposed therapies. A study to evaluate monoclonal antibodies (mAbs) in outpatients with mild-to-moderate COVID-19 is planned for launch in early July. NIAID also is planning separate

clinical trials to assess hyperimmune intravenous immunoglobulin (IVIG) and mAbs for treatment of COVID-19 in hospitalized adults.

On April 6, 2020, the National Heart, Lung, and Blood Institute (NHLBI) launched a clinical trial of HCQ in hospitalized COVID-19 patients through its Prevention and Early Treatment of Acute Lung Injury (PETAL) clinical trials network. NHLBI also 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 (SIREN) 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.

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, 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 Accelerating COVID-19 Therapeutic Interventions and Vaccines (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. NIAID has been asked to lead the effort of U.S. government-supported clinical trials for certain vaccine candidates and some therapeutic interventions that have been considered by ACTIV.

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.

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. RADx 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. This initiative expects to award up to \$500 million to support development of point-of-care and home-based diagnostic devices, as well as innovations that make current laboratory tests faster, more efficient, and more widely accessible. Innovators will be matched with technical, clinical, regulatory, business, and manufacturing experts to increase the odds of success. 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.

NCI 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 sero-protection 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.

Office of the Assistant Secretary for Health

Diagnostics and Testing

Testing for the presence of SARS-CoV-2 is an essential component of our nation's response to the COVID-19 pandemic; its importance is now further magnified as states continue in their various stages of reopening. The indications for viral testing depend heavily on the stage of the pandemic and the extent of mitigation employed. In general, testing may be indicated for diagnosis of those who are symptomatic, tracing of those in contact with those who are infected, and surveillance testing of those who are asymptomatic or mildly symptomatic to achieve infection control and/or other public health objectives.

The Administration has produced numerous documents that establish the strategy and specific tactics for testing in America. These include:

- White House: [Testing Blueprint Opening Up America Again](#)
- White House: [Addendum to the Testing Blueprint](#)
- HHS: [Report to Congress COVID-19 Strategic Testing Plan](#)
- CDC: [Priorities for Testing Patients with Suspected COVID-19 Infection](#)
- CMS: [Long Term Care Facilities \(Skilled Nursing Facilities and/or Nursing Facilities\): CMS Flexibilities to Fight COVID-19](#)
- CMS: [Nursing Home Reopening Recommendations for State and Local Officials](#)

These will be followed soon with a number of additional guidance documents that apply the strategic principles to specific situations. In addition, the Administration is now reviewing testing plans from each state, territory, and major city public health unit, as a requirement of \$10.25 billion in cooperative agreement funding distributed by the CDC.

Currently, there are tests for the presence of the virus and tests for the presence of antibody to the virus. The former determines whether the individual *is* actively infected, and presumably infectious. The latter determines whether the individual *has been* infected, has developed an immune response, and may be protected from subsequent SARS-CoV-2 infections; however, research is ongoing in determining if past infection confers immunity. Today I will

focus mostly on widespread testing for the presence of the virus, which has represented the primary challenge the nation has faced since the onset of the pandemic.

It is useful to understand the overall testing strategy in terms of its chronology and sequential objectives, and to understand that this virus was a new human pathogen for which no diagnostic tests had previously been developed. In addition, the predominant type of test relies on sophisticated RNA amplification technology that can only be done in a laboratory certified to perform moderate or high complexity testing. Point-of-care (POC) tests are an exception in that they are low complexity; however, this class of test still represents a minority of available testing capability and has a defined role because of its low throughput and relatively limited sensitivity especially early or late in the infection. Finally, the pandemic caused an unprecedented demand for all supplies and materials, such that overall demand in a single month approximated total annual demand of some essential supplies and materials. This reality represented substantial challenges, but federal leadership has guided efforts to combat these challenges in close collaboration with states, local jurisdictions, and the private sector. Our overall strategy for testing includes:

- Assuring that those who need testing, receive testing;
- Prioritizing testing to meet the stage of the pandemic;
- Increasing the number, diversity, and quality of tests;
- Enhancing states' ability to collect specimens through novel "front ends" like drive-through community-based testing sites;
- Organizing and galvanizing the industry on an unprecedented scale;
- Enhancing testing to underserved communities;
- Providing surge testing capacity during local outbreaks;
- Supporting critical infrastructure and national security needs; and
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

Stage 1: Launch: Engaging the Emerging Crisis

In the early stages of the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) was engaged in building the foundation for diagnostic testing in the United States. On January 10, 2020, Chinese researchers deposited the 2019-nCoV genome sequence to GenBank and CDC began development of the CDC 2019-nCoV Real-Time PCR Diagnostic Panel. On January 24, CDC publicly posted its assay for the CDC's newly developed diagnostic panel, allowing the global community to develop their own assays using the CDC design. On February 3, CDC submitted an emergency use authorization (EUA) request, and the Food and Drug Administration (FDA) issued an EUA on February 4, just 24 hours after receiving the complete package, enabling use of the CDC's COVID-19 diagnostic panel.

Understanding the importance of increased testing, the FDA engaged test developers from the beginning of the pandemic. Any developer, including labs, could introduce tests through the EUA process, as they had during previous emergencies; and FDA encouraged labs and commercial manufacturers to do so swiftly, engaging with more than 550 test developers since January who indicated their intent to submit requests for EUAs. In mid-January, the Biomedical Advanced Research and Development Authority (BARDA) within ASPR convened a meeting of leading diagnostic companies from across America to encourage development of COVID-19 tests. In the ensuing months, multiple funding opportunities for the development of COVID-19 diagnostic tests were announced and the NIH provided COVID-19 RNA to diagnostic companies to expedite private-sector test development. With a desire to ensure high quality diagnostic testing but also ensure rapid development and dissemination of COVID-19 tests, the FDA has provided voluntary EUA templates for laboratories and manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID-19 tests. This has contributed greatly to the dramatic increases in testing the nation has seen in the past months. The amount and expediency in which EUAs were issued for COVID-19 tests far exceed past viral outbreaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. As of June 25, 2020, FDA has issued more than 150 COVID-19 test EUAs. The timeliness and number of EUAs issued by FDA for COVID-19 tests is unprecedented and has been critical to improving

the testing scale and capacity in our country, while providing enough oversight to assure patients can depend on the results of these tests.

Throughout the COVID-19 outbreak, the Administration has encouraged and worked collaboratively with diagnostic test manufacturers, commercial laboratories, public health laboratories, and professional societies to expand capacity and scale for existing nucleic acid testing platforms. Through the efforts of the Administration, the United States has developed a multilayered, multifaceted approach to testing that can provide the right test to the right person at the right time. This approach includes contributions from state public health labs, high-throughput commercial labs, academic and hospital labs, labs at CDC, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs. In addition, the ecosystem now includes POC testing that can be done in rural areas at high risk without sophisticated supporting infrastructure, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of June 25^h, our nation has performed over 30 million tests, and now at a rate of between 400,000 and 500,000 tests per day; and this number will continue to increase. Commercial laboratories are working more efficiently, processing tests in rapid succession, which ensures patients receive their results, on average, within three days. Hospital and academic laboratories typically provide results within 2 days, and often much sooner. POC tests provide results within 15 minutes.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country. The Corps had unique expertise in COVID-19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 318,000 individuals, and with an overall COVID-19 test positive rate of

approximately 13.5 percent, meaning that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with technological advances such as the validation of the FDA authorized use of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment. The CBTS initiative was an early example to states and localities on how to conduct community based COVID-19 testing, and this model has been replicated throughout the country to screen and test hundreds of thousands more Americans. Majority of the federally supported community based testing sites have been transitioned to be state led efforts and the few remaining sites will be transitioned in the weeks to come.

From the onset in January, and continuing to the present, the President, Vice President, and senior Administration officials have held numerous briefings with governors and their state leadership. Many of these briefings have focused on joint federal-state efforts to expand testing throughout the country. In addition to these calls with the Nation's governors, the White House and senior Administration officials have organized numerous calls to enhance state, local, territorial and tribal testing coordination efforts. The constant communication between the Administration and state leadership has helped provide guidance to states on how to best utilize testing capacity in their own states. Another product that was produced by the Administration to assist the states to leverage the full testing capacity at their disposal was a database of nationwide lab locations and capacity, including the specific testing platforms at each laboratory.

Stage 2: Scaling and Technological Innovation

The identification and expansion of public and private sector testing infrastructure has been, and continues to be, a priority. One example of expanding testing infrastructure through public-private partnerships is the engagement of the Administration with well-known retailers that have a regional or nationwide footprint. As of June 26, and with the assistance of the Federal Government, U.S. retailers have opened and are operating 624 testing sites in 48 states and the District of Columbia, and they have tested over 774,000 individuals. The federal government built public-private partnerships to increase the number of testing sites offered at commercial locations across the country. The public-private partnerships with these retailers are being expanded to support many more testing sites that will be opened and operating in the

coming weeks. These commercial testing locations are uniquely situated to meet the testing needs of communities with moderate to high social vulnerability, which was the focus of the original sites. Going forward, retailers have indicated their intent to open at least one thousand more of these sites depending on local needs.

Another effort of the Administration to further support and expand the testing infrastructure in the United States has been strengthening the testing supply chain. The Administration has massively increased the availability of laboratory and testing supplies by engaging directly with distributors and manufacturers to increase production capacity through direct procurement, application of the Defense Production Act, formation of various public-private partnerships, and improved allocation criteria that ultimately help ensure that supplies meet the state's needs and reach the locations where the supplies are needed most. In addition, validation of additional supply types has led to a dramatic broadening of available supplies and reagents.

In May alone, working collaboratively with FEMA and utilizing their logistics, the Federal Government has procured and began to distribute to states – according to their needs and plans – over 12.8 million specimen collection swabs and more than 8.9 million tubes of transport media. To meet state needs, this procurement and distribution will continue in June and the following months, as necessary.

Stage 3: Support Opening Up America Again

Current efforts are focused on further scaling up testing capabilities to guarantee that each state has the testing supplies and capabilities they need to reopen according to their own individual state plans. For example, the Federal Government procured over 20 million swabs and tubes of transport media (or saline) in June. These supplies will be shipped out to states over the course of the next few months. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million laboratory testing extraction and PCR kits per month, enabling states to complete millions of additional tests starting in May. In mid-March, the FDA issued an EUA for Hologic's Panther COVID-19 test, which runs on more than 600 lab machines across the United States. Beginning in early May, Hologic began shipping several million test kits per month to labs across the nation.

The Administration will continue to work hand in hand with governors to support testing plans and rapid response programs. The Opening Up America Again guidelines, provided by the Administration, describe roles and responsibilities as well as elements of the robust testing plans and rapid response programs called for in the President's Guidelines.

The Laboratory Testing Task Force is providing technical assistance to all 50 states, tribes, and territories through calls with every state public health team to discuss their testing goals and the best mechanisms to achieve them. The federal government is assisting states to develop testing plans, supplying resources to help meet these testing plans, and deploying teams to states that need additional subject matter expertise.

On May 24th, HHS delivered a COVID-19 strategic testing plan to Congress. This Plan is a direct outgrowth of the work done by the Laboratory Testing Task Force and Community Based Testing Task Force, both under the leadership of HHS and supported by FEMA personnel within the NRCC. It outlines how HHS increased domestic testing capacity across the United States and provides additional guidance and information about diagnostic technologies, platforms and inventory that states, territories and tribes can utilize to develop flexible, adaptable, and robust COVID-19 testing plans. This report fulfills a requirement of the Paycheck Protection Program and Health Care Enhancement Act, signed into law on April 24th. Furthermore, HHS recently distributed \$11 billion in support to states, territories, and tribes to support implementation of jurisdictional testing goals as well as a broad array of activities associated with testing, as indicated in the Paycheck Protection Program and Health Care Enhancement Act.

Because of the Administration's success in rapidly scaling up of the testing ecosystem, states will be fully equipped to conduct more COVID-19 tests per capita each month than most countries have tested cumulatively to this date.

The federal government will continue to support Americans by providing expedited regulatory approvals for tests and equipment as necessary and appropriate, updating guidance for administering diagnostic testing, and catalyzing technological and scientific innovation. The process of reopening the United States will be one that is federally supported, state-led and locally executed.

We recognize that vulnerable populations in many underserved communities are among the highest risk of suffering devastating health and economic impacts of COVID-19. The Office of Minority Health issued a Notice of Funding Opportunity on May 1. On June 23rd, the HHS Office of Minority Health (OMH) announced the selection of the Morehouse School of Medicine as the awardee for a new \$40 million initiative to fight COVID-19 in racial and ethnic minority, rural and socially vulnerable communities. The Morehouse School of Medicine will enter into cooperative agreement with OMH to lead the initiative to coordinate a strategic network of national, state, territorial, tribal and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic. The three-year initiative will include the development and coordination of a strategic and structured network of national, state, territorial, and local public and community based organizations that will help mitigate the impact of COVID-19 on racial and ethnic minorities as well as rural and socially vulnerable communities across the nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most.

On June 4th, using authorities provide to the Secretary under the CARES Act, HHS released new mandatory laboratory data reporting guidance for COVID-19 testing. This guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform COVID-19 response efforts, including data on demographic information such as race, ethnicity, age and gender. This will help ensure that all groups have equitable access to testing, and will equip public health professionals with the data to determine accurately the burden of infection on vulnerable groups.

To further support testing efforts in underserved communities, in May the Health Resources and Services Administration (HRSA) awarded \$583 million to 1,385 health centers to support COVID-19 testing efforts. Health centers serve over 28 million patients in 12,000 service delivery sites across the nation and in the territories. They provide care to 1 in 5 of those uninsured, 1 in 5 rural Americans, 1 in 3 individuals below the poverty line, more than 1.4 million homeless individuals, and nearly 1 million migrant agricultural workers. Health centers are uniquely situated in communities to serve those that are most vulnerable and 93 percent of

these centers offer COVID-19 testing. As of June 26, health centers have reported testing nearly 1.3 million individuals in total and racial and/or ethnic minority patients represent 55 percent of those tested in the past week.

United States Public Health Service Commissioned Corps

Since the early stages of the COVID-19 outbreak, the Corps has been an indispensable asset leveraged to address the public health needs of the nation in response to this crisis. The Corps is one of the eight uniformed services of the United States and the only uniformed service committed to protecting, promoting, and advancing the health and safety of the nation. Corps officers serve throughout the nation in communities that are most in need by providing essential healthcare services to underserved and vulnerable populations.

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 4,532 officers as of June 24, 2020, with many of them undertaking multiple or consecutive deployments. Corps officers have been deployed across our country and internationally to assist with the outbreak response, to support the return of American citizens, to assist in the management of hospitalized U. S. citizens with COVID-19 abroad, and to support clinical trials related to COVID-19. Corps officers provided critical assistance to community-based testing sites throughout the nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID-19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a “cavalry” to support healthcare systems under stress in states across the country. COVID-19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City, and to the TCF Center in Detroit. At the end of March, the Navajo Nation requested CDC assistance to provide care amidst a surge of COVID-19 cases. Since that time, the Corps has deployed teams to support the response. The Corps has also deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

The United States Public Health Service Commissioned Corps stands ready and willing to respond to the public health needs of our country and to provide essential healthcare services.

Food and Drug Administration

From the beginning of this public health emergency, FDA has taken an active leadership role in the all-of-government response to the COVID-19 pandemic, inspired by the resiliency of the American people and our great innovators. FDA stood up an internal cross-agency group that continues to ensure we are doing everything possible to protect the American public, helps ensure the safety and quality of FDA-regulated products, and provides the industries we regulate the tools and flexibility to do the same. Work has focused on facilitating the development and availability of medical countermeasures to diagnose, treat, and prevent COVID-19, surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary to protect the health. This work is a key component of the federal government's efforts to address this pandemic and reopen the economy so Americans can get back to work and school.

Diagnostic Testing

An important part of FDA's role concerns determining whether the tests developed for clinical use in the United States provide accurate and reliable results and to help provide timely access to such tests. In general, during an emergency, including this pandemic, FDA oversees the validity of tests developed by others through the Emergency Use Authorization (EUA) process. Every action FDA has taken regarding testing during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make tests available with a level of oversight to help ensure accurate tests are being deployed.

COVID-19 has created a demand for new tests that is unprecedented in both volume and urgency. FDA has been extremely proactive and supportive of diagnostic test development by all comers, laboratories, and large and small commercial manufacturers. Even prior to any diagnosed U.S. cases of COVID-19, FDA proactively reached out to developers to encourage the development of tests and to offer assistance from the Agency to help facilitate development. To balance the urgent need to increase diagnostic testing capacity in the U.S. with the need to

provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA has announced several policies to facilitate oversight. These include engaging in rolling reviews of EUA submissions, and authorizing tests that have the necessary data to support that the criteria for issuance are met. To date, we have authorized more than 150 EUAs for COVID-19 tests. States that have the capacity and expertise to do so have been authorizing tests for use within a laboratory in that state.

In a public health emergency, getting an accurate test is important not only for the individual patient, but for the public at large. False positive or false negative results can contribute to the spread of COVID-19, so all tests used for COVID-19 should be validated before use. FDA's public health emergency policies do not change that. As with medical treatments, we want tests to be safe and, accurate. FDA is monitoring imported test kit products and where appropriate detaining and examining them at the ports and border and is engaging in outreach when we become aware that test developers are making false or misleading claims about their tests. We are monitoring the market for fraudulent tests and are not issuing EUAs for tests that do not meet the EUA standards. FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk. FDA updates its website continually to make clear which tests have been authorized by the Agency, and which tests have not.

FDA has been working around the clock to 1) encourage and support test development for the U.S. market, working with over 500 developers since January; 2) issue EUAs for diagnostic tests, including those for home self-collections; 3) research and mitigate shortages of test components, including identifying and sharing scientifically acceptable alternatives for components on FDA's website; 4) arrange with the Department of Defense weekly airlifts of swabs to the United States; 5) engage nontraditional device manufacturers to support use of new swabs and other supplies that are needed in the United States; and 6) offer support to developers through a hotline and key resources, including FAQs that are updated regularly and serve as a clearinghouse for scientific information that helps everyone increase testing capacity.

Serological Testing

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like the virus that causes COVID-19. Such a test detects the body's immune response to an infection. These tests do not diagnose a current

COVID-19 infection; however, they can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have overcome an infection in the past and may have developed an immune response. These tests may also aid in identifying individuals with antibodies to the virus that causes COVID-19 so they may donate convalescent plasma as a possible treatment for severely ill COVID-19 patients, which is a potential treatment currently being researched.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serological tests to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable, without FDA authorization and as further recommended in the policy. The policy was intended to allow for early patient access and flexibility for developers, with appropriate transparency regarding the limitations of these tests. At the time FDA issued this policy, flexibility was important to allow for early use of antibody tests to begin to answer some of the critical population-level questions about the prevalence of COVID-19 infections in different communities, whether the presence of antibodies conveys immunity and, if so, for how long, while also encouraging test developers to seek an EUA, as many did. Answering these questions is critical for informing how best to use these tests, but we could not answer these questions without tests being available.

Once FDA had authorized more serology tests, we built on this policy by updating it on May 4th and again on May 11th to outline key expectations for antibody test developers, including that commercial manufacturers would submit EUA requests, with their validation data, within 10 business days from the date they notified FDA of their validation testing or from the publication date of the policy, whichever was later. FDA also provided specific performance recommendations for serology test developers. The policy for laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing regarding their developing and performing their own serology tests was not changed. Such laboratories perform their own validation and provided notification to FDA while following other recommendations with respect to labeling as described in the policy.

FDA has also introduced a more streamlined process to support EUA submissions and review. Two voluntary EUA templates for antibody tests have been made available – one for commercial manufacturers and one for CLIA certified high-complexity labs that decide to seek

FDA authorization. These templates can help facilitate the preparation and submission of an EUA request and can be used by interested developers. Also, as we do for diagnostic tests, we are happy to work with developers of serology tests on other approaches if they do not want to use one of the templates.

We are continuing to provide updated information and educational materials to states and health care partners. When particular commercial manufacturers that are currently marketing serology tests under the May 4th and May 11th policy fail to submit an EUA within 10 business days of notification or policy publication (whichever is later), we have been removing those tests from our website notification list and are sharing this information publicly. We will also keep up our work to stop illicit tests from entering the U.S. and to keep fraudulent products off the market.

In addition, FDA issued an umbrella EUA for certain antibody tests that undergo a validation evaluation at NCI or another government agency designated by FDA. Tests that FDA confirms meet the performance and labeling criteria, among other conditions outlined in the umbrella EUA, can be authorized under this umbrella EUA, streamlining the submission and review of these important tests.

FDA will continue to appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. Importantly, we continue to work with developers of serological tests and are reviewing submitted EUA requests to authorize even more of these tests. I continue to work closely with my fellow Coronavirus Task Force members in examining the role testing will play as we look to reopen our country's schools, businesses, and public services.

Vaccine and Therapeutic Development

At this time, there is no FDA-approved vaccine to prevent being infected with COVID-19, nor are there any FDA-approved drug products to treat COVID-19. FDA is working closely with federal partners, vaccine developers, researchers, manufacturers, and experts across the globe to help expedite the development and availability of vaccines and drugs to prevent or treat COVID-19 infections. FDA intends to use regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID-19.

Since the beginning of the COVID-19 pandemic, FDA has been working tirelessly to facilitate the development and availability of therapeutics for use by patients, physicians, and health systems as expeditiously and safely as possible. FDA announced on March 31, 2020 the creation of an emergency review and development program for possible therapies for COVID-19: the Coronavirus Treatment Acceleration Program, or “CTAP”. The Agency is supporting the program by reassigning staff and working continuously to review requests from companies, scientists, and doctors who are working to develop therapies. Under CTAP, FDA is using every available authority and regulatory flexibility to facilitate the development of safe and effective products to treat patients with COVID-19.

Further, FDA is partnering with the NIH in its efforts to develop a national strategy for a coordinated research response to the pandemic. The Accelerating COVID-19 Therapeutic Interventions and Vaccines, or ACTIV, partnership is developing a framework for prioritizing vaccine and drug candidates, streamlining related clinical trials, coordinating regulatory processes, and leveraging assets among all partners to rapidly respond to COVID-19 and future pandemics.

There are a variety of therapeutic products being evaluated, including antiviral drugs and immunotherapies, that may be helpful in reducing lung inflammation and improving lung function in COVID-19 patients. All this work is beginning to pay off, and we have announced the positive results of the NIAID trial of remdesivir in patients with severe COVID-19. On May 1, FDA issued an EUA for remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease.

Another potential approach for treatment is the use of antibody-rich products such as convalescent plasma and hyperimmune globulin. These blood products are manufactured from plasma donated by people who have recovered from the virus and such products are being studied to determine if they could shorten the length, or lessen the severity, of the illness. We are evaluating convalescent plasma in the context of clinical trials and facilitating a national expanded access program and emergency access for individual patients, as appropriate. A key to ensuring the availability of convalescent plasma to those in greatest need, as well as to supporting clinical development of convalescent plasma and hyperimmune globulin, has been by persuading fully recovered COVID-19 patients to donate plasma if they meet FDA's donor

eligibility criteria. To that end, FDA continues to work with blood collectors to facilitate the collection of convalescent plasma, and to work with developers of these therapies to move forward with clinical evaluations. Thousands of COVID-19 patients have received investigational COVID-19 convalescent plasma under FDA's pathways for use of investigational products, including expanded access and clinical trials.

Medical Product Supply

FDA monitors and proactively adjusts to the worldwide demand and supply chain disruptions for medical products caused by the COVID-19 pandemic. We are working closely with manufacturers to help ensure they continue to notify the Agency of any permanent discontinuance or interruption of drug, biological product, and device manufacturing in a timely manner. In addition to our usual communication with drug manufacturers, we are work closely with healthcare and pharmacy systems, hospitals, providers, and others on the frontlines of COVID-19 patient care to identify current or emerging regional shortages of critical care drugs used to treat COVID-19.

FDA understands the significant impact shortages can have on patient care and is doing everything within our authorities to help prevent and alleviate this impact. For example, we issued temporary policies under which outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or federal facilities can compound certain drugs used to treat patients with COVID-19 under particular conditions explained in FDA guidance.

In addition, when we identify a shortage, we react swiftly to mitigate the impact to U.S. patients and health care professionals, and quickly share that information with the public. For example, the Agency quickly identified the need for making hand sanitizers available as demand spiked. FDA has published and updated three guidances to facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. As another example, the Agency granted an EUA to authorize use of propofol approved in the European Union, thus alleviating a shortage of this critical drug for COVID-19 patients who need to be on a ventilator.

We are working to increase the supply of personal protective equipment (PPE) and other critical devices that patients and those on the front lines of the U.S. response rely upon. FDA has

reached out to over 1000 manufacturers since January and has helped facilitate an increase of the availability of PPE while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them. FDA has issued several EUAs to help make more respirators available to health care personnel and ease burdens on the health care system. These allow for the emergency use of NIOSH-approved respirators in health care settings for healthcare personnel and the importation of non-NIOSH approved respirators that meet certain specified criteria, as set forth in the various EUAs. FDA has also issued several guidances to provide flexibility for those manufacturing PPE for the COVID-19 response, and we have published conservation strategies for gloves and masks and gowns. To support these efforts further, FDA has issued several EUAs for devices used to decontaminate respirators for reuse by health care workers in hospital settings, where appropriate.

FDA has also issued guidances for several other critical devices including ventilators, clinical electronic thermometers, and imaging systems, as well as remote digital pathology and remote monitoring devices intended to help facilitate remote care that puts patients and health care providers at less risk for exposure to COVID-19.

FDA has worked steadily to support those manufacturing PPE, as well as those who are dealing with limited supplies and shortages, to provide alternatives when there are no other options available. This includes initiating biweekly virtual town hall meetings for those seeking and manufacturing respirators to ask questions and discuss challenges they are facing.

FDA's policies and active engagement with the medical product and healthcare community have helped to accelerate patient access to critical devices. FDA appreciates Congress including provisions in the CARES Act for additional device shortages authority during or in advance of a declared public health emergency and looks forward to continuing to work with members of Congress to expand further these authorities, consistent with the FY 2021 Budget so that we can address shortages in other situations as well.

Food Supply

FDA is working with our federal, state, and local partners as well as industry to help ensure a safe and adequate food supply for both people and animals. I want to reassure you there is no evidence of food or food packaging being associated with transmission of COVID-19.

Although food production and manufacturing in the United States remains strong, resilient, and is for the most part dispersed throughout the United States, some components are under stress. We are monitoring these situations closely and identifying mitigation strategies.

There has been a significant shift in where consumers are buying food, because of the pandemic. We have taken steps to provide temporary guidance to provide flexibility in packaging and labeling requirements to help industry divert products manufactured for food service and institutional use to retail grocery stores.

FDA recognizes that the food supply chain is dependent on the safety of the nation's food and agricultural workforce. Along with our federal partners, we have provided best practices for food and agricultural workers, industry, and consumers on how to stay safe, and help ensure the continuity of operations in the food and agriculture critical infrastructure sector during the pandemic and as retail establishments begin to reopen. FDA's Coordinated Outbreak Response and Evaluation team has been working throughout the pandemic, is fully staffed, and on-the-job looking for signs of foodborne illness outbreaks. FDA continues to monitor closely the overall safety of the nation's food supply. Importantly, we continue to work with CDC, the U.S. Department of Agriculture, and our state and local partners to protect consumers from foods contaminated with pathogens. For example, in March, FDA found and detained *Salmonella*-contaminated tahini products at the port of entry; products that were already in U.S. distribution were recalled. Earlier this month FDA started investigating a multistate outbreak of *Cyclospora* illnesses potentially linked to store brand garden salads; three retailers have recalled the product.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from firms and individuals selling unproven products with false or misleading claims to prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil and criminal enforcement actions, where appropriate. For example, FDA has sent hundreds of abuse complaints to domain name registrars and internet marketplaces, which in most instances have voluntarily removed listings for products that fraudulently claim to diagnose, cure, mitigate, treat, or prevent COVID-19. The Agency also has sent more than 50 warning letters to sellers of such fraudulent products. Working with the Department of Justice, FDA has sought and obtained several preliminary injunctions that require defendants to halt the sale of fraudulent

products claiming to treat or prevent COVID-19, including one product that, when used as directed, is equivalent to industrial bleach.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining, reviewing, and sampling import entries, and refusing admission where appropriate. We protect the supply chain in two equally critical ways: first, we help ensure safe products are coming in and second, that illegal, dangerous and fraudulent products do not get into the country. As FDA import staff screen medical products entering our country, we also find and block the entry of fraudulent products that falsely claim to prevent, treat, mitigate, diagnose, or cure COVID-19. For example, in March, at the border, FDA intercepted fraudulent COVID-19 “treatment kits” that were falsely declared as “water treatment.” Import examination of these shipments found misbranded “kits” intended to treat SARS-CoV-2. This joint investigation, which included FDA’s Office of Criminal Investigations, led to an arrest in the UK by law enforcement partners there. In addition, in April, FDA intercepted a bulk shipment of hydroxychloroquine coming from China going to a physician in California. The physician was charged with smuggling hydroxychloroquine from China to make his own pills and concealed the shipment from CBP by misdeclaring it as yam extract. In May, FDA worked with U.S. Customs and Border Protection (CBP) to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before getting into U.S. commerce.

We are in close communication with our partners at U.S. CBP to proactively identify and mitigate any potential backlogs. FDA participates in FEMA Supply Chain Task Force meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by FEMA, to facilitate the lawful entry and use of imported medical products coordinated through FEMA, and to inform medical product supply chain discussions.

Conclusion

HHS appreciates the support and interest of Congress in our work related to COVID-19. We look forward to continuing to work together as the country continues to open safely again. Thank you for the invitation to testify today and we look forward to answering your questions.