U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Administration's Efforts to Produce, Stockpile, and Distribute Critical Supplies

Witness appearing before the

House Select Subcommittee on the Coronavirus Crisis:

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Introduction

Chairman Clyburn, Ranking Member Scalise, and distinguished Members of the Subcommittee, thank you for the opportunity to testify before you today regarding COVID-19 testing and testing supplies. I am ADM Brett Giroir, the Assistant Secretary for Health (ASH) at the U.S. Department of Health and Human Services (HHS).

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.

HHS has integrated seamlessly into the Federal Emergency Management Agency (FEMA) process, working closely with our Federal, state, and local partners on a daily basis. The National Response Coordination Center (NRCC) provided invaluable and unequalled infrastructure, communications, methodology, and personnel upon which to build an integrated and effective pandemic response – the enormity of which has been unequalled in modern history. The interagency group met daily to report results from each task force, department, and critical agency, and to hear reports from the individual FEMA/HHS regions. Leadership and decision-making are also structured and collaborative. The Unified Coordination Group (UCG), of which I am a principal along with the Assistant Secretary for Preparedness and Response (ASPR), met daily, and now as needed, to provide strategic direction and leadership.

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 to our COVID-19 efforts. Within HHS, the Assistant Secretary for Health, along with additional components not represented today, have critical roles in the response to this public health emergency as discussed below.

Diagnostics and Testing

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

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

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

These will be followed soon with a number of additional guidance documents that apply the strategic principles to specific situations. In addition, the Administration is now reviewing testing plans from each state, territory, and major city public health unit, as a requirement of

$10.25 billion in cooperative agreement funding distributed by the Centers for Disease Control and Prevention (CDC).

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

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

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

- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities.

Stage 1: Launch: Engaging the Emerging Crisis

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

Additionally, understanding the importance of increased testing, the U.S. Food and Drug Administration (FDA) engaged test developers from the beginning of the pandemic. Any developer, including labs, could introduce tests through the Emergency Use Authorization (EUA) process, as they had during previous emergencies; and FDA encouraged labs and commercial manufacturers to do so swiftly, engaging with more than 550 test developers since January who indicated their intent to submit requests for EUAs. In mid-January, the Biomedical Advanced Research and Development Authority (BARDA) within ASPR, convened a meeting of leading diagnostic companies from across America to encourage development of COVID-19 tests. In the ensuing months, multiple funding opportunities for the development of COVID-19 diagnostic tests were announced and the National Institutes of Health (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, FDA has provided voluntary EUA templates for laboratories and manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID-19 tests. This has contributed greatly to the dramatic increases in testing the nation has seen in the past months. The amount and expediency in which EUAs were issued for COVID-19 tests far exceed past viral outbreaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. As of June 25, 2020, FDA has issued more than 150 COVID-19 test EUAs. The timeliness and number of EUAs issued by FDA for COVID-19 tests is unprecedented and has been critical to improving the testing scale and capacity in our country, while providing enough oversight to assure patients can depend on the results of these tests.

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

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

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country. The Corps had unique expertise in COVID-19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 318,000 individuals, with an overall COVID-19 test positivity rate of approximately 13.5 percent. 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 the FDA-authorized use of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment (PPE). The CBTS initiative

provided 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. The majority of the federally supported community based testing sites have been transitioned to be state-led efforts and the few remaining sites will be transitioned in the weeks to come.

Since early January, the Administration has maintained constant contact with state and local governments 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 June 26, and with the assistance of the Federal Government, U.S. retailers have opened and are operating 624 testing sites live in 48 states and the District of Columbia, and they have tested over 744,000 individuals. The Federal Government built public-private partnerships to increase the number of testing sites offered at commercial locations across the country. 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 greatly 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 June 29, working collaboratively with FEMA and utilizing their logistics management system, the Federal Government has procured and distributed to states – according to their needs and plans – nearly 27 million specimen collection swabs and more than 20 million tubes of transport media. To meet state needs, this procurement and distribution system will continue at least through December 2020, with needs continually assessed.

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. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million laboratory testing extraction and PCR kits per month, enabling states to complete millions of additional tests starting in May. In mid-March, the FDA issued an EUA for Hologic's Panther COVID-19 test, which runs on more than 600 lab machines across the United States. Beginning in early May, Hologic began shipping several million test kits per month to labs across the nation.

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

The Testing and Diagnostics Workgroup 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. This ongoing partnership with the states has resulted in the submission of formal state, territory, and large locality plans that detail how the

state will test, surge, reach vulnerable groups including racial and ethnic minorities, disabled, and elderly, contact trace, and train. These plans are being modified and optimized by states following interagency review and continued technical assistance.

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

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

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

We recognize that vulnerable populations in many underserved communities are among the highest risk of suffering devastating health and economic impacts of COVID-19. The HHS Office of Minority Health (OMH) issued a Notice of Funding Opportunity on May 1. On June 23, the 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 a cooperative

agreement with OMH to lead the initiative to coordinate a strategic network of national, state, territorial, tribal and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic. The three-year initiative will include the development and coordination of a strategic and structured network of national, state, territorial, and local public and community-based organizations that will help mitigate the impact of COVID-19 on racial and ethnic minorities as well as rural and socially vulnerable communities across the nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most.

On June 4, using authorities provide to the HHS 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 HHS's 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 94 percent of these centers offer COVID-19 testing. As of June 26, health centers have reported testing nearly 1.3 million individuals in total and racial and/or ethnic minority patients represent 55% of those tested in the past week.

Role of the of the Assistant Secretary for Health on the Unified Coordination Group

On January 31, 2020, the Secretary of HHS declared a public health emergency for the United States in response to the COVID-19 pandemic. Also, in accordance with Presidential Policy Directive 44 and section 2801 of the Public Health Service Act (as amended by the Pandemic and All-Hazards Preparedness Act), HHS assumed the role of Lead Federal Agency for Federal public health and medical services, under the National Response Framework. On March 13, 2020, the President declared a nationwide emergency under the Stafford Act. In the following days after the President's announcement, FEMA assumed the primary lead role under the White House Coronavirus Task Force in coordinating Federal support and operations in the Whole-of-America response to the COVID-19 pandemic.

Consistent with the National Response Framework, the UCG takes action to ensure that all levels of government work together in response to COVID-19. Given the scope of COVID-19, the UCG considers and resolves (or elevates to the White House Coronavirus Taskforce, as appropriate) strategic operational and policy decisions. As suggested in the Biological Incident Annex, the UCG is comprised of principals based on the key operational areas of the response.

As part of the UCG, the Assistant Secretary for Health operationalizes the spectrum of public health and science issues related to COVID-19 response efforts, oversees the U.S. Public Health Service Commissioned Corps, providing it with strategic and policy direction, and leads diagnostic testing.

United States Public Health Service Commissioned Corps

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

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more

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

Thank you for the opportunity to provide an update on the activities of HHS related to testing and testing strategies responding to the COVID-19 pandemic. I am happy to answer any questions.