U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

"COVID-19:  Safely Getting Back to Work and Back to School"

Witnesses appearing before the

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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.

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 ʻ nd ʻ nd ʻ β ȳ ¥ End

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

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

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 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

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

*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.

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 beeninfected, 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 unpre

- 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

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 laborato

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

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.

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

The Laboratory Testing Task Force is providing technical assistance to all 50 states,
tribes and territories through calls w4(ssi)MET2000290.00000912 0 612 792 rh 1 72v1 728.026709.08 seW*a) p

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

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 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

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 hal EMCe3/.te, FDA

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 q612 792 eW*nBT/F2 12 Tf-1(s un92 reW*nBT/F2 12 0 1 11(e)4( w of)

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-

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

## 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.