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COVID-19: An Update on the Federal Response

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Introduction

Chairman Alexander, Ranking Member Murray and distinguished members of 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 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. Congress passed 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 Food and Drug Administration (FDA), and the Assistant Secretary for Health, 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 prevent illness, save lives and protect America from health, safety, and security threats. CDC has a key role in

preparedness and response in the United States and abroad, and addressing infectious diseases like COVID-19 is central to our mission.

When there is an emerging pathogen like the SARS-CoV-2 virus, CDC expertise lies in our ability to study the new pathogen to understand how it is transmitted, and translate that knowledge into public health action. Since first learning of the cluster of cases in Wuhan, China, CDC has rapidly advanced the science around this new human pathogen, SARS-CoV-2. CDC has been both on the forefront of understanding this new disease and led the nation's efforts to protect Americans from infection. Currently, over 6,700 CDC employees have been engaged in the agency's COVID-19 response, and over 1,200 of these staff have been deployed to nearly 200 different locations in the United States and abroad. CDC staff have conducted rapid investigations of outbreaks that identified highest-risk priority populations and settings. Understanding specific population-level vulnerabilities and how infections spread in various types of settings has been instrumental in the development of guidance that will help keep the American people healthy and allow critical infrastructure services to be provided safely. For example, after data emerged that contrary to expectation, SARS-CoV-2 could be transmitted by people without symptoms, CDC recommended that people wear masks around others who do not live in their households, especially in settings where it is difficult to maintain a distance of six feet. There is increasing evidence that masks help prevent people who have COVID-19, including those without symptoms, from spreading SARS-CoV-2 to others.

The *Morbidity and Mortality Weekly Report* (MMWR), sometimes called the "voice of CDC," has published more than 100 COVID-19 reports since the beginning of the pandemic, providing cutting-edge scientific articles that have been viewed by tens of millions of readers. These reports have provided the public, scientists, healthcare workers, and policymakers critical information about the virus, how it spreads, and the communities it has impacted. MMWR publications yielded the earliest descriptions of asymptomatic and pre-symptomatic transmission of the virus and elucidated the substantial risk of transmission at large gatherings, choir practices, and congregate living situations, including nursing homes, prisons and jails, meat processing plants, homeless shelters, and camps for children. They have described the disparate impact of COVID-19 in racial and ethnic minorities and identified the elevated risk of severe outcomes for older adults and people with underlying conditions. Finally, the MMWR has indicated what successful control of the virus looks like, through careful mitigation efforts in everyday high-risk

settings such as hair salons and childcare centers. In short, MMWR's rapid publication of the highest quality science has laid the foundation of what we know about COVID-19 and illuminated the way forward.

In addition to publishing our own scientific information on SARS-CoV-2 and COVID-19, CDC scientists are monitoring in real time the rapidly expanding scientific literature and have reviewed over 100,000 scientific papers thus far. This ensures that CDC responders are armed with the best information available. This comprehensive understanding of the emerging science base helps direct CDC's scientific agenda and informs CDC guidance, and helps guide CDC's direct support of clinicians and the public. Since January 20, 2020, CDC's hotline for public inquiries has responded to nearly 500,000 calls and e-mails, including 32,000 from clinicians.

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 carry out research and share new knowledge related to this novel pathogen and its consequences. CDC provides guidance for healthcare professionals, essential workers, businesses, schools, and the public to encourage safer practices, improve health outcomes, and save lives. CDC works with partners to develop decision tools to assist STLT officials and other stakeholders with mitigation strategies. Importantly, CDC is preparing the nation's public health system and the private sector to disseminate a safe and effective vaccine when one is available. CDC is leveraging investments in global health security and pandemic influenza preparedness infrastructures in over 60 countries to mitigate the effects of COVID-19 and stop the disease from spreading.

As of September 20, 2020, there have been 6,748,935 COVID-19 cases reported and 198,754 deaths attributed to the virus in the United States. The latest data can be found on CDC's website: https://www.cdc.gov/covid-data-tracker/index.html. The U.S. Government has taken unprecedented action to address the public health threat posed by this new coronavirus. CDC has substantial supplemental funding to help respond to this pandemic at home and abroad. This funding supports a federally guided, STLT government managed, and locally implemented response to COVID-19 in the United States.

With funds provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act and the CARES Act, CDC is providing jurisdictions with resources needed

to detect, respond, and prevent the spread of SARS-CoV-2 and to inform community mitigation strategies.

CDC's highest priority is to ensure that STLT public health programs have the resources they need to address the COVID-19 pandemic. These jurisdictions are best positioned to understand the unique situation of each community, including the status of their public health infrastructure and workforce and its needs for enhancement. CDC is supporting STLT partners who are working to identify cases; conduct contact tracing; implement containment measures and mitigate spread of the virus in the community. CDC is working alongside these health departments to improve surveillance and reporting and enhance testing capacity. Together, STLT and CDC teams are responding to COVID-19 outbreaks in high-risk settings and implementing best practices to control the spread of the virus.

As a public health agency and the nation's primary resource for STLT health departments on managing disease outbreaks, CDC provides guidance and support for the development and implementation of effective containment and community mitigation strategies. The goal is for all jurisdictions to have robust public health systems, which include a contact tracing infrastructure that meets their unique needs. As of September 2020, CDC has posted over 30 contact tracing 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. To support these activities, CDC has awarded $12.1 billion to these entities in FY 2020, including $10.25 billion in funds executed on behalf of HHS to be used primarily to support each jurisdiction's testing goals (as outlined in state testing plans).

Testing Strategy

Beginning in April, the White House, and Federal partners including CDC, convened calls with all 50 states, Puerto Rico, and the District of Columbia to identify testing capacities and needs. Through these calls and other outreach efforts, CDC, under the leadership of the Office of the Assistant Secretary for Health (OASH), has worked with individual jurisdictions to identify needs, develop plans, and offer technical assistance to enhance testing capacity. From June 30 to July 17, following an initial review by CDC and OASH, the Association of Public Health Laboratories (APHL) reviewed individual state testing plans with a focus on achieving

increased monthly testing targets. These discussions and plans for action emphasize the need to serve disproportionately affected populations and include focused efforts for long-term care facilities, federally qualified health centers, American Indian/Alaska Native serving health facilities, and urban health facilities, among others.

CDC is working with STLT health departments to support forward-looking testing strategies that ensure that populations at higher risk, such as persons of color, have adequate access to testing. For example, CDC worked with the Health Resources and Services Administration (HRSA) and Federally Qualified Health Centers (FQHCs) to survey FQHCs and better understand the populations they are serving. Approximately 60 percent of responding FQHCs are in urban areas, where persons of Hispanic or Latinx ethnicity were the largest proportion of individuals testing positive for SARS-CoV-2. This information allows STLT health departments to implement strategies to increase testing in FQHCs and provide them with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

CDC has developed a new multiplex 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, using a single sample collected from an individual. Testing for all three viruses will allow public health laboratories to continue surveillance for influenza while testing for SARS-CoV-2. 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. The FDA issued an Emergency Use Authorization (EUA) for this combined laboratory test on July 2, 2020, and CDC released these reagents for distribution to states' public health laboratories on August 5, 2020. As of August 17, 2020, 135 multiplex kits were shipped to more than 100 laboratories. Each kit provides approximately 500 tests. Adjusting for the controls, 135 kits provides approximately 67,000 tests. CDC has provided these kits to each state's or territory's main public health laboratory, as well as any regional or local laboratories that are approved to provide SARS-CoV-2 surge testing support. Importantly, multiplex assay technical information is publicly available on CDC's website so that commercial developers can use this information in developing proprietary tests. CDC also granted assay manufacturers a right of reference to the data submitted in its EUA request to FDA, allowing developers to use the data to streamline their

efforts when requesting an EUA. CDC took these steps to catalyze the development and validation of assays that can detect and differentiate SARS-CoV-2 from influenza by the commercial sector.

In March 2020, CDC and public health partners began seroprevalence surveys of community transmission of SARS-CoV-2. Seroprevalence surveys help identify infections that might be missed due to lack of symptoms or testing not being performed. Serology studies can also help determine risk factors associated with SARS-CoV-2 infection, including transmission in health care settings, and inform guidance and mitigation strategies. For example, CDC has published the results from one of the seroprevalence studies that used remnants of samples collected during routine clinical care. This was done in conjunction with two commercial companies and results suggested that greater than 10 times more SARS-CoV-2 infections occurred than the number of reported COVID-19 cases. Another study on healthcare personnel who routinely cared for COVID-19 patients found that 6 percent had evidence of previous SARS-CoV-2 infection. This study identified two factors potentially associated with SARS-CoV-2 infection among health care personnel: personal protective equipment (PPE) shortages and not wearing a mask while interacting with patients.

Data Collection, Analysis and Understanding of the Pandemic

CDC, in concert with HHS, continues to focus on data modernization efforts including expanding core data, informatics, and IT capacity; advancing interoperable systems and tools; strengthening and expanding collaboration with and support for partners and; coordinating data and IT investments and governance.

Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is leveraging all available surveillance systems, including influenza and viral respiratory disease systems, to monitor COVID-19 and protect disproportionately affected communities. These data collected by CDC help target critical COVID-19 interventions. In collaboration with STLT public health partners, CDC is committed to making data available to the public, while protecting individual privacy.

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. 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. Modernization efforts include support for the surveillance and data workforce, a key asset of the public health system. For example, CDC is working closely with our partners to help STLT health departments implement the Sara Alert system. Sara Alert is a standards-based, open source tool that automates the process of public health monitoring and reporting individuals exposed to, or infected with, COVID-19. To date, nine states and two territories, along with eight counties and one Tribal Council, have adopted the Sara Alert system. Almost 350,000 individuals have been monitored since April 8. During an average week, close to 80,000 individuals roll in and roll back off of monitoring through Sara Alert.

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 provide weekly estimates for age-specific hospitalization rates and describe characteristics of persons hospitalized with COVID-19 illness as well as predictors of those with more severe outcomes. CDC's existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and other long-term care facilities. NHSN also continues to collect data from hospitals across the United States to address healthcare-associated infections and fight against antibiotic resistance.

The COVID-19 Case Report Form includes variables such as race and ethnicity to enable identification of populations that may be at higher risk for severe illness and risk factors. Though states are not required to report demographic information in the Case Report Form, they have improved the completeness of their reporting. In particular, the percentage of reports that include race data has increased from 21 percent in April to 63 percent in mid-September, while the percentage of reports that include ethnicity data increased from 18 percent to 52 percent during the same time period. While progress has been made, CDC will continue to work with states, tribes, territories, and other health system partners to improve completeness of the data.

Health Disparities

COVID-19 has disproportionately impacted many racial and ethnic groups. CDC continuously looks to enhance our COVID-19 outreach and mitigation efforts for communities

identified as highest risk. For example, CDC is supporting local activities in Black and African American, Hispanic/Latino, American Indian and Alaska Native, and Asian American, Pacific Islander, and Native Hawaiian communities to deliver COVID-19 prevention messages and community mitigation strategies. CDC recently released a COVID-19 Health Equity Strategy (www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html) that provides an evidence-based, comprehensive and coordinated framework for reducing COVID-19 disparities. The Strategy includes expanded plans for collecting and reporting timely, complete, representative, and relevant data on testing, incidence, vaccination, and severe outcomes among populations at highest risk. Additionally, CDC is working with existing program grantees, such as Racial and Ethnic Approaches to Community Health (REACH), and tribal grantees through a number of programs, to enhance outreach to populations at increased risk of complications from COVID-19. These broad-based community engagements and strategies are working with the aim of ensuring equitable access to testing, health care, and future COVID-19 vaccines.

American Indian and Alaska Native communities are some of the most affected by COVID-19. As of August 2020, CDC has provided $206.4 million to tribal nations, consortia, and organizations for responding to COVID-19 across tribal communities. This amount exceeds the minimum of $165 million directed by Congress through the Coronavirus Preparedness and Response Supplemental Appropriations Act and the CARES Act. CDC is using a multifaceted approach, guided by data, to allocate COVID-19 funding to tribal communities, enabling broad access to COVID-19 resources through a variety of direct and indirect supports.

Children

We are learning more about how COVID-19 impacts children every day. Although children are less likely than adults to develop severe illness when infected with SARS-CoV-2, household studies and outbreak investigations confirm that children can transmit the virus and often have the same or higher viral loads in their nasopharynx compared with adults. Though the mortality rate is low for children aged 18 years and younger, COVID-19–associated hospitalization rates increased among this age group during the summer. From March 1, 2020 to July 25, 2020, one in three hospitalized children was admitted to an intensive care unit.

CDC is committed to providing schools, teachers, staff, parents, and caregivers with information and guidance to help keep our children as safe and healthy as possible as schools

reopen. CDC has developed enhanced guidance based on the most recent science, including considerations for operating schools during COVID-19, considerations for Institutions of Higher Education regarding the appropriate use of testing, and a school decision-making tool for parents, guardians, and caregivers. These resources provide students, school administrators, and parents the information they need to guide decision-making and how to adapt to local conditions.

Vaccine Planning

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 a safe and effective COVID-19 vaccine once available. CDC is working closely with the Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts who develop recommendations on the use of vaccines to control disease in the United States. ACIP members have expertise in areas such as vaccinology, immunology, internal medicine, family medicine, virology, public health, infectious diseases, and/or preventive medicine, and one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. An August ACIP meeting focused on post-marketing vaccine safety surveillance, epidemiology of individuals at increased risk of COVID-19, and modeling allocation strategies of the initial COVID-19 vaccine supply. Any recommendations ACIP makes and CDC adopts for who should get COVID-19 vaccine and in what order will be grounded in guidance from the country's foremost experts on immunization science.

CDC is using its expertise in public health preparedness and response, along with its immunization infrastructure, to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring. On September 10, CDC and its Operation Warp Speed partners conducted a vaccine implementation tabletop exercise in Washington, D.C. The exercise walked through end to end stages of vaccine implementation for different scenarios.

CDC is working closely with state, local and tribal health departments and community organizations to prepare a detailed yet flexible plan for vaccine distribution that will be informed by a prioritization framework recommended by ACIP and adopted by the CDC Director. These efforts include 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. State and local health departments have conducted pandemic vaccination planning with immunization and preparedness funding from CDC for over a decade. Updating these vaccination response plans for implementation of COVID-19 vaccines will build readiness for timely administration when a vaccine becomes available. During August 2020, CDC completed in-person and virtual site visits to assess needs as vaccine planning intensifies. Lessons learned during these site visits will inform CDC's provision of technical assistance to all jurisdictions to aid in the development of state-specific COVID-19 vaccination plans.

In addition, some state and local health departments utilized supplemental resources to build infrastructure that would address current COVID-19 response needs and incorporated planning for future phases. One example is in Chicago, where the health department has developed the Chi COVID Coach app to communicate directly with Chicago's residents who may be COVID-19 positive. The forward-thinking app, built by private sector companies, can be adapted throughout the course of the pandemic. It now allows users to register to receive a vaccine once they become available.

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 and beyond. Circulation of SARS-CoV-2 and influenza virus at the same time could place a tremendous burden on the health care system. Therefore, getting a seasonal flu vaccine is especially important. 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 works with public health and clinical partners each year to increase the number of people who get a flu vaccine and eliminate barriers to vaccination. Ongoing COVID-19 activity may affect where and how flu vaccines are given. On June 4, CDC awarded $140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to launch a scale up for influenza season, given the increased risk of COVID-19. Funds are supporting staffing and preparedness with a focus on ensuring flu vaccine coverage for populations most at risk.

Conclusion

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

defeat COVID-19. 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, now and in the future.

National Institute of Allergy and Infectious Diseases

The 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. 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 and Monoclonal Antibodies to Prevent SARS-CoV-2 Infection and/or COVID-19

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 recently established the COVID-19 Prevention Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research

Consortium (IDCRC), and the AIDS Clinical Trials Group (ACTG), in partnership with the Department of Defense (DOD). The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from SARS-CoV-2 infection and/or COVID-19. The CoVPN is a functional unit of "Operation Warp Speed" (OWS), a public-private partnership led by HHS to invest in and coordinate the development, manufacture, and distribution of safe and effective COVID-19 vaccines, therapeutics, and diagnostics. The CoVPN is participating in harmonized protocols developed in collaboration with the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, vaccine manufacturers, and Biomedical Advanced Research and Development Authority (BARDA). The network is participating in numerous trials at more than 100 clinical trial sites across the United States and internationally. The CoVPN has developed an extensive community engagement framework to reach out to the diverse communities most affected by COVID-19; to understand their interest in, and concerns about, research participation; and to partner with them to ensure their input is reflected in study implementation.

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. On July 14, 2020, interim findings from the Phase 1 clinical trial were published in the *New England Journal of Medicine*. The investigational mRNA-1273 vaccine was generally well tolerated and induced robust neutralizing antibody responses in healthy adults in this interim analysis of data from the ongoing trial. This trial also enrolled older adults, and Moderna recently presented encouraging interim safety and immunogenicity data that suggested the immune responses in older adults were consistent with those reported in younger adults. On May 29, 2020, a Phase 2 clinical trial, sponsored by Moderna, was initiated to further study the safety and immune responses to the experimental mRNA vaccine. On July 8, 2020, Moderna announced that the Phase 2 trial was fully enrolled, with one cohort of younger adults and a separate cohort of older adults. NIAID and BARDA are working with Moderna on a Phase 3 clinical trial with the CoVPN that launched on July 27,

2020. The vaccine efficacy trial was the first to be initiated under OWS. 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.

On August 31, 2020, NIAID announced the launch of a Phase 3 clinical trial with AstraZeneca of the AZD1222 COVID-19 vaccine candidate, which uses a chimpanzee adenovirus-vectored vaccine approach developed by researchers at the University of Oxford in collaboration with scientists at NIAID's Rocky Mountain Laboratories in Hamilton, Montana. On September 8, 2020, AstraZeneca paused enrollment in this and other studies of its candidate vaccine to allow for the review of safety data following a serious adverse event in a single trial participant in the United Kingdom. This pause is consistent with standard practice for such events and is a sign that safeguards for volunteers are robust. The U.S. trial will resume when the independent Data and Safety Monitoring Board overseeing the trial and the FDA determine that it is safe to proceed. This event and subsequent review exemplify how OWS is working with industry partners to ensure the safety of COVID-19 vaccine candidates.

NIAID expects to announce the launch of an OWS-supported Phase 3 clinical trial with the CoVPN for the Janssen-developed Ad26-vectored vaccine candidate shortly. Along with the Pfizer-supported study of its mRNA vaccine candidate (developed with BioNTech), four candidate COVID-19 vaccines will have entered Phase 3 clinical trials in the United States. An OWS-supported Phase 3 study with the CoVPN for the Novavax, Inc., candidate vaccine, an adjuvanted recombinant protein vaccine, is expected to begin in October 2020.

The rigorous clinical testing required to establish vaccine safety and efficacy means that it might take some time for an FDA-licensed COVID-19 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates will prove safe and effective by late 2020 or early 2021.

In addition to vaccine candidates, the CoVPN is evaluating monoclonal antibodies directed against SARS-CoV-2 as tools to prevent transmission and spread. On August 10, 2020, NIAID scientists, collaborating with Regeneron Pharmaceuticals, initiated a Phase 3 clinical trial to evaluate the investigational monoclonal antibody combination known as REGN-COV-2. The trial will enroll approximately 2,000 volunteers to determine whether REGN-COV-2 can prevent infection or disease symptoms in asymptomatic adults who are household contacts of persons with SARS-CoV-2 infection. In addition, NIAID scientists are collaborating with Eli Lilly and

Company in conducting a Phase 3 clinical trial of the monoclonal antibody LY-CoV555 to prevent SARS-CoV-2 infection in people at high risk of exposure due to living or working in skilled nursing or assisted living facilities.

Identifying Therapeutics to Treat COVID-19

Safe and effective therapeutics for COVID-19 are 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 investigational 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.* The adaptive design of ACTT has enabled the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib. This drug was added to the second iteration of the study (ACTT-2); enrollment for ACTT-2 is now complete. On September 14, 2020, Eli Lilly and Company and Incyte announced the preliminary finding that ACTT-2 participants receiving baricitinib in combination with remdesivir showed a modest benefit in recovery time versus those treated with remdesivir alone. On August 5, 2020, NIAID launched a clinical trial to evaluate the use of interferon beta-1a, which is used to treat individuals with multiple sclerosis, in combination with remdesivir in the third iteration of the study (ACTT-3).

In addition to the prevention studies described above, monoclonal antibodies also are a promising approach for the *treatment* of COVID-19. On August 20, 2020, NIH and OWS convened a scientific summit to explore the current scientific evidence and future opportunities for monoclonal antibodies that neutralize SARS-CoV-2 as possible treatments for COVID-19. On August 4, 2020, as part of the ACTIV partnership and in collaboration with other NIH Institutes, NIAID launched two OWS-supported studies, ACTIV-2 and ACTIV-3, to evaluate the use of the monoclonal antibody LY-CoV555 to treat COVID-19 in outpatient and hospitalized

settings, respectively. The ACTIV-2 and ACTIV-3 clinical trials utilize master protocols that allow for inclusion of additional investigational therapeutics as the trials continue. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin for treatment of COVID-19 in both outpatients and hospitalized adults.

The National Heart, Lung, and Blood Institute (NHLBI) has established the Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (CONNECTS) to better understand the impact of COVID-19 on the heart, lungs, blood, and blood vessels, and to identify therapies that will slow or halt disease progression and speed recovery. CONNECTS will leverage existing NIH-funded clinical trial networks to conduct adaptive trials, in which researchers can test a variety of interventions simultaneously, easily share their data, and quickly identify the most promising treatments. CONNECTS also will bring together ongoing NIH-funded epidemiological cohort studies to examine the characteristics of individuals who do and do not develop SARS-CoV-2 infection and to help shed light on who is at risk for developing severe illness due to COVID-19. This knowledge will identify risk factors, inform strategies for primary and secondary prevention, and suggest biomarkers of infection and adverse outcomes. It also will inform us about the natural history and long-term consequences of the disease. Among the first trials to be conducted through CONNECTS, and as part of the ACTIV initiative, on September 10, 2020, NHLBI launched two adaptive Phase 3 clinical trials evaluating the safety and effectiveness of varying types of blood thinners (antithrombotics) to treat adults diagnosed with COVID-19. Researchers have noted that many patients who died from COVID-19 had formed blood clots throughout their bodies, including in their smallest blood vessels. This unusual clotting (thrombosis) has caused multiple health complications, from organ damage to heart attack and stroke. Collectively known as ACTIV-4 Antithrombotics, the trials will provide critical insights to help guide the care of patients with COVID-19, hoping to prevent life-threatening blood clots that occur in many COVID-19 patients. The trials will be conducted at more than 100 sites around the world; one trial focuses on hospitalized COVID-19 patients and the other focuses on outpatients. A third clinical trial to start later will focus on recovering patients discharged after hospitalization for moderate to severe COVID-19.

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, NHLBI, NCATS, the National Cancer Institute (NCI), 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 has established the COVID-19 Treatment Guidelines Panel, comprised of representatives of NIH and five other federal agencies along with representatives of nine professional organizations, academic experts, and treating physicians including providers from high COVID-19 incidence areas, and community representatives. On April 21, 2020, the panel issued the initial iteration of the COVID-19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments and address considerations for special populations, including pregnant women and children. Based on a randomized controlled trial of the antiviral drug remdesivir compared to placebo, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID-19 in hospitalized patients who require supplemental oxygen with the caveat that due to insufficient data, the panel could not recommend for or against the use of remdesivir for those patients who require oxygen delivery through a high-flow device, noninvasive, ventilation, invasive mechanical ventilation, or ECMO. On June 25, 2020, based on a preliminary analysis of the data from the *Randomised Evaluation of COVID-19 Therapy* (RECOVERY) study sponsored by the University of Oxford, the treatment guidelines were updated again to recommend the glucocorticoid dexamethasone for the treatment of COVID-19 in hospitalized patients with severe disease requiring supplemental oxygen, including those on high flow oxygen or mechanical ventilation. Recently the treatment guidelines were updated to emphasize that potentially effective treatments for COVID-19 not be withheld from pregnant women. The guidelines are updated regularly as new evidence emerges.

In addition, the Pediatric Trials Network, funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), has incorporated testing of 12 drugs in its ongoing clinical trials that may prove helpful specifically for treating children with COVID-19 and/or multisystem inflammatory syndrome in children (MIS-C).

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 drive the development of new products by fall 2020. This $500 million initiative supports 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. To date, NIH has awarded more than $370 million in Phase 2 contracts to 16 organizations for technology validation, clinical studies, scale-up, and manufacturing. These funds, combined with additional pending projects in the RADx pipeline, are projected to produce millions of new tests per day for a total of more than 6.5 million tests per day by the end of the year. 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 vulnerable populations. On June 12, 2020, NIH announced four new funding opportunities for community-engaged projects within RADx-UP. The goal of this is to better understand factors that have led to a disproportionate burden of the pandemic on underserved and vulnerable populations so that interventions can be implemented to decrease these disparities. Awards are expected to be made in late September or early October 2020.

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 establishment of registries of tested subjects for seroprotection studies.

NIAID, NCI, and NHLBI, along with scientists from CDC, BARDA, FDA and DOD, convened the COVID-19 Serology Studies workshop to bring together over 300 scientists and clinicians from the federal government, industry, and academia on May 7, 2020. Participants discussed the role of serology testing in understanding and responding to the COVID-19 public health crisis and explored strategies to address key scientific opportunities and knowledge gaps in this emerging field. On July 14, 2020, a report of the conclusions and recommendations from the workshop was published in the journal *Immunity*. The group recommended that additional research is needed to determine whether, and to what extent, a positive antibody test means a person may be protected from reinfection with SARS-CoV-2. Additional research also is needed to determine the duration of protection. They also emphasized that serology tests should not be used as a stand-alone tool to make decisions about personal safety related to SARS-CoV-2 exposure until additional information about SARS-CoV-2 immunity is available.

NIAID, NCI, NCATS, and NIBIB also are partnering on a 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. Public interest in participating was extremely robust and recruitment was significantly expanded by leveraging the NCATS Clinical and Translational Science Awards (CTSA) program. Enrollment is now complete. 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 a database that is collecting data on

the prevalence and spectrum of neurological symptoms observed in patients with SARS-CoV-2 infection. NHLBI and NICHD are leading a trans-NIH effort, with participation from NIAID, to coordinate research into MIS-C, an extremely serious inflammatory condition that has been associated with SARS-CoV-2 infection in children and adolescents. This centralized effort will permit data to be shared across studies to determine the spectrum of illness in children and predict the long-term consequences of infection.

To improve participation of minority communities in research on vaccines and therapeutics for COVID-19, NIH established the Community Engagement Alliance Against COVID-19 Disparities (CEAL) initiative led by NHLBI and the National Institute on Minority Health and Health Disparities. The initiative is bringing together community leaders to act as "champions" to share information with their communities about COVID-19 research, how to participate, and the importance of having diverse participants who represent all people in need of vaccines and treatments. NIH intramural and NIH-funded extramural researchers are helping to provide authoritative, expert information that champions can tailor to their communities. Together, these champions and researchers are leading CEAL research teams in African American, Hispanic or Latino, and Native American communities that are hardest hit by COVID-19 to provide timely, accurate information about COVID-19 prevention and treatment, and to ensure that COVID-19 clinical studies include appropriate representation of the racial and ethnic minority populations that have been disproportionately affected by the pandemic.

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 (Added 9/11)

Diagnostics and Testing

Testing is an essential component of the public health response to SARS-CoV-2 (the virus that causes COVID-19). It enables clinical decision making, informs resource allocation and disease prevalence monitoring, and is necessary to minimize community and economic

disruption through targeted infection prevention and control measures. The indications for viral testing depend on the stage of the pandemic and the extent of community spread. In general, testing is indicated for diagnosis of those who are symptomatic or asymptomatic, tracing of those in contact with those who are infected, screening of specific employees (for example nursing home staff), and surveillance testing of those who are asymptomatic to achieve infection control and/or other public health objectives.

Repeated testing of a majority of the U.S. population is not feasible at this time, nor necessary to ensure a safe return to work, school, and other activities. Rather, a targeted testing strategy that rapidly diagnoses those who are ill, protects the vulnerable, and identifies emerging outbreak areas – when combined with public health mitigation measures like mask wearing – is proven to reduce the spread and flatten the curve.

To date, the United States has realized over 95 million tests, at an average current rate of between 700,000 – 800,000 tests per day, with enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. In June, July, and August, states far surpassed their goals for testing. Specifically, state goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, states far exceeded their goals by conducting over 25 million tests. In August the nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. Over the next several months, the nation's testing capacity will continue to increase. We anticipate that supplies and reagents will be sufficient to conduct approximately 90 million tests in September. If pooling of specimens from different individuals occurs today even for a fraction of these tests, there is capacity to perform more than 100 million tests per month. Pooling allows for more people to be tested at once in a "batch", using fewer testing resources. Turnaround time in providing test results continues to improve. Currently, 97 percent of American Clinical Laboratory Association tests ordered in the previous week received results within 3 days, and 99 percent received results within 5 days.

The role of the federal government is to set the overall testing strategy and requirements, provide technical guidance, secure the supply chain, scale scarce resources, enable innovation, and support state plans to achieve the overall national objectives as well as any specific state objectives. States, territories, and tribes are responsible for formulating and implementing testing plans that meet national objectives and additional goals for their state. The academic,

commercial, and private sectors will continue to develop and produce technologies, supplies, and services to meet the needs of the states and the nation at large.

The national strategy for testing was formally outlined in the *Testing Blueprint: Opening Up America Again*, and the *Addendum to the Testing Blueprint*. The immediate objectives of the strategy are to:

- Identify newly emergent outbreaks
- Support public health isolation and contract tracing
- Diagnose COVID-19 rapidly in hospitalized patients
- Protect the vulnerable
- Support safe reopening of schools and businesses
- Enable state testing plans

The national strategy for testing was further enumerated in the COVID-19 Strategic Testing Plan Report to Congress initially submitted to Congress on May 24th. On August 22nd, HHS submitted the first update to the Strategic Testing Plan. The report 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.

Identifying Newly Emergent Outbreaks

In addition to public health surveillance systems monitored by the CDC, the nation is currently maintaining sufficient baseline testing for SARS-CoV-2 in order to detect early changes in percent positivity. At present, a minimum target of testing 2 percent of a state's population per month has been sufficient to detect early changes in percent positivity, and thus enable state and local officials – with the technical assistance of the federal team – to implement mitigation steps rapidly to curb the emerging outbreak.

In order to ensure that states meet this 2 percent threshold to detect any threat of emergence in that state, the federal government will continue to:

- Assist states with the procurement of collection supplies to achieve a minimum of 2 percent population testing per month; and if possible, provide more supplies if needed to meet the approved state plan targets. To date, the federal government has procured and delivered 95 million swabs and 77 million tubes of media;

- Ensure sufficient supply of reagents to achieve testing goals in the context of point of care utilization and use of commercial referral labs;
- Prioritize states with outbreaks or potential outbreaks, if needed, and;
- Continue to expand the availability and use of point of care tests.

Support Public Health Isolation and Contact Tracing

A key function of testing is to support identification of SARS-CoV-2 of infected individuals, many of whom may be asymptomatic, in communities identified with outbreaks or emerging outbreaks. In response to "hotspot areas", the federal government has set up surge testing to increase baseline testing 2X-5X for short periods of time. Surge testing sites have been implemented in Miami, FL; Jacksonville, FL; Edinburg, TX; Yuma County, AZ; Pima County, AZ; Coconino, AZ; Phoenix, AZ; Atlanta, GA; Birmingham, AL; Cochise County, AZ; Mohave County, AZ; Yavapai County, AZ; Baton Rouge, LA; New Orleans, LA; Bakersfield, CA; Houston, TX; Harris County, TX; Clark County, NV; and Honolulu, HI, and these 19 sites have conducted approximately 290,000 tests. Surge testing is a supportive adjunctive activity; it cannot substitute for disciplined adherence to mitigation measures including masking, hygiene, social distancing, avoidance of indoor crowded areas and crowds, and protection of the vulnerable. These mitigation techniques, when combined with selective surge testing, have proven highly effective in reversing recent community outbreaks.

In order to support public health isolation and contact tracing, and to reduce turnaround time, the federal government has:

- Provided massive surge testing to localities prioritized by the White House Coronavirus Taskforce, and agreed to by state and local officials;
- Augmented testing, both baseline and surge, for FQHCs and retail sites;
- Supported local testing efforts with surges of collection supplies and reagents;
- Worked collaboratively to validate and promote EUAs for pooling across all laboratory platforms;
- Worked collaboratively to validate and promote EUAs for new extraction methods to increase productivity;
- Invested in new testing technologies that improve sensitivity, specificity, and/or turnaround time, including new point-of-care tests, and;

- Provided point-of-care testing to all nursing homes in America.

Diagnose COVID-19 Rapidly in Hospitalized Patients

Because there are now treatments authorized by the FDA for hospitalized patients with COVID-19, including remdesivir, convalescent plasma, and steroids, it is critical to diagnose patients as soon as possible. Currently, large commercial labs are prioritizing inpatient samples to ensure diagnosis within 24-36 hours. Our best information also suggests that the great majority of individual hospitals are able to meet this time frame for patients within their hospital systems.

Protect the Vulnerable

The elderly, particularly those in nursing homes, are much more likely to suffer serious consequences, including death, from COVID-19. In addition to the elderly, racial and ethnic minorities are also disproportionately affected.

To ensure that specimens are collected without overburdening the traditional health care system, and to ensure testing in the most vulnerable communities, in mid-March, the federal government established Community-Based Testing Sites (CBTS) in White House Task Force on Coronavirus-prioritized locations across the country based on CDC data. The CBTS model was developed for states, local public health agencies, healthcare systems, and commercial partners as they work together to stop the spread of COVID-19 in their communities, focusing initially on healthcare facility workers and first responders. The CBTS federally supported, state managed, locally executed model has been a profound success, testing approximately 400,000 individuals. For the initial 41 sites, CBTS 1.0, the federal government provided a federal physician who ordered all of the COVID-19 tests, the federal contracts for shipping the specimens, laboratory processing, patient notification, and logistics (to include supplies, personal protective equipment, and language translation services). The federal government also utilized U.S. Public Health Service personnel to provide data management, safety, and quality control checks at each site.

Building on the initial success of the CBTS model, the federal government next leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart), also known as CBTS 2.0, to accelerate testing for more

Americans in more communities across the country. The public-private partnership model operates on the federally-supported, state managed model.

As the transition of CBTS federally run sites to state-run sites has been completed, the federal government has broadened its community testing support to a more sustainable model -- specifically by continued support of retail and pharmacy partnerships in more than 800 locations in all 50 states and the District of Columbia, which collectively have conducted over 2 million tests to date. The federal government focused on communities with high social vulnerability using the CDC's Social Vulnerability Index (SVI) as one of the main factors to select site locations. Approximately 65 percent are located in communities with moderate to high social vulnerability. The SVI measures the resilience of communities when confronted by external stressors along four main themes: socioeconomic status, household composition and disability, minority status, and housing type.

This pharmacy and retail partnership provides convenient access to COVID-19 testing, but it is also a bridge for retailers to implement new regulatory flexibilities and expanded reimbursement options HHS has provided through private insurance, Medicare, and Medicaid. This partnership also leverages the newly expanded authority given to pharmacists to order and administer COVID-19 testing; this effort is also known as CBTS 3.0. Now, CVS and Walmart have over 1,900 sites utilizing these new regulatory and reimbursement options with over 2 million tests performed.

HRSA supported health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care to medically underserved communities and vulnerable populations across the United States. Nationwide, nearly 1,400 HRSA-funded health center grantees operate approximately 13,000 sites, providing primary and preventive care to more than 28 million patients each year. Over 91 percent of health center patients are individuals or families living at or below 200 percent of the Federal Poverty Guidelines and nearly 63 percent are racial and/or ethnic minorities. Health centers are uniquely situated in communities to serve those that are most vulnerable and 97 percent of these centers offer COVID-19 testing. As of September 4, 2020, health centers have administered 3,690,098 COVID-19 tests (including 215,231 antibody detection tests), with over 49 percent of tests provided to racial and/or ethnic minority patients. Of these tests, 444,186 returned positive, and among racial and/or ethnic minorities, 59 percent tested positive.

To prevent further spread and deaths in nursing homes, CDC and the Centers for Medicare & Medicaid Services (CMS) recommended that nursing homes perform baseline testing of all residents and staff, followed by routine testing of residents and/or staff to reduce outbreaks, morbidity, and mortality, based on additional factors. CMS requires a regimen of staff and resident testing based on the degree of community spread.

To protect the vulnerable and to assist states in meeting these recommendations and requirements, on July 14, 2020, the Trump Administration announced that HHS would embark on a one-time procurement of rapid point-of-care testing instruments and tests to be distributed to nursing homes using the Defense Production Act. Through this aggressive action, nursing homes will be able to augment their current capacity for coronavirus testing, bolstering their response and helping to prevent the spread of SARS-CoV-2. This will facilitate baseline testing among nursing home residents and staff, and enable a pathway to conduct ongoing testing according to public health guidelines.

I am pleased to announce that all 13,850 initially eligible nursing homes have received one or more point-of-care (POC) instruments, and nearly 5 million tests. Following this initial distribution, we will facilitate nursing homes being able to reorder supplies via their normal commercial distribution channels. Additional billions of dollars in funding have been provided by HHS to support this effort.

Vulnerable populations in many underserved communities are suffering disproportionate health impacts resulting from COVID-19, including numbers of infections, hospitalizations, and deaths. As part of the HHS response to this crisis, on June 23, 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.

Morehouse School of Medicine has entered into a 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.

Support Safe Reopening of Schools and Businesses

While we must be prudent to protect those most vulnerable, we must also be mindful of the prolonged effects that school and business closures have on millions of children and parents. The efforts of the federal government to galvanize the testing infrastructure in the United States, and the efforts to reduce turnaround times, have provided communities with the resources they need to safely reopen schools and businesses.

Enable State Plans

To enable states to achieve the testing goals developed in coordination with the federal government, the federal government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The federal government then provided this information to states so they could better determine how to optimize their testing strategy. The federal government also purchased and allocated POC devices and over 2.3 million tests; developed, implemented, and facilitated community-based testing sites across the country; and provided significant guidance and technical assistance for state plans. The increase in the numbers of tests performed since early March is a direct reflection of these efforts.

States and territories have now submitted two iterations of their testing plans. These plans were developed in collaboration with federal multidisciplinary experts through teleconferences and other meetings. Plans were reviewed by a multidisciplinary federal team that included leadership from CDC, the Immediate Office of the Secretary, and the Office of the Assistant Secretary for Health.

The first iteration of the jurisdictional testing plans for May and June were released to the public on July 10, 2020, and are available for viewing on the following website: https;//www.hhs.gov/coronavirus/testing-plans/index.html. The federal team provided feedback to each state, and each state incorporated this feedback into detailed plans covering July through December. The state plans for July-December have been reviewed and scored and were released

to the public on August 10, and are available for viewing on the following website: https://www.hhs.gov/coronavirus/testing-plans/index.html

To ensure states meet their testing goals, the federal government procured FDA-authorized swabs and transport media, and is distributing these supplies to a single location in each state determined by the Governors' offices. Starting in May and through September 11, the federal government has distributed over 95 million swabs and more than 77 million tubes of transport media.

Moving forward, jurisdictions should use the $10.25 billion provided to states, territories, and localities by the federal government to support the purchase of tests and related supplies, personnel for contact tracing, and reporting infrastructure, etc., for their jurisdictions, as needed to fulfill their approved testing plans.

Other Initiatives

In order to capture feedback and foster communication between federal officials and the private sector, HHS created the National Testing Implementation Forum (Forum). The Forum brings together representatives from key stakeholder groups to share information and provide input to federal leaders about SARS-CoV-2 testing. Members of the Forum provide their perspectives on how HHS can best identify and address end-to-end testing supply chain issues across commercial, public health, academic, and other sectors and define optimal testing in various settings (diagnostic, screening, surveillance, others). Members also provide input to improve technical assistance across the nation to prioritize testing among the vulnerable and underserved and create a sustainable diagnostics ecosystem that is sustainable and fully capable for future public health challenges. The first Forum meeting was held on July 30th and the principal topic of discussion was the testing supply chain. On August 13th the second meeting was held and surveillance and reopening strategies were discussed. The third forum, with the topic of engaging minority and underserved communities, was held on September 3rd.

On August 27th, the Administration announced that a $760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 Ag Card point-of-care tests. This initiative will expand strategic testing in the United States. The Abbott BinaxNOW COVID-19 Ag Card, which recently received an EUA from the FDA, does not require

instrumentation and will deliver COVID-19 test results in 15 minutes or less. This test uses nasal swabs and can be easily deployed in many settings across the country.

United States Public Health Service Commissioned Corps

Since the early stages of the COVID-19 pandemic, 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 53 officers on January 24, 2020 to 4,170 officers deployed as of September 8th, with many officers being deployed numerous times. 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, Michigan. 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 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, help ensure the safety, efficacy, and quality of FDA-regulated medical products, and provide the

industries we regulate with 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 public 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

This pandemic has created a demand for new tests that is unprecedented in both volume and urgency. FDA's important role in testing includes determining whether the tests developed for use in the U.S. provide sufficiently accurate and reliable results and helping to provide timely access to such tests.

Even prior to any diagnosed U.S. cases of COVID-19, FDA proactively reached out to developers to encourage and facilitate the development of tests and to offer assistance from the Agency. FDA has been proactive and supportive of test development by all interested parties to speed development and quickly authorize tests that the science supports. The Agency has worked with over 500 developers since January and has been working around the clock to issue over 240 Emergency Use Authorizations (EUAs) for tests. The sheer volume and variety of available tests is a testament to FDA's support of innovative test design and our commitment to public health. From molecular diagnostic tests, to rapid antigen tests, to antibody tests, to tests run in clinical labs, to tests run in emergency rooms, pharmacies and nursing homes (point-of-care, or POC, tests), to samples self-collected at home, FDA has authorized a multitude of options. We have also been working with developers on tests that can be administered and delivered entirely outside of a lab or health care setting, such as in a patient's home.

In a public health emergency, obtaining an accurate test result is important not only for the individual patient, but for the public at large. Similarly, timely access to diagnostic tests is critically important. To best address these dual, and sometimes competing, needs, FDA has used its EUA authorities. EUAs permit the emergency use of a product, in this case a test, when FDA determines that certain criteria are met based on the totality of the scientific evidence available. The EUA process made it possible for molecular diagnostic tests to be developed, validated, and offered for clinical use within weeks rather than months or longer.

To balance the urgent need to increase diagnostic testing capacity in the United States with the need to provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA announced several policies to facilitate oversight. FDA has engaged in rolling reviews of EUA submissions, authorized tests that had the necessary data to support that the criteria for issuance are met, and issued a policy for states that have the capacity and expertise to authorize tests for use within a laboratory in that state.

From the beginning of the pandemic, FDA also developed several EUA templates, which have helped to streamline the EUA submission process as well as provide helpful information to developers that can speed validation and authorization of new tests. FDA's EUA templates are intended to help developers provide appropriate validation data and other information to FDA, but alternative approaches can be used, and FDA would consider issuing EUAs for tests if the data show that the known and potential benefits outweigh the known and potential risks of the tests, among other considerations. FDA developed EUA templates for molecular diagnostic, serology, and antigen tests as well as for tests with at-home specimen collection. On July 29, 2020, FDA published a new template for at-home and over-the-counter diagnostic tests for use in non-lab settings, such as homes, offices, or schools, and that could be available without a prescription. This template helps continue to facilitate innovation in test development, and is intended to provide recommendations to help foster development of tests that are simple enough to use at home and could provide results within minutes. However, our recommendations are just that — recommendations. FDA is always open to alternative proposals from developers and will continue to consider those. More significant trade-offs in test accuracy may be appropriate where the need for availability and fast results is not being met. Yet, even in those circumstances, steps can be taken to protect consumers, including strategies to increase accuracy. For example, strategies for serial testing with less sensitive diagnostic tests, such as 70 percent sensitivity, could be considered cumulatively rather than based on one-time testing. Any proposal for serial testing should generally include estimated manufacturing capabilities to ensure a sufficient supply of tests with which to conduct multiple tests per person. As with all EUA requests, the FDA will evaluate the totality of the evidence to determine whether the known and potential benefits outweigh the known and potential risks, among other considerations.

FDA provided regulatory flexibility to developers of tests due to the unprecedented nature of this public health emergency and the need to ensure timely patient access to COVID-19

tests. However, flexibility never meant we would allow fraud. Unfortunately, FDA continues to see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans. Some test developers have falsely claimed their tests are FDA-approved or authorized. Others have falsely claimed that their serology tests can diagnose COVID-19 or that they are authorized for at-home testing. FDA also became aware that a concerning number of commercial serology tests were performing poorly based on an independent evaluation by the NCI.

When we become aware of these issues, we have and will continue to take appropriate action against firms unlawfully marketing and selling their tests. FDA has and continues to issue Warning Letters and continues examining shipments of tests at ports of entry, the borders, and international mail centers, detaining and refusing fraudulent test kits.

To date, FDA has refused admission to more than 470 shipments of tests at the border, representing more than 460,000 tests overall, helping to prevent fraudulent tests from entering the country in the first place. FDA's actions have resulted in sellers of unapproved and unauthorized products removing false or misleading COVID-19 claims. FDA also has sent abuse complaints to online marketplaces and domain registrars for websites or listings that were offering to distribute fraudulent COVID-19 test kits for at-home testing. FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk.

To further support efforts to ensure that patients and health care providers can depend on the results of COVID-19 tests, FDA has announced our participation in the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder collaborative project to advance the development of diagnostics through the generation of real-world evidence. Organized by the Reagan-Udall Foundation for FDA in collaboration with Friends of Cancer Research, this initiative is designed to allow the community to analyze both diagnostic and clinical data in real time, which has the potential to contribute to the scientific evaluation of diagnostic tools and medical interventions for COVID-19.

Evidence generated by the Accelerator project is intended to be complementary to other studies that have been conducted or are underway as well as to provide actionable information about the prevalence of SARS-CoV-2 in specific populations and highlight individual risk factors for patients. This helps improve our understanding of the disease, allows us to tailor

public health interventions and strategies to mitigate risks for individuals and communities, and will help to stop the spread of SARS-CoV-2.

In addition, FDA also continues to work with NIH, the CDC, and BARDA regarding the NCI's independent evaluation of certain commercial antibody tests for the U.S. Government, including antibody tests that are not the subject of an EUA or pre-EUA, as well as those that are under FDA review. Where appropriate, FDA is using NCI data to inform future decision making, such as whether to authorize the test, engage the test developer for additional information to support its continued use, or take other action regarding tests that do not perform adequately, including removing them from our notification list and working with developers to stop distribution in the United States.

We are continuing to provide updated information and educational materials to states and health care partners. When commercial manufacturers that are currently marketing serology tests as outlined in FDA policy fail to submit an EUA within 10 business days of notification, we have been removing those tests from our website notification list and are sharing this information publicly.

In parallel with FDA's engagement with developers and monitoring the marketplace, FDA has: researched and mitigated shortages of test components, including identifying and sharing alternatives for components on FDA's website; arranged with DOD weekly airlifts of swabs to the United States; engaged nontraditional device manufacturers to support the manufacture of new swabs and other supplies that are needed in the United States; maintained public FAQs that are updated regularly; served as a clearinghouse for scientific information that the community may leverage to increase testing capacity; and operated a hotline (FDA continues to provide other means for industry to contact the FDA directly).

The availability of accurate tests has been a priority issue for public health authorities throughout the COVID-19 pandemic. However, it is important to note that the specific need for tests and the evidence available for different tests have evolved over time. At all stages of the pandemic, FDA has sought to provide regulatory clarity to innovators and adapt policies based on the latest available data. FDA will continue supporting any testing proposal where, among other criteria, the test benefits outweigh the risks based on sound science, and we continue to work with test developers and encourage those with novel testing ideas to reach out – by email, phone, or during our weekly test developer town hall meetings.

FDA will continue to appropriately balance assurances that tests are accurate and reliable with timely access to such tests as continually evolving circumstances and public health needs warrant. FDA continues to work closely with White House 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 Development

At this time, there is no FDA-approved vaccine to prevent SARS-CoV-2 infection and/or COVID-19, and FDA is providing regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID-19. In this crisis, in which there is so much at stake, we are facilitating expedited vaccine development without sacrificing our standards for quality, safety, and effectiveness.

FDA is working closely with federal partners, vaccine developers, researchers, and manufacturers to help expedite the development and availability of safe and effective vaccines to prevent infection with SARS-CoV-2 infections. Knowledge sharing is considered a key part of the scientific process and it could efficiently advance these efforts. We are utilizing all appropriate regulatory authorities and are providing rapid scientific and technical advice to sponsors and researchers to help expedite the development and availability of safe and effective COVID-19 vaccines.

On June 30, FDA took additional action to facilitate the development of safe and effective vaccines to prevent COVID-19 by providing guidance that includes recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, entitled Development and Licensure of Vaccines to Prevent COVID-19, reflects the advice and assistance FDA has been providing to companies, researchers and others, and describes the Agency's current recommendations regarding the data needed to facilitate the manufacturing, nonclinical and clinical development, and approval of COVID-19 vaccines.

The guidance provides an overview of key considerations to help manufacturers satisfy requirements for chemistry, manufacturing and controls, and nonclinical and clinical data needed for development and licensure to assess the safety and effectiveness of vaccines, and for post-licensure safety evaluation of COVID-19 vaccines. The guidance explains that, given our current understanding of SARS-CoV-2 immunology, the goal of development programs at this

time should be to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.

In its interactions with vaccine developers, FDA provides sponsors with advice regarding the data needed to support the manufacturing, clinical development, and approval of vaccines, including such advice to those sponsors pursuing development of vaccines to prevent COVID-19. The size of clinical trials to evaluate the efficacy of COVID-19 vaccines will depend on a number of factors including the criteria for demonstrating safety, efficacy, and the incidence of COVID-19 in the population and areas where the trials are conducted. The guidance document conveys that FDA would expect that a COVID-19 vaccine would be at least 50 percent more effective than placebo in preventing COVID-19 or SARS-CoV-2 infection among the clinical trial participants. FDA anticipates that clinical trials to demonstrate vaccine efficacy would also be of sufficient size to provide an acceptable safety database. However, further pre-licensure safety evaluation may be needed if safety concerns arise during clinical development.

While FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards. This is particularly important, as we know that some people are skeptical of efforts to develop a safe and effective COVID-19 vaccine. To help ensure an evaluation process that is as transparent as possible, and to help the public understand the FDA's process for evaluating the safety and effectiveness of new vaccines, FDA will convene a meeting of our Vaccines and Related Biological Products Advisory Committee on October 22, 2020, to address the general development of COVID-19 vaccines. We stand ready to rapidly schedule additional meetings of this Committee after submission to discuss Biologic License Applications or request for an Emergency Use Authorization for COVID-19 vaccines.

It is clear that manufacturing and fill finish capacity will need to be scaled up on U.S. soil in order to have a safe and effective vaccine widely available in a timely manner. FDA is committed to working with sponsors by providing timely regulatory advice and technical assistance regarding manufacturing to help support such scale-up activities, including sponsors who may be proceeding at risk to scale-up manufacturing while clinical trials are being completed.

We have not lost sight of our responsibility to the American people to maintain our regulatory independence and ensure our decisions related to all medical products, including

COVID-19 vaccines, are based on science and the available data. This is a commitment that the American public can have confidence in and one that FDA will continue to uphold.

Therapeutic Development

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 has supported 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 ACTIV partnership developed 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 key areas, such as in reducing lung inflammation and improving lung function in COVID-19 patients. All this work is beginning to pay off. For example, we saw positive results of the National Institute of Allergy and Infectious Diseases (NIAID) trial of remdesivir in patients with severe COVID-19. On May 1, 2020, FDA issued an EUA for remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. On August 28, 2020, FDA broadened the EUA for remdesivir to include all hospitalized patients for treatment of COVID-19, irrespective of their severity of disease.

Another potential approach for treatment is the use of antibody-rich products such as convalescent plasma and hyperimmune globulin. These investigational blood products are manufactured from plasma donated by people who have recovered from the SARS-CoV-2 virus, and such products are being studied to determine if they could shorten the length, or lessen the

severity, of COVID-19. We are evaluating convalescent plasma in the context of traditional clinical trials, and on August 23, 2020, FDA issued an EUA for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients. This EUA followed FDA's extensive review of the science and data generated over several months prior to the EUA. This data stemmed from efforts to facilitate expanded access to convalescent plasma for COVID-19 patients. Clinical trials to definitively demonstrate safety and efficacy of convalescent plasma remain ongoing.

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 to encourage 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 collection entities to facilitate the collection of convalescent plasma, and to work with developers of such 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.

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 (human and animal), biological product, and device manufacturing in a timely manner.

Drugs and Biological Products

In addition to our usual communication with drug manufacturers, we 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 for outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or federal facilities, regarding the compounding of certain drugs used to

treat hospitalized patients with COVID-19 when approved drugs are not available. The Agency has also published guidance to help applicants and manufacturers provide FDA with timely and informative notifications about changes in the production of certain drugs and biological products and urging the submission of these notifications, which may assist in our efforts to prevent or mitigate shortages of such products.

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. The Agency quickly identified the need for making hand sanitizers available as demand spiked, while also continuing our mission to ensuring these products remain safe for consumer use by removing adulterated products from the market. FDA has published and continues to update three guidance documents designed to help facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. The agency has initiated several enforcement initiatives and import alerts to stop adulterated and subpotent hand sanitizer products from getting U.S. distribution channels through importation into the United States. The Agency has also issued three EUAs to authorize the emergency use of products currently authorized for marketing in the European Union, which has helped to alleviate shortages of some therapies that are essential for the care of critically ill COVID-19 patients.

Medical Devices

FDA continues doing everything in our authority to help increase the availability of PPE and other critical medical devices relied upon by patients and those on the front lines of the U.S. response. FDA has reached out to over 1,000 manufacturers since January and has helped facilitate an increase in the availability of these devices, while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them.

One way FDA has helped to increase the supply of medical devices in the United States is by issuing EUAs. For PPE, FDA has issued EUAs to make more respirators available by authorizing certain existing supplies of PPE for healthcare personnel use that are not traditionally intended for use in health care settings, authorizing imported respirators that are demonstrated to meet comparable performance standards so that they can be used in health care settings, authorizing systems for decontamination of PPE so they can be reused as appropriate. The Agency has also issued EUAs for face masks (as source control to help stop the spread of the virus), surgical masks, face shields, and certain gowns and other apparel for use in health care

settings in accordance with CDC recommendations (including but not limited to shoes and shoe covers, non-surgical isolation gowns, surgical helmets, and surgical caps). The need for PPE continues to outpace the available supply, but these EUAs have been critical to maximize available supply in the United States and help bolster manufacturing of new supply to support the COVID-19 response.

FDA has seen an unprecedented volume of EUA requests for medical devices—some of which have been for ventilators, infusion pumps, remote or wearable patient monitoring devices, and blood purification devices for which FDA has reviewed premarket submissions but has never issued EUAs in prior emergencies. FDA has also seen EUA requests for novel medical products that it has never previously reviewed under any circumstances, such as decontamination systems for PPE.

Another way FDA has helped to support increasing the supply of PPE and other devices during the pandemic is through issuance of several guidance documents intended to help manufacturers develop new products more quickly and efficiently. These guidance documents are for PPE and other devices including facemasks (as source control to help stop the spread of the virus), surgical masks and respirators, gowns, other apparel and gloves, as well as guidance for sponsors requesting EUAs for decontamination systems and bioburden reduction systems for face masks and respirators. FDA has also published guidance documents for a wide variety of other medical devices, including ventilators and accessories, infusion pumps and accessories, remote ophthalmic assessment and monitoring devices, non-invasive remote monitoring devices used to support patient monitoring, imaging systems, and non-invasive fetal and maternal monitoring devices used to support patient monitoring.

In addition, FDA has provided conservation strategies intended to outline contingency and/or crisis circumstances when reuse, extended use, and preservation of certain devices may be necessary if supplies are short or unavailable. To date, FDA has published conservation strategies for gloves, masks and gowns.

In these ways, FDA has worked consistently to support those manufacturing PPE and other devices, as well as those who are dealing with limited supplies and shortages, to provide alternatives when other options are not available. This includes close collaboration with many non-traditional device manufacturers who have turned their operations to manufacturing PPE and other devices. FDA has worked interactively with manufacturers to continue increasing the

supply of medical devices to meet continuing unmet needs all over the country. FDA also provided instructions for importers to facilitate the import entry process for PPE and other devices, to help expand access to these products. To further support these efforts, FDA initiated biweekly virtual town hall meetings for those seeking and manufacturing respirators and other PPE to ask questions and discuss challenges they are facing.

We are also in close communication with our partners at U.S. Customs and Border Protection (CBP) to proactively identify and mitigate any potential backlogs of lawfully marketed medical products for COVID-19. FDA participates in HHS Supply Chain Advisory Group meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by HHS, to facilitate the lawful entry and use of imported medical products coordinated through HHS, and to inform medical product supply chain discussions.

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 further expand these authorities, consistent with the FY 2021 Budget.

Inspections

Despite pausing on-site domestic and foreign routine surveillance inspections in March 2020 to safeguard the health and well-being of our staff, our investigators continued to conduct mission critical inspections both domestically and abroad and other activities to ensure FDA-regulated industries were meeting applicable FDA requirements. In July 2020, FDA resumed prioritized on-site domestic routine surveillance inspections. To arm our investigators with the most reliable and accurate information, the FDA developed a rating system to assist us in determining when and where it is safest to conduct prioritized domestic inspections. The COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. We have also made the Advisory Level data available to our state partners who carry out inspections of FDA-regulated entities on the agency's behalf under contract. We will continue

closely monitoring reopening criteria established at the federal, state or county levels are planning to identify when and where to resume domestic inspections, investigations, sample collections and analyses, prioritizing these assignments based on risk and other factors. Similarly, we will use data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so.

FDA has determined that, for the foreseeable future, prioritized domestic inspections will be pre-announced to FDA-regulated businesses. This will help ensure the safety of FDA investigators and firm employees, providing the safest possible environment to accomplish our regulatory activities, while also ensuring the appropriate staff are on-site to assist FDA staff with inspection activities.

Over the course of the COVID-19 pandemic we have had great success by using a number of tools as part of the agency's risk-based approach to ensuring safety. This includes denying entry of unsafe products offered for import into the United States, conducting physical examinations and/or product sampling at our borders, utilizing remote regulatory assessment tools to verify compliance with safety regulations, and continuing to work with federal, state and local partners to monitor the medical product and food supply for indications of interruptions or shortages. As the COVID-19 pandemic continues, we will continue to adjust our processes and guidance as necessary to maintain the appropriate level of review to ensure the safety of consumer products, including hand sanitizer, diagnostic tests and more.

In response to ensuing travel restrictions due to the pandemic, FDA is utilizing its authority under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to request records in advance of or in lieu of drug inspections, and is also utilizing establishment inspection reports from capable foreign regulatory authorities under the Mutual Recognition Agreement (MRA). Both options help inform decisions related to drug approvals or addressing drug shortages.

Our Foreign Supplier Verification Program, or FSVP, remains a high priority for U.S. food imports and is critical to ensuring the safety of food received from foreign suppliers. In March of this year, we started using remote FSVP Assessment Protocols to conduct inspections and have found that these inspections have been effective and help ensure compliance with the new importer requirements under FSMA during the current pandemic.

Food Supply

FDA is working with federal, state, and local partners as well as industry to help ensure a safe and adequate food supply for both people and animals. We 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 and initiating responses as needed. 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.

In July, FDA announced the New Era of Smarter Food Safety Blueprint outlining the Agency's plans over the next decade to create a more digital, traceable, and safer food system. The challenges that have arisen during the pandemic have made it clear that the actions called for in the blueprint will strengthen how we approach the safety and security of the food supply, not just in the normal course of events but especially in times of crisis.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from firms and individuals selling unapproved products with false or misleading claims that the products prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil

and criminal enforcement actions, where appropriate. In March 2020, FDA launched Operation Quack Hack, which leverages agency expertise and advanced analytics to protect consumers from fraudulent medical products including unproven cures, illegitimate test kits, and substandard or counterfeit respirators. FDA has sent thousands of abuse complaints to domain name registrars and internet marketplaces. The Agency also has sent more than 110 warning letters to sellers of fraudulent products. Working with the Department of Justice, FDA has sought and obtained 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. For example, in March, at the border, FDA intercepted at the border 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 thereafter charged with mail fraud stemming from the allegations that he smuggled hydroxychloroquine from China to make his own pills and concealed the shipment from CBP by mis-declaring it as yam extract. In May, FDA worked with CBP to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before getting into U.S. commerce.

More recently, FDA has taken steps to address hand sanitizer products that pose safety concerns, such as products that contain or may contain toxic chemicals like methanol or 1-propanol, or that do not meet the required alcohol levels. FDA has issued warnings to consumers not to use these hand sanitizers, and has taken steps to help ensure that these dangerous or subpotent products do not enter domestic commerce. FDA has coordinated with CBP to identify such products, and we have listed products made by more than 40 manufacturers on import alert.

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.