

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

“COVID-19: Safely Getting Back to Work and Back to School”

Witnesses appearing before the
Senate Health, Education, Labor and Pensions Committee:

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

Robert R. 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

Stephen M. Hahn, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration

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Introduction

Since President Trump took office, his work to protect the health and safety of the American people has included a specific focus on monitoring, preparing for, and responding to biological threats, such as infectious disease outbreaks. As soon as the United States became aware of a novel coronavirus at the end of 2019, the U.S. Government was tracking its spread and began preparing necessary responses.

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

The Department of Health and Human Services (HHS) is working closely with all of our government partners in this response. We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility. Within HHS, the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID), the Assistant Secretary for Health, and the Food and Drug Administration (FDA), along with additional components not represented today, play critical roles in the response to this public health emergency as discussed below.

Centers for Disease Control and Prevention

CDC is America's health protection agency, and works 24/7 to save lives and protect America from health, safety and security threats, both foreign and in the United States. Addressing infectious diseases like COVID-19 is fundamental to our mission and is our highest priority. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and pandemic influenza to meet new challenges presented by COVID-19. These challenges are many, and they are historic. Every single American is affected by this pandemic, and CDC is leaning into this public health crisis with every applicable asset we have. CDC is drawing on its emergency response capacity and its relationships with state, tribal, local, and territorial (STLT), global, and private sector partners; and is leveraging our workforce's strengths in public health surveillance, and laboratory capacity, to address this public health emergency. CDC is developing guidance for healthcare professionals and the public to encourage safer practices, improve health outcomes, and save lives. CDC is also working with partners to develop guidance and decision tools to assist state and local officials and other stakeholders in adjusting mitigation strategies. Importantly, CDC is preparing the nation's public health system and the private sector for a vaccine when one is available. Abroad, CDC is leveraging investments in global health security, pandemic influenza preparedness and public health infrastructures and capacities built through programs like the President's Emergency Plan for AIDS Relief to support countries in mitigating and containing COVID-19. The emergence and rapid spread of COVID-19 confirms that an infectious disease threat anywhere is a threat to Americans everywhere, including here at home.

When, in late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered in Wuhan, China, CDC began monitoring the outbreak. At the beginning of January, CDC began developing situation reports, which were shared with HHS, and reaching out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response structure to facilitate staffing and communications. On January 21, 2020, CDC officially activated its Emergency Operations Center for COVID-19. Using the IM structure, CDC immediately set up task forces to address key needs and reached out frequently to our state and local partners. On March 17, 2020, CDC joined other HHS components and the Federal

Emergency Management Agency (FEMA) in coordinating activities through FEMA's National Response Coordination Center. Addressing COVID-19 is taking an all-of-government effort.

Congress has addressed the urgent need to respond to this pandemic at home and abroad and has allocated substantial resources for CDC's COVID-19 activities through the statutes mentioned above. This funding supports a federally guided, state managed, and locally implemented response to COVID-19 in the United States. With support provided by Congress for global disease detection and emergency response through COVID-19 appropriations, CDC is supporting prevention, preparedness, and response efforts in partnership with public health agencies, health ministry counterparts and multilateral and non-governmental agencies worldwide. Here in the United States, CDC is working with STLT partners to focus use of these resources to establish and enhance case identification; conduct contact tracing; implement appropriate containment and community mitigation measures; improve public health surveillance; enhance testing capacity; control COVID-19 in high-risk settings; protect vulnerable and high-risk populations; and work with healthcare systems to manage and monitor capacity. As of May 1, 2020, CDC has announced or obligated \$1.627 billion in awards to jurisdictions across America from the funds provided by Congress.

CDC is providing direct technical assistance and support to STLT partners as they consider approaches to mitigate and contain COVID-19. The White House, and federal partners including CDC, have convened calls with all 50 states, Puerto Rico and the District of Columbia to identify state capacities and needs. The federal government has committed to ensuring that states can meet testing objectives for the month of May, as identified by each state. Through these calls and other outreach efforts, CDC has worked with jurisdictions to identify needs and develop plans to enhance testing capacity, state surveillance, contact tracing, and surge staffing. These discussions and plans for action will emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

In addition, CDC has launched a multifaceted approach to enhance and complement STLT efforts and expand support to communities during the current public health emergency. The COVID Response Corps is a new, nationwide community-focused initiative to identify surge staffing and resources to STLT health departments on the frontlines of the fight against

COVID-19. Response Corps members will augment health department teams and engage in core public health functions including contact tracing, testing, infection prevention and control, call center activities, COVID-19 education, and public health surveillance.

CDC relies on timely and accurate public health surveillance data to guide public health action and inform the nationwide response to COVID-19. This crisis has highlighted the need to continue efforts to modernize the public health data systems that CDC and states rely on for accurate data. Public health data surveillance and analytical infrastructure modernization efforts started in FY2020 using funds provided by Congress, which have been augmented by \$500 million provided for these efforts under the CARES Act. Timely and accurate data are essential as CDC and the nation work to understand the impact of COVID-19 on all Americans, particularly for populations at greater risk for severe illness, such as older Americans, those with chronic medical conditions, and some racial and ethnic minorities. CDC is also working to understand the impact of COVID-19 on healthcare workers, first responders, and other essential workers. Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is capitalizing on multiple existing surveillance systems run in collaboration with STLT partners, including influenza and viral respiratory disease systems. In collaboration with STLT partners, CDC is committed to making data available to the public, while protecting individual privacy. CDC's population-based COVID-NET system monitors COVID-19 associated hospitalizations that have a confirmed positive test in greater than 250 acute care hospitals in 99 counties in 14 states. Data gathered are used to estimate age-specific hospitalization rates on a weekly basis and describe characteristics of persons hospitalized with COVID-19 illness. CDC is using these data to monitor hospitalizations by race, ethnicity, underlying condition, age, and gender, and is now including this information in CDC's weekly COVIDView summary. CDC is now receiving more granular data on deaths by state and locality, allowing us to identify and address where there may be racial and ethnic disparities in morbidity and mortality. CDC also is augmenting the existing National Healthcare Safety Network to monitor and analyze the capacity of the healthcare system daily—including hospitals and nursing homes—so that federal, state, and local officials can adjust their response and mitigation efforts as needed.

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

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

During the week of March 30, CDC and public health partners began the first stage of studies of community transmission of SARS-CoV-2. These initial studies use serum samples collected in the state of Washington and New York City. In April, the second stage expanded to include serologic testing in more areas with high numbers of people with diagnosed infections. It also includes studies of households in some states. By using seroprevalence surveys, CDC can learn about people who have been infected, including those infections that might have been

missed due to lack of symptoms or testing not being performed for other reasons. These surveys can also track how infections progress through the population over time. This is done by taking “snap shots” of the percentage of people from the same area who have antibodies against SARS-CoV-2 (also called the seroprevalence) at different time points.

On April 27, 2020, CDC updated testing prioritization and focused testing guidelines for those who may have or who are at risk for active SARS-CoV-2 infection. Clinicians considering testing of persons with possible COVID-19 should continue to work with their local and state health departments to coordinate testing through public health laboratories or use clinical laboratory viral tests for COVID-19 that has been issued an Emergency Use Authorization (EUA) by FDA or are being offered as outlined in FDA’s policy regarding COVID-19 tests. 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. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing) but some people may present with other symptoms as well. Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID-19 infections in a jurisdiction.

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 individuals and communities. These recommendations include actions that every American should take, such as following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. CDC guidance is available here <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick-prevention.html>.

First responder and healthcare guidance documents cover a range of topics - from addressing potential work-related exposures, implementing infection prevention and control measures in health facilities, and optimizing the supply of personal protective equipment to clinical evaluation, testing, and clinical care. CDC is providing these recommendations to support communities’ efforts, while recognizing that each sector and community is unique and

will need to consider these in the context of their community-level data and circumstances. CDC teams on the ground and those aiding from Atlanta are and will continue working with state and local officials to integrate these recommendations into COVID-19 plans.

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 awardees to help ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking. CDC remains committed to supporting the COVID-19 response with all available resources.

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 it, 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 infectious diseases as they emerge, 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 improved our fundamental understanding of coronaviruses and provides a strong

foundation for our accelerated efforts to address the challenge of COVID-19 by developing vaccines, therapeutics, and diagnostics.

Developing Vaccines to Prevent SARS-CoV-2 Infection

A safe and effective vaccine for SARS-CoV-2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks. NIAID is supporting development of several SARS-CoV-2 vaccine candidates, including vaccines based on platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

The NIAID Vaccine Research Center has collaborated 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. The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA plans to support advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories (RML) are collaborating with University of Oxford researchers to develop a SARS-CoV-2 chimpanzee adenovirus-vectored vaccine candidate, now in a Phase 1/2 clinical trial supported by the University of Oxford. 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 safety and efficacy means that it might take some time for a licensed SARS-CoV-2 vaccine to be available to the general public. The COVID-19 response currently is focused on the proven public health practices of containment and mitigation.

Identifying Therapeutics to Treat COVID-19

Effective therapeutics for COVID-19 are critically needed to treat many patients globally who have been infected with SARS-CoV-2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial to evaluate the safety and efficacy of therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of COVID-19 in hospitalized adults. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the immunosuppressive drug baricitinib, which was recently added to the study. An analysis of preliminary data from 1,063 patients enrolled in the trial indicated that those who received remdesivir had a 31 percent faster time to recovery, 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, though the mortality data did not reach statistical significance. A mortality rate of 8 percent was observed for the group receiving remdesivir versus 11.6 percent for placebo. NIAID is developing and testing other novel and repurposed therapies, including monoclonal antibodies (mAbs). NIAID also is planning clinical trials to evaluate hydroxychloroquine (HCQ) and azithromycin in patients with mild to moderate COVID-19, and hyperimmune intravenous immunoglobulin (IVIG) for treatment of COVID-19.

On April 6, 2020, the National Heart, Lung, and Blood Institute (NHLBI) launched a clinical trial of HCQ in hospitalized COVID-19 patients through its Prevention and Early Treatment of Acute Lung Injury (PETAL) clinical trials network. NHLBI also sponsored the addition of a U.S. site for a Canadian Institutes for Health Research-funded trial of colchicine—an anti-inflammatory drug commonly used to treat gout—for treating COVID-19 in the outpatient setting. Additionally, NHLBI is leveraging the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID-19, can help reduce the progression of COVID-19 in patients with mild symptoms.

The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection, a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS-CoV-2 therapeutics for further investigation. Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the

development and testing of mAbs and antiviral drugs for potential treatment of COVID-19. NIAID, the National Cancer Institute (NCI), NHLBI, NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke are all engaged in this critical effort.

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID-19 therapeutics and vaccines. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership brings together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. Other federal partners include BARDA, the Department of Defense (DOD), the Department of Veterans Affairs, CDC, and FDA.

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 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. The guidelines will be updated regularly as new credible 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 will work to identify, support, and make innovative strategies for COVID-19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. RADx will leverage the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for 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 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 test developers. In addition, NCI is coordinating with FDA and NIAID to assess the sensitivity and specificity of marketed SARS-CoV-2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV-2.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the U.S. 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 clinical course of infection, including incidents of thrombosis, strokes and 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; 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 will help to identify individuals or groups at high risk.

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 safe and effective COVID-19 vaccines and therapeutics, and sensitive, specific, and rapid point-of-care diagnostic 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 will be further magnified as states enter Phase-1 of reopening. The indications for viral testing depend heavily on the stage of the pandemic and the extent of mitigation employed. In general, testing may be indicated for diagnosis of those who are symptomatic, tracing of those in contact with those who are infected,

and surveillance testing of those who are asymptomatic or mildly symptomatic to achieve infection control and/or other public health objectives.

The focus of this testimony is on testing for the presence of the virus, in contrast to testing for the presence of antibody to the virus. The former determines whether the individual *is* actively infected, and presumably infectious. The latter determines whether the individual *has been* infected, has developed an immune response, and may be protected from subsequent SARS-CoV-2 infections.

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. New 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 limited utility because of its low throughput. 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 components. This reality represented substantial challenges, but federal leadership has guided efforts to combat these challenges in close collaboration with states, local jurisdictions, and the private sector. Our overall strategy for testing includes:

- Assuring that those who need testing, receive testing
- Prioritizing testing to meet the stage of the pandemic
- Increasing the number and diversity of tests
- Enhancing states' ability to collect specimens through novel "front ends" like drive-through sites
- Organizing and galvanizing the industry on an unprecedented scale
- Enhancing testing to underserved communities
- Providing surge testing capacity during local outbreaks

- Supporting critical infrastructure and national security needs
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

The overall testing strategy is outlined chronologically as we met the needs of each evolving stage of the pandemic.

Stage 1: Launch: Engaging the Emerging Crisis

In the beginning stages of the COVID-19 pandemic, CDC was engaged in building the foundation for diagnostic testing in the United States. On January 10, 2020, Chinese researchers deposited the 2019-nCoV genome sequence to GenBank and CDC began development of the CDC 2019-nCoV Real-Time PCR Diagnostic Panel. On January 24th, CDC publicly posted its assay for the CDC's newly developed diagnostic panel, allowing the global community to develop their own assays using the CDC design. On February 3rd, CDC submitted an EUA request, and the FDA issued an EUA on February 4th, enabling use of the CDC's COVID-19 diagnostic Panel.

Understanding the importance of increased testing, the FDA moved swiftly to engage with more than 470 test developers that indicated their intent to submit requests for EUAs. In mid-January, BARDA convened a meeting of leading diagnostic companies from across America to encourage development of COVID-19 tests. In the ensuing months, multiple funding opportunities for the development of COVID-19 diagnostic tests were announced and NIH provided COVID-19 RNA to diagnostic companies to expedite private-sector test development. With a desire to ensure high quality diagnostic testing but also ensure rapid development and dissemination of COVID-19 tests, the FDA has provided EUA templates for laboratories and manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID-19 tests. This has contributed greatly to the dramatic increases in testing the nation has seen in the past months. The amount and expediency in which EUAs were issued for COVID-19 tests far exceed past viral outbreaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. Currently, FDA has issued more than 70 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.

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

As of the beginning of May, our nation is performing more than 200,000 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.

Concurrent to the federal government's efforts to expand capacity and scale of laboratories testing capabilities across the country, the Administration also worked with 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 and fourteen sites remain open with federal support. These sites are located in Colorado, Texas, Illinois, New Jersey, and Pennsylvania. 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 140,000 individuals, and with an overall COVID-19 test positive rate of approximately 17 percent, meaning that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with

technological advances such as the validation of 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.

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

Stage 2: Scaling and Technological Innovation

The identification and expansion of public and private sector testing infrastructure has been, and continues to be, a priority. One example of expanding testing infrastructure through public-private partnerships is the engagement of the Administration with well-known retailers that have a regional or nationwide footprint. As of May 5 and with the assistance of the federal government, United States retailers have opened and are operating 102 testing sites in 31 states. In an effort to expand testing further, the federal Government is building upon the 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 also 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 hundreds more of these sites depending on local needs.

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

As of April 30, the federal government had directly procured 6.7 million swabs, 3.3 million vials of transport media, 15 million lancets, and 15 million alcohol pads. As of March 27th, the federal government had also facilitated the nationwide delivery of 175.2 million masks, 14.7 million gowns, and 793.8 million gloves. Through the mechanisms mentioned above, we are unlocking the full potential of laboratories in the United States and this is allowing testing capacity to expand consistently.

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 is procuring over 21 million swabs and 13 million collection tubes with transport media (or saline) in May. These supplies will be shipping out to states over the course of the month. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million extraction and PCR kits in May, enabling states to complete millions of additional tests in May. In mid-March, the FDA issued an EUA for Hologic's Panther COVID-19 test, which runs on more than 600 lab machines across the United States. Hologic will be shipping several million test kits to labs across the nation starting in early May.

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, describes roles and responsibilities as well as elements of the robust testing plans and rapid response programs called for in the President's Guidelines.

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

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

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

We recognize that vulnerable populations in many underserved communities are among the highest risk of suffering devastating health and economic impacts of COVID-19. We issued a Notice of Funding Opportunity on May 1. 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 minority as well as rural and socially vulnerable communities across the nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most.

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 U.S. 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 3,200 officers today with many of them undertaking multiple or consecutive deployments. Corps officers have been deployed across our country and internationally to assist with the outbreak response, to support the return of American citizens, to assist in the management of hospitalized United States citizens with COVID-19 abroad, and to support clinical trials related to COVID-19. Corps officers provided critical assistance to community-based testing sites throughout the nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID-19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a “cavalry” to support healthcare systems under stress in states across the country. COVID-19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City; and to the TCF Center in Detroit. The Corps is also preparing to send teams to the Navajo Nation to provide care amidst a surge of COVID-19 cases.

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.

U.S. Food and Drug Administration

From day one of this emerging 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. Long before the first domestic case was reported, FDA stood up an internal cross-agency group that continues to ensure we are doing all we can to protect the American public, helps ensure the safety and quality of FDA-regulated products and provides the industries we regulate the tools and flexibility to do the same. Work has focused on facilitating medical countermeasures to diagnose, treat and prevent the disease, and surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary to protect the health of Americans. 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

In an emergency, FDA oversees the validity of tests developed by others through the Emergency Use Authorization (EUA) process. Every action FDA has taken during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make tests available with providing a level of oversight that helps to ensure accurate tests are being deployed.

COVID-19 has created a demand for new tests that is unprecedented in both volume and urgency. As with other emergencies, FDA has been extremely proactive and supportive of diagnostic test development by all comers—laboratories, and large and small commercial manufacturers. Even prior to any U.S. cases of COVID-19, FDA proactively reached out to developers to encourage the development of tests and to see what the Agency could do to facilitate development. In its COVID-19 Testing Guidance, FDA has provided flexibility to encourage innovation and help speed development of COVID-19 tests. FDA is engaging in rolling reviews of EUA submissions and is quickly authorizing tests that the science and data support. As outlined in the guidance, certain laboratories and commercial manufacturers are developing their own diagnostic tests and, once validated, are beginning to use them while they prepare an EUA submission for FDA review. In addition, under our policies, states that have the capacity and expertise to do so have been authorizing tests for use within a laboratory in that state.

In a public health emergency, getting an accurate test is important not only for the individual patient, but for the public at large. All tests should be validated before use because it is critical that these tests work. FDA's policies do not change that. False positive and false negative results can contribute to the spread of COVID-19. As with medical treatments, we want tests to be safe and, in the case of diagnostics, accurate. FDA plays an important role helping to ensure we are getting accurate answers. We are monitoring the market for fraudulent and harmful tests. FDA has and will continue to take appropriate action against firms that place the public health at risk and follow up with bad actors. There are several cases where developers of tests have updated or changed claims at FDA's urging.

FDA is working on several fronts to provide more clarity about which tests have been reviewed and authorized by FDA and which have not. FDA has been posting on its website the tests for which it has received a notification as outlined in its COVID-19 testing policies.

FDA has been working around the clock to 1) encourage and support test development for the U.S. market, working with over 470 developers since January; 2) issue EUAs for diagnostic tests, including those for home self-collections; 3) research and mitigate shortages of test components, including identifying and sharing scientifically acceptable alternatives for components on FDA's website; 4) arrange with the Department of Defense weekly airlifts of swabs to the United States; 5) engage nontraditional device manufacturers to support use of new swabs and other supplies that are needed in the United States; 6) offer support to all developers through a 24-hour hotline and key resources, including FAQs, that it updates regularly as it serves as a clearinghouse for scientific information that helps everyone increase testing capacity.

Serological Testing

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like the virus that causes COVID-19. Such a test detects the body's immune response to an infection. These tests do not diagnose COVID-19; however, we believe these tests can play a critical role in the fight against COVID-19 by helping healthcare professionals to identify individuals who may have overcome an infection in the past and 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, which requires more data and research to determine if this is a safe and effective treatment for COVID-19, but may help those who are seriously ill from COVID-19.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serological tests that begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable, without FDA authorization, and as further outlined in the policy. The policy is intended to allow for early patient access and flexibility for developers, with appropriate transparency regarding the limitations of these tests. On May 4th, FDA took important steps to build on this policy by updating it to outline key expectations for antibody test developers: 1) commercial manufacturers will 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 this policy, whichever is later, and 2) FDA has provided specific performance threshold recommendations for all serology test developers. The policy for laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing, regarding their developing and performing their own serology tests, has not changed. They continue to perform their own validation and provide notification to FDA, and should follow the other recommendations with respect to labeling as described in the policy. In addition to these updates, we are introducing 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 who decide to seek FDA authorization. These templates will facilitate the preparation and submission of an EUA request and can be used by an interested developer. And 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, FDA issued an umbrella EUA for certain antibody tests that undergo a validation evaluation at NCI, or another government agency designated by FDA. Tests that FDA confirms meet the performance and labeling criteria outlined in the EUA may be added under the umbrella EUA, streamlining the submission and review of these important tests. We are continuing to provide updated information and educational materials to states and health care partners. If particular commercial manufacturers that are currently marketing serology tests under the policy fail to submit an EUA within 10 business days of notification or policy publication (whichever is later), we intend to share this information publicly and take appropriate action as needed. We will also keep up our work to stop illicit tests from entering the U.S., and to keep fraudulent products off the market.

FDA will continue to take steps to balance assurances appropriately that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. To date, FDA has issued numerous EUAs for serological tests, issued an "umbrella" EUA for certain serological tests, and is working with hundreds of developers on pre-EUAs.

Importantly, we are working with developers and other partners to evaluate the validity of serological tests, and are working to authorize even more of these tests under EUAs. I continue

to work closely with my fellow Coronavirus Task Force members in examining the role testing will play as we look to reopen our country's schools, businesses, and public services.

Vaccine Development and Treatment Interventions

At this time there is no FDA-approved vaccine to prevent being infected with COVID-19. FDA is working closely with federal partners, vaccine developers, researchers, manufacturers, and experts across the globe to help expedite the development and availability of vaccines and drugs to prevent or treat COVID-19 infections. FDA intends to use regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID-19.

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

Therapeutic Development

At this time there are no FDA-approved drug products to treat COVID-19. Since the beginning of the COVID-19 pandemic, FDA has been working tirelessly to facilitate the development and availability of therapeutics for use by patients, physicians, and health systems as expeditiously and safely as possible. FDA recently announced the creation of an emergency review and development program for possible therapies for COVID-19: the Coronavirus Treatment Acceleration Program, or "CTAP". The Agency has been supporting the program by reassigning staff and working day and night 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.

There are a variety of therapeutic areas being evaluated, including antiviral drugs and immunotherapies, that may be helpful in reducing lung inflammation and improving lung function in COVID-19 patients. All this work is beginning to pay off, and we have recently

announced the positive results of the recent 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 promising 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. It is important that we evaluate convalescent plasma in the context of clinical trials as well as facilitate emergency access for individual patients, as appropriate. As this work moves forward, the key to ensuring the availability of convalescent plasma to those in greatest need, as well as to support clinical development of convalescent plasma and hyperimmune globulin, is getting fully recovered COVID-19 patients to donate plasma if they meet FDA's donor eligibility criteria. To that end, FDA is working with blood collectors to facilitate the collection of convalescent plasma, and working with developers of these therapies to move forward with clinical evaluations.

Medical Product Supply

FDA has been monitoring and proactively adjusting 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 and biological product manufacturing in a timely manner. In addition to our usual communication with drug manufacturers, we are working 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.

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

We are working to increase the supply of personal protective equipment (PPE) and other critical devices that patients and those on the front lines of the U.S. response rely upon. FDA has issued three EUAs to help make more respirators available to health care personnel and help 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, gowns, and masks. 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.

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

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

Food Supply

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

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 workers, industry, and consumers on how to stay safe, keep food safe, and ensure the continuity of operations in the food and agriculture critical infrastructure sector during the pandemic.

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 such as listeria, salmonella and E. coli. FDA's Coordinated Outbreak Response and Evaluation team has remained at work during the pandemic, is fully staffed, and on-the-job looking for signs of foodborne illness outbreaks.

Fraudulent Products

FDA is exercising its regulatory authority to protect consumers from firms selling unproven products with false or misleading claims, including by issuing warning letters and pursuing enforcement actions such as injunctions, against firms and individuals that violate the law. For example, we are actively monitoring for firms selling fraudulent and unproven products with claims to prevent, treat, mitigate, diagnose, or cure COVID-19.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining and reviewing import entries, and refusing admission where appropriate. We are in close communication with our partners at U.S. Customs and Border Protection to proactively identify and mitigate any potential backlogs. FDA participates in FEMA Supply Chain Task Force meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by FEMA, to facilitate the lawful entry and use of imported medical products coordinated through FEMA, and to inform medical product supply chain discussions.

Conclusion

Thank you for the opportunity to be here to provide an update on the activities of HHS in responding to COVID-19 and to answer any questions.