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The Urgent Need for a National Plan to Contain the Coronavirus

Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Robert Redfield, M.D., Director, Centers for Disease Control and Prevention

Admiral Brett P. Giroir, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services

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Introduction

Chairman Clyburn, Ranking Member Scalise and distinguished members of this select subcommittee. 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. We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility. Within HHS, the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID), 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, both abroad and in the United States. CDC has a key role in preparedness and response, and addressing infectious diseases like COVID-19 is central to our mission. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and the H1N1 pandemic influenza, to meet new challenges presented by COVID-19. These challenges are many, and they are historic. Every single American is affected by this pandemic, and CDC is combatting this public health crisis with every applicable asset we have. CDC is drawing on its emergency response capacity and its relationships with state, tribal, local, and territorial (STLT), global, and private sector partners; and is leveraging our workforce's strengths in public health surveillance, prevention, and laboratory capacity, to develop and provide the nation with the science-backed information and analysis needed to address this public health emergency. CDC has developed and continues to update guidance for healthcare professionals and the public to encourage safer practices, improve health outcomes, and save lives. CDC is also working with partners to develop guidance and decision tools to assist state and local officials and other stakeholders in adjusting mitigation strategies. CDC has been recommending that people wear cloth face coverings in public settings around others outside of their households; there is increasing evidence that these masks help prevent people who have COVID-19 from spreading the virus to others. Importantly, CDC is collaborating to prepare the nation's public health system and the private sector to disseminate rapidly a vaccine to the American people when one is available. Abroad, CDC is leveraging investments in global health security, pandemic influenza preparedness and public health infrastructures and capacities built through assets like CDC's Field Epidemiology Training Program and National Public Health Institutes program to support countries in mitigating and containing COVID-19. CDC's experts in over 60 countries work hand-in-hand with host governments in responding to COVID-19. Since the beginning of the outbreak, they have been providing technical assistance, and now programmatic funding, to help countries mitigate the effects of COVID-19 and stop the disease from spreading. The emergence and rapid spread of SARS-CoV-2, the virus that causes COVID-19, confirms that an infectious disease threat anywhere is a threat to Americans everywhere, including here at home.

When, in late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered in Wuhan, China, CDC began monitoring the outbreak. At the beginning of January, CDC began developing regular situation reports, including input from our respiratory disease experts in the CDC Country Office in China, which were shared with HHS, and reached out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response structure to facilitate staffing and communications. On January 21, 2020, CDC officially activated its Emergency Operations Center for COVID-19. Using the IM structure, CDC immediately set up task forces to address key needs, reach out to our state and local partners, and deploy staff where needed to support state and local screening and investigation efforts. CDC is an integral part of the COVID-19 response and coordinates with other agencies through the Joint Coordination Center (JCC) led by Secretary Azar. Addressing COVID-19 is an all-of-government effort.

As of July 29, 2020, in the U.S., there have been 4,339,997 COVID-19 cases, 148,866 deaths. The latest data can be found on CDC's website: https://www.cdc.gov/covid-data-tracker/index.html. Congress has addressed the urgent need to respond to this pandemic at home and abroad and has allocated substantial resources for CDC's COVID-19 activities through the statutes mentioned above. This funding supports a federally guided, state managed, and locally implemented response to COVID-19 in the United States.

Throughout the United States, CDC is working with STLT partners to focus use of these resources to establish and enhance case identification; conduct contact tracing; implement appropriate containment and community mitigation measures; improve public health surveillance; enhance testing capacity; control COVID-19 in high-risk settings; protect vulnerable and high-risk populations; and work with healthcare systems to manage and monitor capacity. Contact tracing is a core disease control strategy that involves timely contact investigation followed by the implementation of an intervention (for example, isolation and quarantine) that interrupts disease transmission. Case investigation and contact tracer staff have been employed as local and state health department personnel for decades to address other infectious diseases, and contact tracing is a key strategy for preventing further spread of SARS-CoV-2 as well as a key component of state plans to reopen.

Prior to COVID-19, there were about 2,000 contact tracers in the U.S. Various studies estimate that about 100,000 contact tracers may be needed for COVID-19 (https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200410-national-plan-to-contact-tracing.pdf). To support health department needs, as of July 23, 2020, CDC has announced or obligated $12.1 billion in direct awards to jurisdictions across America from the funds provided by Congress, including $10.25 billion from the Paycheck Protection Program and Health Care Enactment Act.

In addition, to support STLT surge staffing needs, CDC is working with a variety of partners across the public and private sectors as well as collaborating with other federal agencies to explore innovative solutions to help states fill workforce gaps. For example, CDC is partnering with the Corporation for National and Community Service, which oversees the AmeriCorps program, to facilitate conversations with state public health agencies. This effort can spur new partnerships and help states supplement their workforce by identifying new, potential workers that they can access within their own state. Many of CDC's over 300 field staff that are already embedded into local health departments are contact tracers and have been reassigned to help meet local COVID-19 contact tracing needs. In addition, CDC has launched a multifaceted approach to enhance and complement STLT efforts and expand support to communities during the current public health emergency.

As a public health agency and the nation's primary resource for STLT health departments on managing disease outbreaks, CDC provides guidance and support to health departments in the development and implementation of effective containment and community mitigation strategies. STLT jurisdictions are best positioned to understand the unique situation of each community, including the current status of their existing public health infrastructure and workforce and any needs for enhancement. The goal is for state, tribal, local, and territorial jurisdictions to have robust public health systems which include a contact tracing infrastructure that meets the unique needs of each jurisdiction. As of July 2020, CDC has posted over a dozen 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.

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 has worked with individual jurisdictions to identify needs, develop plans, and offer technical assistance to enhance testing capacity, state surveillance, contact tracing, and surge staffing. Through CDC funding, CDC, the HHS Office of Assistant Secretary for Health, and the Association of Public Health Laboratories are currently reviewing individual state testing plans with a focus on achieving increased monthly testing targets. These discussions and plans for action emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

CDC is working with state and local health departments to support forward-looking testing strategies that ensure that vulnerable or high-risk populations, such as persons of color, have adequate access to testing. CDC is working with the HHS Health Resources and Services Administration and Federally Qualified Health Centers to develop and implement a strategy to increase testing in these clinics and to provide the clinics with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

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

In March 2020, CDC and public health partners began seroprevalence surveys of community transmission of SARS-CoV-2, the virus that causes COVID-19. These studies use serum samples collected across the nation, including household studies in some states. Seroprevalence surveys help track how infections progress through the population over time and identify infections that might have been missed due to lack of symptoms or testing not being performed. CDC is conducting many seroprevalence studies and has recently published the results from a study that used remnants of samples collected during routine clinical care. This was done in conjunction with two commercial companies and results indicated that it is likely that greater than 10 times more SARS-CoV-2 infections occurred than the number of reported COVID-19 cases.

On April 27, 2020, CDC updated testing prioritization and focused testing guidelines for those who may have or who are at risk for active SARS-CoV-2 infection. Clinicians considering testing of persons with possible COVID-19 should use a diagnostic laboratory test that has been properly validated for the detection of SARS-CoV-2. Healthcare providers should coordinate testing through clinical or public health laboratories that are certified to perform diagnostic testing. Increasing testing capacity will allow clinicians to consider the medical necessity of COVID-19 testing for a wider group of symptomatic patients and persons without symptoms in certain situations. CDC recommends that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19.

CDC has also 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 simultaneously will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find co-infections of influenza and SARS-COV-2, which is

important for doctors to diagnose and treat people properly. The FDA issued an Emergency Use Authorization at CDC's request for this combined laboratory test on July 2, 2020. The multiplex assay is accessible to the public health laboratory community and technical information is publicly available on CDC's website so that commercial developers can use this information in developing proprietary tests if they wish. CDC expects that private sector laboratory test developers may be creating similar multiplex assays to meet clinician needs during influenza season.

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 to monitor COVID-19 and protect vulnerable communities, including influenza and viral respiratory disease systems. In collaboration with STLT public health partners, CDC is committed to making data available to the public, while protecting individual privacy. CDC is using diverse systems to define a more complete picture of the outbreak, including race/ethnicity data and is working with communities of color to protect communities at risk. CDC has recently updated the COVID-19 Case Report Form to allow for better collection of data on populations that have previously been under-represented in reporting. The initial Case Report Form included questions for sex, age, race and ethnicity and whether the case is part of a recognized outbreak. The revised form includes additional variables for populations, such as tribal nations, that may be at higher risk for severe illness and risk factors such as homelessness and disabilities. States have improved the completeness of their reporting in the past three months. In particular, the percentage of reports that include race data has increased from 21 percent in April to 59 percent in late July, while the percentage of reports that include ethnicity data increased from 18 percent to 50 percent during the same time period. While progress has been made, CDC will continue to work with states to improve completeness of the data. New reporting requirements require states to report race, ethnicity and other important demographic information with test results providing information on those impacted.

CDC's population-based COVID-NET system monitors COVID-19 associated hospitalizations that have a confirmed positive test in greater than 250 acute care hospitals in 99 counties in 14 states. Data gathered are used to estimate age-specific hospitalization rates on a weekly basis and describe characteristics of persons hospitalized with COVID-19 illness. CDC

staff also have access to HHS Protect, a platform for sharing healthcare information that allows the U.S. government to harness the full power of data for the COVID-19 response. CDC's existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and long-term care facilities. The NHSN also collects data from hospitals across the U.S. to address healthcare-associated infections and fight against antibiotic resistance.

The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID-19. CDC develops and disseminates guidance for a range of audiences, individuals and communities, including business, schools, and healthcare professionals. These recommendations include actions that every American should take, such as following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. Last week, CDC released new science-based resources and tools to support opening schools this fall. These resources provide students, school administrators, and parents the information they need to guide their decision-making on attending in-person curriculum and how to adapt to local conditions. Working in collaboration with their local health departments, schools can implement mitigation strategies - such as use of cloth face coverings, social distancing, hand washing, cohorting, and cleaning and disinfection - to help protect the health and safety of students, teachers, staff, and their community. CDC's school resources can be found here: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/index.html.CDC guidance is available here: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html

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

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

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

In addition, on June 4, CDC awarded $140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable state health departments to launch an initial scale up for influenza season, given the increased risk of COVID-19. Funds will, among other activities, begin to support staffing and preparedness this summer and focus on ensuring flu vaccine coverage for these vulnerable populations. Due to the risk of COVID-19, the goal is to significantly increase flu coverage for vulnerable populations during the 2020-21 flu season, ensure Americans are aware of the importance of getting vaccinated this flu season, and significantly increase access to flu vaccines for uninsured, high-risk adults.

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

chronic medical conditions, and some racial and ethnic minorities. Modernization efforts include support for the surveillance and data workforce, a key asset of the public health system. The vision is a real-time, interoperable networked health data system capable of moving faster than the health threats we combat, and we are moving toward that goal.

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

National Institute of Allergy and Infectious Diseases

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

NIAID responds rapidly to threats of emerging infectious diseases, by accelerating fundamental basic research efforts, engaging a domestic and international basic and clinical research infrastructure that can be quickly mobilized, and leveraging collaborative and highly productive partnerships with industry. NIAID also provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research on emerging and re-emerging infectious diseases. These research resources help bridge gaps in the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by product developers and incentivizing companies to partner with us in developing safe and effective countermeasures including vaccines, therapeutics, and diagnostics.

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

Developing Vaccines to Prevent SARS-CoV-2 Infection

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

NIAID 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 DOD. The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines, monoclonal antibodies, and drugs intended to treat and protect people from 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 COVID-19 vaccines, therapeutics, and diagnostics. The CoVPN will participate in harmonized protocols, developed in collaboration with the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership. The network is expected to participate 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; understand interest in, and concerns about, research participation in these communities; and 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. This trial was recently expanded to enroll older adults to better define the safety of and immune response to the vaccine across various age groups. On 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. On May 29, 2020, a Phase 2 clinical trial, sponsored by Moderna, was

initiated to further study the safety and immune response to the experimental mRNA vaccine. On July 8, 2020, Moderna announced that the Phase 2 trial was fully enrolled, with one cohort of healthy 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 Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA is supporting advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana, are collaborating with University of Oxford researchers to develop a SARS-CoV-2 chimpanzee adenovirus-vectored vaccine candidate AZD1222, formerly known as ChAdOx1. The University of Oxford has partnered with the pharmaceutical company AstraZeneca on this vaccine candidate, now in a Phase 2/3 clinical trial supported by the University. BARDA recently announced plans to support advanced development and production of AZD1222. RML investigators also have partnered with University of Washington scientists to investigate another mRNA vaccine candidate against SARS-CoV-2. NIAID is working with additional academic and industry partners to develop several other vaccine concepts.

The rigorous clinical testing required to establish vaccine safety and efficacy means that it might take some time for a licensed SARS-CoV-2 vaccine to be available to the general public, 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 plans to evaluate monoclonal antibodies directed against SARS-CoV-2 as tools to prevent transmission and spread. One clinical study will evaluate the use of these monoclonal antibodies for prevention of SARS-CoV-2 infection in households in which there is a confirmed case of COVID-19. A second clinical study will examine monoclonal antibodies for prevention among staff and residents in senior living facilities.

Identifying Therapeutics to Treat COVID-19

Effective therapeutics for COVID-19 are critically needed to treat patients who have been infected with SARS-CoV-2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID-19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of severe COVID-19 in hospitalized adults (ACTT-1). An analysis of preliminary data from ACTT-1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, although the mortality data did not reach statistical significance. A mortality rate of 7.1 percent was observed for the group receiving remdesivir versus 11.9 percent for placebo. These initial findings were published on May 22, 2020, in the *New England Journal of Medicine.* The adaptive design of this trial will enable 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. NIAID plans to evaluate the use of interferon beta-1a, which is used to treat individuals with multiple sclerosis, in the third iteration of the study (ACTT-3).

Monoclonal antibodies are another promising approach for the treatment of COVID-19. At least 21 companies are developing monoclonal antibodies that target SARS-CoV-2 and several of them have started early clinical trials. Monoclonal antibodies that target over-exuberant immune responses also are being studied. As part of the ACTIV partnership, and in collaboration with other NIH Institutes, NIAID plans to launch a series of OWS-supported studies to evaluate monoclonal antibodies in both outpatient and hospitalized settings. Outpatient studies of direct-acting antivirals also are scheduled to begin in August. 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 will also tell us about the natural history and long-term consequences of the disease. Among the first trials launched through CONNECTS, and in alignment with the ACTIV initiative, NHLBI will soon begin a series of clinical trials on the use of anticoagulants, hoping to stem the life-threatening blood clots that occur in many COVID-19 patients. Additionally, CONNECTS will leverage the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID-19, can help reduce the progression of COVID-19 in patients with mild symptoms. NHLBI also sponsored the addition of U.S. sites for a Canada-funded trial of colchicine—an anti-inflammatory drug commonly used to treat gout—for treating COVID-19 in the outpatient setting.

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

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID-19 therapeutics and vaccines. The ACTIV public-private partnership brings together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. Other federal partners include

BARDA, DOD, the Department of Veterans Affairs, CDC, and FDA. NIAID has been asked to lead the effort of U.S. government-supported clinical trials for certain vaccine candidates using the CoVPN and some therapeutic interventions that have been considered by ACTIV.

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

Enhancing Diagnosis and Understanding the Pathogenesis of COVID-19

NIH is supporting an HHS-wide effort to promote the development and commercialization of diagnostic tests to detect current SARS-CoV-2 infection. On April 29, 2020, NIH announced the Rapid Acceleration of Diagnostics (RADx) initiative, which is working to identify, support, and make innovative strategies for COVID-19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. RADx is leveraging the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for the potential roll out of new products by fall 2020. This initiative expects to award up to $500 million to support development of point-of-care and home-based diagnostic devices, as well as innovations that make current laboratory tests faster, more efficient, and more widely accessible. Innovators will be matched with technical,

clinical, regulatory, business, and manufacturing experts to increase the odds of success. In addition, NIAID is using CARES Act funds to support diverse SARS-CoV-2 diagnostic platforms including RT-PCR and enzyme-linked immunosorbent assays, and facilitating development of sensitive, specific, and rapid diagnostic tests by providing critical SARS-CoV-2 isolates and reagents to the developers of tests.

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 understand factors that have led to disproportionate burden of the pandemic on vulnerable populations so that interventions can be implemented to decrease these disparities.

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

NIAID, NCI, and NHLBI, along with scientists from CDC, BARDA, FDA and DOD, recently convened the COVID-19 Serology Studies workshop to bring together over 300 scientists and clinicians from the federal government, industry, and academia to discuss the role of serology testing in understanding and responding to the COVID-19 public health crisis and to explore strategies to address key scientific opportunities and knowledge gaps in this emerging field. Last month, 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 new study to investigate whether adults in the United States without a confirmed history of infection with SARS-CoV-2 have antibodies to the virus, indicating prior infection. In addition, NIH is supporting COVID-19 natural history studies to understand the incidence of infection in specific populations, including children and their household contacts, and aspects of the clinical course of infection, including incidents of thrombosis, strokes, heart attacks, and other sequelae of infection. Some of these studies will examine the quality and durability of the immune response to SARS-CoV-2 and evaluate whether unique immune responses may be associated with clinical disease trajectories; this information may be leveraged to develop SARS-CoV-2 therapeutics or vaccines. Natural history studies also will inform our understanding of COVID-19 pathogenesis, including factors that may predict disease progression and help to identify individuals or groups at high risk.

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

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

Office of the Assistant Secretary for Health

Diagnostics and Testing

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

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

- White House: Testing Blueprint Opening Up America Again
- White House: Addendum to the Testing Blueprint
- HHS: Report to Congress COVID-19 Strategic Testing Plan
- CDC: Overview of Testing for SARS-CoV-2
- CDC: Interim Considerations for K-12 School Administrators for SARS-CoV-2 Testing
- CDC: Interim Considerations for Institutes of Higher Education Administrators for SARS-CoV-2 Testing
- CDC: SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces
- CDC: Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings
- CMS: Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19
- CMS: Nursing Home Reopening Recommendations for State and Local Officials

In addition, the Administration is now reviewing testing plans from each state, territory, and major city public health unit, as a requirement of $10.25 billion in cooperative agreement funding distributed by the CDC. The State Testing Plans serve as a roadmap for each state's testing strategy for SARS-CoV-2. The overall goals for each state were determined in collaboration with the state and Federal experts considering multiple factors, including the rate of new cases, plans for mitigation, percent positivity. The plans submitted by the states will be continually improved through the ongoing collaboration of states with federal experts to meet the evolving circumstances in each jurisdiction. State Testing Plans for May through June for the 64 jurisdictions who received funding for COVID testing from the Paycheck Protection and Health Care Enhancement Act can be found here. Plans for July through December are currently under review.

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

Our overall strategic framework for testing is built on the principals outlined in the original *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 to facilitate community mitigation measures and allocation of national resources;
- Support public health isolation and contact tracing to control community spread;

- Diagnose COVID-19 rapidly in hospitalized patients to accelerate treatment and/or enrollment in clinical trials;
- Protect the vulnerable to minimize morbidity and mortality;
- Support safe reopening of schools and businesses by surveillance network that does not impede the clinical diagnostics system; and
- Enable state testing plans to achieve overall national objectives as well as state-specific goals.

Stage 1: Launch: Engaging the Emerging Crisis

In the early stages of the COVID-19 pandemic, the CDC was engaged in building the foundation for diagnostic testing in the United States.

Additionally, understanding the importance of increased testing, FDA engaged test developers from the beginning of the pandemic. With a desire to ensure high quality diagnostic testing but also ensure rapid development and dissemination of COVID-19 tests, FDA has provided voluntary EUA templates for laboratories and commercial manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID-19 tests. The amount and expediency in which EUAs were issued for COVID-19 tests far exceed past viral outbreaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. As of July 23, 2020, FDA has issued more than 180 COVID-19 test EUAs. The timeliness and number of EUAs issued by FDA for COVID-19 tests is unprecedented and has been critical to improving the testing scale and capacity in our country, while providing enough oversight to assure patients can depend on the results of these tests.

Throughout the COVID-19 outbreak, the Administration has encouraged and worked collaboratively with diagnostic test commercial manufacturers, commercial laboratories, public health laboratories, and professional societies to expand capacity and scale for existing nucleic acid testing platforms. Administration efforts have led the United States to develop a multilayered, multifaceted approach to testing that can provide the right test, at the right time, to the right people, with actionable results. This approach includes contributions from state public

health labs, high-throughput commercial laboratories, academic and hospital laboratories, laboratories at CDC, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs. In addition, the ecosystem now includes POC testing that can be done in rural areas at high risk without sophisticated supporting infrastructure, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of July 23rd, our nation has performed over 51 million tests. We are now conducting approximately 770,000 tests per day; and this number will continue to increase. Commercial laboratories are working more efficiently, processing tests in rapid succession, which ensures patients receive their results, on average, within three days. Hospital and academic laboratories typically provide results within 2 days, and often much sooner. POC tests provide results within 15 minutes.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country. The Corps had unique expertise in COVID-19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 390,000 individuals, with an overall SARS-CoV-2 test positivity rate of approximately 15 percent, and serving as a model for all future iterations of community based testing. This positivity rate means that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with technological advances such as the validation of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment. The CBTS initiative was an early example to states and localities on how to conduct community based COVID-19 testing, and this model has been replicated throughout the country to screen and test hundreds of thousands more Americans.

Since early January, the Administration has maintained constant contact with state and local governments and tribal nations to expand testing throughout the country. The constant communication between the Administration and state leadership has helped provide guidance to states on how to best utilize testing capacity in their own states. Another product that was produced by the Administration to assist the states to leverage the full testing capacity at their disposal was a database of nationwide lab locations and capacity, including the specific testing platforms at each laboratory.

Stage 2: Scaling and Technological Innovation

The identification and expansion of public and private sector testing infrastructure has been, and continues to be, a priority. One example of expanding testing infrastructure through public-private partnerships is the engagement of the Administration with well-known retailers that have a regional or nationwide footprint. As of July 24, and with the assistance of the Federal Government, U.S. retailers have opened and are operating 706 testing sites and they have tested over 1,156,000 individuals. The Federal Government built public-private partnerships to increase the number of testing sites offered at commercial locations across the country. The public-private partnerships with these retailers are being expanded to support many more testing sites that will be opened and operating in the coming weeks. These commercial testing locations are uniquely situated to meet the testing needs of communities with moderate to high social vulnerability, which was the focus of the original sites. Going forward, retailers have indicated their intent to open at least one thousand more of these sites depending on local needs.

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

In May and through July 23, working collaboratively with FEMA and utilizing their logistics, the Federal Government has procured and began to distribute to states – according to their needs and plans – over 41 million specimen collection swabs and more than 32 million tubes of transport media. To meet state needs, this procurement and distribution will continue at least December 2020, and will be necessary if it needs to continue past that point.

In order to capture feedback and foster communication between federal officials and the private sector, HHS created the *National Testing Implementation Forum*. The Forum will bring together representatives from key stakeholder groups to share information and provide input to federal leaders about SARS-CoV-2 testing. The members of the Forum will 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). The Forum will seek new techniques and technologies, and identify any barriers to a streamlined national laboratory testing reporting system and defined reporting standards. The Forum will also provide input to improve technical assistance across the nation to target testing among the vulnerable and underserved and create a sustainable diagnostics ecosystem that is sustainable and fully capable for future public health challenges.

Stage 3: Support Opening Up America Again

Current efforts are focused on further scaling up testing capabilities to guarantee that each state has the testing supplies and capabilities they need to reopen according to their own individual state plans. For example, the Federal Government will continue to procure and distribute collection swabs and tubes of transport media at least through December 2020 allowing the states to test at least 2 percent of their population each month.

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

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

In early July, HHS announced surge testing efforts in prioritized communities across the country. These free COVID-19 testing sites temporarily increase federal support to communities where there has been a recent and intense level of new cases and hospitalizations related to the ongoing outbreak. HHS, in partnership with each of the local communities and private partners, will perform surge testing by offering 5,000 tests per-city per-day at no charge to those tested. These sites will be live anywhere from five to 12 days.

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

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

Protecting the Vulnerable

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

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

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

million homeless individuals, and nearly 1 million migrant agricultural workers. Health centers are uniquely situated in communities to serve those that are most vulnerable and 93 percent of these centers offer COVID-19 testing. As of July 17, Health Centers have reported testing nearly 2.1 million individuals in total and racial and/or ethnic minority patients represent 54 percent of those tested.

To promote and protect the health and safety of vulnerable older adults, HHS has undertaken a large-scale procurement of FDA-authorized rapid point-of-care diagnostic test instruments and tests to be distributed to every nursing home in the United States. This bold action to facilitate on-site testing among nursing home residents and staff will provide nursing homes the ability to augment their current capacity for SARS-CoV-2 testing, bolstering their response and helping to prevent the spread of this virus. Distribution has already begun with nursing homes prioritized by the Centers for Medicare & Medicaid Services (CMS).

United States Public Health Service Commissioned Corps

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

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 5,600 deployments as of July 23, 2020. Corps officers provided critical assistance to community-based testing sites throughout the nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID-19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a “cavalry” to support healthcare systems under stress in states across the country. COVID-19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City, and to the TCF Center in Detroit. At the end of March, the Navajo Nation requested CDC

assistance to provide care amidst a surge of COVID-19 cases. Since that time, the Corps has deployed teams to support the response. The Corps has also deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

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

Food and Drug Administration

From the beginning of this public health emergency, FDA has taken an active leadership role in the all-of-government response to the COVID-19 pandemic, inspired by the resiliency of the American people and our great innovators. FDA stood up an internal cross-agency group that continues to ensure we are doing everything possible to protect the American public, helps ensure the safety and quality of FDA-regulated products, and provides the industries we regulate 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

FDA has been proactive and supportive of test development by all interested parties—including laboratories, and large and small commercial manufacturers — to speed development and to 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 180 Emergency Use Authorizations (EUAs) for tests, including molecular, antigen, serology and tests with at-home specimen collection indications.

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.

In a public health emergency, obtaining an accurate test result is important not only for the individual patient, but for the public at large. False positive or false negative results can contribute to the spread of SARS-CoV-2, so all tests used for COVID-19 should be validated before use. 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.

Even prior to any diagnosed U.S. cases of COVID-19, FDA proactively reached out to developers to encourage the development of tests and to offer assistance from the Agency to help facilitate development. To balance the urgent need to increase diagnostic testing capacity in the U.S. with the need to provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA announced several policies to facilitate oversight. These included engaging in rolling reviews of EUA submissions, and authorizing tests that had the necessary data to support that the criteria for issuance are met. FDA has developed several EUA templates, including those for diagnostic, serological, and testing with at-home specimen collection. These templates help to streamline the EUA submission process as well as provide helpful information to developers that can speed validation and authorization of new tests. And, states that have the capacity and expertise to do so have been authorizing tests for use within a laboratory in that state.

FDA is also monitoring imported test kit products and where appropriate detaining and examining these at ports and border. We are also engaging in outreach when we become aware that test developers are making false or misleading claims about their tests. We are monitoring the market for unapproved, un-cleared, or unauthorized tests and have issued Warning Letters.

FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk. Importantly, FDA continues to update its website to make clear which tests have been authorized by the Agency, and which tests have not.

FDA also 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.

FDA has worked around the clock to 1) support test development by laboratories and commercial manufacturers; 2) research and mitigate shortages of test components, including identifying and sharing scientifically acceptable alternatives for components on FDA's website; 3) arrange with the Department of Defense weekly airlifts of swabs to the United States; 4) engage nontraditional device manufacturers to support the manufacture of new swabs and other supplies that are needed in the United States; 5) offer support to developers through key resources, including FAQs that are updated regularly, serve as a clearinghouse for scientific information that the community may leverage to increase testing capacity; and 6) operate a hotline and provide other resources for industry to contact the FDA directly.

Serology Testing

Serology tests detect antibodies or proteins present in the blood when the body is responding to a specific infection, like the virus that causes COVID-19. Such a test detects the

body's immune response to an infection. These tests do not diagnose a current COVID-19 infection; however, they can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have overcome an infection in the past and may have developed an immune response. These tests may also aid in identifying individuals with antibodies to the virus that causes COVID-19 so they may donate convalescent plasma as a possible treatment for severely ill COVID-19 patients, which is a potential treatment currently being researched.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serology tests to market or use their tests once they have performed the appropriate validation to determine that their tests are accurate and reliable, without FDA authorization and as further recommended in the policy. The policy led to early patient access with appropriate transparency regarding the limitations of these tests. At the time FDA issued this policy, flexibility was important as early use of antibody tests allowed us to begin to answer some of the critical population-level questions about the prevalence of COVID-19 infections in different communities, whether the presence of antibodies might convey immunity and, if so, for how long, while also encouraging test developers to seek an EUA, as many did. Failure to answer these questions could lead to inappropriate decisions by Federal, State, and local governments, businesses, and other entities. Early availability of serology tests has helped generate important information that can inform the future use of serology tests.

To help mitigate the trade-off of helping to ensure early availability and having time to obtain a good understanding of test performance, FDA's March 16 policy was intended to limit antibody testing to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) by the Centers for Medicare & Medicaid Services (CMS) to perform testing in high-complexity and point-of-care settings when covered by such certificates – that is, labs with special clinical and technical expertise – as long as the tests were properly validated and labeled as outlined in our policy, and the developer notified FDA. Notably, use of antibody tests in other settings, including at home, prior to issuance of an EUA authorizing such use is not permitted under CLIA, and our March 16 policy did not change that.

Once FDA had authorized more serology tests, we built on this policy by updating it on May 4th and again on May 11th to outline key expectations for antibody test developers, including

that commercial manufacturers would submit EUA requests, with their validation data, within 10 business days from the date they notified FDA of their validation testing or from the publication date of the policy, whichever was later. FDA also provided specific performance recommendations for serology tests. FDA is constantly reassessing the evolving situation and updates its policies as needed.

The policy for laboratories certified under CLIA to perform high-complexity testing regarding their developing and performing their own serology tests has not changed. Such laboratories perform their own validation and provided notification to FDA while following other recommendations with respect to labeling as described in the policy. FDA is focusing its EUA review and authorization efforts on serology tests of commercial manufacturers, which have the potential to be distributed more broadly because they can be used at a number of laboratories, compared to laboratory developed tests, which can be performed only at the one CLIA-certified high-complexity lab that validated the test in-house.

FDA has also introduced a more streamlined process to support EUA submissions and review. Two voluntary EUA templates for antibody tests have been made available – one for commercial manufacturers and one for CLIA certified high-complexity labs that decide to seek FDA authorization. These templates can help facilitate the preparation and submission of an EUA request and can be used by interested developers. Also, as we do for diagnostic tests, we are happy to work with developers of serology tests on other approaches if they do not want to use one of the templates.

In addition to reviewing data submitted in the form of EUA requests, FDA also continues working with the NIH , the CDC, and BARDA regarding the National Cancer Institute's (NCI) independently validating certain 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. FDA is using NCI data to inform future decision making, such as whether to authorize the test, guide us in engaging the test developer for additional information to support its test remaining on the market, or take other action regarding tests that do not perform adequately, including removing them from our notification list and stopping their distribution in the U.S.

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

under the 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.

FDA will continue to appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. Importantly, we continue to work with developers of serological tests and are reviewing submitted EUA requests to authorize even more of these tests. FDA continues to work closely with 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 intends to use 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, manufacturers, and experts across the globe to help expedite the development and availability of vaccines to prevent infection with COVID-19 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 feedback and 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 recommendations and assistance FDA has been providing over the past several months 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, and for post-licensure safety evaluation of 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.

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 is supporting the program by reassigning staff and working continuously to review requests from companies, scientists, and doctors who are working to develop therapies. Under CTAP, FDA is using every available authority and regulatory flexibility to facilitate the development of safe and effective products to treat patients with COVID-19.

Further, FDA is partnering with the NIH in its efforts to develop a national strategy for a coordinated research response to the pandemic. The 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 reducing lung inflammation and improving lung function in COVID-19 patients. All this work is beginning to pay off, and we announced the positive results of the NIAID trial of remdesivir in patients with severe COVID-19. On May 1, FDA issued an EUA for remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease.

Another potential approach for treatment is the use of antibody-rich products such as convalescent plasma and hyperimmune globulin. These blood products are manufactured from plasma donated by people who have recovered from the virus and such products are being studied to determine if they could shorten the length, or lessen the severity, of the illness. We are evaluating convalescent plasma in the context of traditional clinical trials and are helping to facilitate a national expanded access program and emergency access for individual patients, as

appropriate. A key to ensuring the availability of convalescent plasma to those in greatest need, as well as to supporting clinical development of convalescent plasma and hyperimmune globulin, has been by persuading fully recovered COVID-19 patients to donate plasma if they meet FDA's donor eligibility criteria. To that end, FDA continues to work with blood 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, including expanded access and clinical trials.

Medical Product Supply

FDA monitors and proactively adjusts to the worldwide demand and supply chain disruptions for medical products caused by the COVID-19 pandemic. We are working closely with manufacturers to help ensure they continue to notify the Agency of any permanent discontinuance or interruption of drug (human and animal), biological product, and device manufacturing in a timely manner. 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.

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

We are working to increase the supply of PPE, and continue doing everything in our authority to increase the availability of PPE and other critical devices that patients and those on the front lines of the U.S. response rely upon. FDA has reached out to over 1,000 manufacturers since January and has helped facilitate an increase of the availability of PPE while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them. FDA has issued several EUAs to help make more respirators available to health care personnel and ease burdens on the health care system. These allow for the emergency use of NIOSH-approved respirators in health care settings for healthcare personnel and the importation of non-NIOSH approved respirators that meet certain specified criteria, as set forth in the various EUAs. FDA has also issued several guidances to provide flexibility for those manufacturing PPE for the COVID-19 response, and we have published conservation strategies for gloves and masks and gowns. To support these efforts further, FDA has issued several EUAs for devices used to decontaminate respirators for reuse by health care workers in hospital settings, where appropriate.

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

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

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

Food Supply

FDA is working with our federal, state, and local partners as well as industry to help ensure a safe and adequate food supply for both people and animals. 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. FDA continues to monitor closely the overall safety of the nation's food supply. Importantly, we continue to work with CDC, the U.S. Department of Agriculture, and our state and local partners to protect consumers from foods contaminated with pathogens. For example, in March, FDA found and detained *Salmonella*-contaminated tahini products at the port of entry; products that were already in U.S. distribution were recalled. In June, FDA started investigating a multistate outbreak of Cyclospora illnesses potentially linked to store brand garden salads, and products were recalled.

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. For example, FDA has sent hundreds of abuse complaints to domain name registrars and internet marketplaces, which in most instances resulted in those registrars on marketplaces voluntarily removing websites or listings selling products that fraudulently claim to diagnose, cure, mitigate, treat, or prevent COVID-19. The Agency also has sent more than 90 warning letters to sellers of such 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 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 the US Customs and Border Protection (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.

We are in close communication with our partners at U.S. CBP to proactively identify and mitigate any potential backlogs of lawfully marketed medical products for COVID-19. FDA participates in FEMA Supply Chain Task Force meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by

FEMA, to facilitate the lawful entry and use of imported medical products coordinated through FEMA, and to inform medical product supply chain discussions.

Conclusion

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