U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

Witness appearing before the
Senate Homeland Security and Governmental Affairs Committee:

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

June 9, 2020

Introduction

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) 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 Nation Response Coordination Center (NRCC) has 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 meets 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. Led by the FEMA Administrator, there is a Unified Coordinating Group (UCG) that meets daily to provide strategic direction and leadership. I am a member of that group, along with the Assistant Secretary for Preparedness and Response (ASPR).

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.

Currently, there are tests for the presence of the virus and tests 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; however research is ongoing in determining if past infection confers immunity. Today I will focus mostly on widespread testing for the presence of the virus, which has represented the primary challenge the nation has faced since the onset of the pandemic.

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 and limited sensitivity especially very early or very 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 beginning stages of the COVID-19 pandemic, the Centers for Disease Control and Prevention (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 24, 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 3, CDC submitted an emergency use authorization (EUA) request, and the U.S. Food and Drug Administration (FDA) issued an EUA on February 4, just 24 hours after receiving the complete package, enabling use of the CDC's COVID-19 diagnostic panel.

Understanding the importance of increased testing, the FDA engaged test developers from the beginning of the pandemic. Any developer, including labs, could always introduce tests through the 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, the 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. Currently, FDA has issued more than 100 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 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 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, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of the end of May, our nation has performed nearly 17 million tests, and now at a rate of between 400,000 and 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 2 days, and often much sooner. POC tests provide results within 15 minutes.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country and currently 13 sites remain open with Federal support. These sites remain operational 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 236,000 individuals, and with an overall COVID-19 test positive rate of approximately 14 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 the FDA authorized use 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 June 3, and with the assistance of the Federal Government, United States retailers have opened and are operating 437 testing sites in 48 states and the District of Columbia and they have tested over 484,000 individuals. 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 at least one thousand more of these sites depending on local needs.

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

In May alone, working collaboratively with FEMA and utilizing their logistics, the Federal Government has procured and began to distribute to states – according to their needs and plans – over 12.8 million specimen collection swabs and more than 8.9 million tubes of transport media. To meet state needs, this procurement and distribution will continue in June and the following months, as necessary.

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 procured over 20 million swabs and tubes of transport media (or saline) in May. These supplies will be shipped out to states over the course of the next few months, starting in May. 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 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.

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

associated with testing, as indicated in the Paycheck Protection Program and Health Care Enhancement Act.

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 Office of Minority Health 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 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. In addition, guidance was released on June 4 which will require that demographic data are collected and reported with COVID-19 lab results. The guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19. This will ensure that underserved communities are benefitting from the Federal Government investments.

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 Corona Virus 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 Unified Coordination Group (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. Additionally, the Assistant Secretary for Health serves as the HHS lead for diagnostic testing, with leadership authority over FDA and CDC.

United States Public Health Service Commissioned Corps

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

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 4,100 officers as of May 25, 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, 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. 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. Most recently, the Corps deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

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

Conclusion

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