DEPARTMENT OF HEALTH AND HUMAN SERVICES

Hearing on an Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

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

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Testimony of the Department of Health and Human Services on COVID-19

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.

Within the first two weeks of China's initial report of the outbreak in December 2019, China reported 45 pneumonia cases and two deaths. . More recently, there has been an increase in cases outside of China.

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, which is in the same family of viruses as that cause the common cold, There are many types of human coronaviruses including some that commonly cause

onset in early December. CDC immediately began monitoring the outbreak, and within days – by January 7, 2020 – had established a Center-led Incident Management Structure. On January 21, 2020, CDC transitioned to an Agency-wide response based out of its Emergency Operations Center. This allows CDC to provide increased operational support to meet the outbreak's evolving challenges and provides strengthened functional continuity to meet the long-term commitment needed

support ministries of health around the globe to prepare and respond to the outbreak. For example, the U.S. Government is helping to support countries to implement recommendations provided by WHO related to the identification of people who might have this new infection, diagnosis and care of patients, and tracking of the outbreak. CDC staff are also starting to work together with interagency colleagues in those countries to conduct investigations that will help inform response efforts going forward.

The Agency is using its existing epidemiologic, laboratory, and clinical expertise to gain a more comprehensive understanding of COVID-19. CDC is leveraging prior programmatic investments in domestic and global public health capacity and preparedness to strengthen the Agency's response to COVID-19. Thus far, this response has been built largely on the foundation of our seasonal and pandemic influenza program's infrastructure. The ongoing response to COVID-19 also demonstrates CDC's continued commitment to strengthen global health security. CDC has been engaged in global health security work for over seven decades. Thanks to investments in Global Health Security, the U.S. Government's work has helped partner countries build and improve their public health system capacity. This global effort strengthens the world's ability to prevent, detect, and respond to infectious diseases like this new coronavirus.

This outbreak also underscores the need for the United States to continue to play a leadership role on the global stage, and to strengthen global capacity to stop disease threats at their sources, before they spread. Furthermore, the outbreak demonstrates the importance of continued investment in our nation's public health infrastructure. Despite years of progress in domestic disease prevention and response, efforts to help modernize our federal, state, and local capability and health systems that are crucial to responding to and understanding unprecedented threats continue.

The U.S. Government has taken unprecedented steps to prevent the spread of this virus and to protect the American people and the global community from this new threat and allow State, local, territorial, and private partners time to prepare for any necessary response and mitigation activities. Since February 2, 2020, pursuant to arrival restrictions imposed by the Department of Homeland Security, flights carrying persons who have recently traveled from or were otherwise present within mainland China or other affected countries have been funneled to designated U.S. airports with CDC quarantine stations. At these airports, passengers are subject to enhanced illness screening and self-monitoring with public health supervision up to 14 days from the time the passenger departs the affected country. This enhanced entry screening serves two critical purposes. The first is to detect illness and rapidly respond to symptomatic people entering the country. The second purpose is to educate travelers about the virus and what to do if they develop symptoms.

These measures are part of a layered approach which includes our other core public health efforts, including aggressively tracking COVID-19 around the globe, building laboratory capacity, and preparing the national healthcare s(o 4 Tre(a)Tj -0.ng)]TJ 30.2ealheand

CDC has issued guidance for people at high risk of exposure to the virus, including flight crews, recent travelers to China, and healthcare workers. Through its extensive Health Alert Network, CDC shared guidance for clinical care for healthcare professionals and state and local health departments. Health departments, in consultation with healthcare providers, can evaluate patients and determine whether someone

prevention and treatment.

This has allowed BARDA to leverage existing partnerships, accelerating the development of COVID-19 medical countermeasures, including diagnostics, therapeutics, and vaccines. Established partners, including Regeneron, Janssen, and Sanofi Pasteur, have shown success in developing both prophylactic and therapeutic medical countermeasures for emerging infectious diseases.

BARDA is collaborating with Regeneron to leverage their partnership agreement to develop multiple monoclonal antibodies that, individually or in combination, could be used to treat this emerging coronavirus. Regeneron's monoclonal antibody discovery platform, called VelocImmune, was used to develop a promising investigational three-antibody therapeutic which was deployed to treat Ebola in the most recent outbreak in the Democratic Republic of the Congo, and an investigational two-antibody therapeutic to treat MERS. The technology shortened multiple aspects of the product development timeline for therapeutics to treat MERS and Ebola from years to months. The technology helped shorten certain stages of drug development, including the process of antibody discovery and selection, preclinical-scale manufacturing, and clinical-scale manufacturing. BARDA and Regeneron are working to utilize these monoclonal antibodies, produced by a single clone of cells or a cell line with identical antibody molecules, which will bind to certain proteins of a virus, reducing the ability of the COVID-

This same approach was used to develop and manufacture Janssen's investigational Ebola vaccine with BARDA support; that vaccine is being used in the Democratic Republic of the Congo as part of the current Ebola outbreak response. Additionally, BARDA and Janssen are working together to help develop treatments for coronavirus infections. Janssen will conduct high throughput screening on thousands of potential antiviral compounds in order to identify medicines that could safely and effectively be used to reduce the severity of illness and treat COVID-19 infections, as well as identify compounds that have antiviral activity against SARS-CoV-2 as an initial step in developing new treatments. These products include those in development to treat and prevent MERS or SARS, which are caused by coronaviruses also related to COVID-19.

Finally, in their work with Sanofi Pasteur, BARDA is able to leverage a licensed recombinant influenza vaccine platform to produce a recombinant SARS-CoV-2 vaccine candidate. The technology produces an exact genetic match to proteins of the virus. DNA encoding the protein will be combined with DNA from a virus harmless to humans, and used to rapidly produce large quantities of antigen which stimulate the immune system to protect against the virus. The antigens will be separated and collected from these cells and purified to create working stocks of vaccine for advanced development.

BARDA has initiated early steps of medical countermeasures development with partners and will continue to work to accelerate this process. Availability of these medical countermeasures is essential to save lives and protect Americans against 21st century public health threats.

Our nation's healthcare system is better prepared than it has ever been. For example, all 50 states have Pandemic Plans, as a requirement of CDC's Public Health Emergency Preparedness Program (PHEP) and ASPR's Hospital Preparedness Program (HPP). HPP was

established after the September 11, 2001, terrorist attacks, with the goal of improving the capacity of local hospitals across the country to deal with disasters and a large influx of patients in an emergency. Using HPP funding, state grantees initially purchased equipment and supplies needed for emergency medical surge capacity. Over time, the program has successfully evolved to support local, coordinated healthcare coalitions, including hospitals, public health facilities, emergency management agencies, and emergency medical services providers. Investments administered through PHEP and HPP have improved individual health care entities' preparedness and have built a system for coordinated healthcare system readiness. HPP is the only source of federal funding to prepare the nation's mostly private health care system to respond to emergencies, including COVID-19.

Beginning in 2018, ASPR has been supporting Regional Disaster Health Response Systems (RDHRS) pilot projects. The RDHRS concept aims to provide funding directly to hospitals and healthcare systems to establish multi-state regional partnerships to increase preparedness and response capability and capacity for hospitals and healthcare facilities in advance of, during, or immediately following incidents, including emerging infectious diseases. Two sites were selected in September 2018 to begin development of RDHRS pilots. In 2019, two grants were awarded to support new centers of excellence pilots focused on pediatric disaster care. The RDHRS and Pediatric Disaster Care Center of Excellence cooperative agreement requirements are intentionally aligned to ensure synergy between the programs and collaboration between all sites and facilities. Ultimately, these efforts inform best

departments would be severely strained, which is why supporting models such as the Hospital Preparedness Program healthcare coalition network is so important.

The National Ebola Training and Education Center (NETEC) combines the resources of healthcare institutions experienced in treating Ebola to offer training, readiness consultations, and expertise to help facilities prepare for Ebola and other special pathogens. The regional Ebola and other special pathogen treatment centers, of which ASPR and CDC funded 10 across the country, all have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients, including pediatric patients. The NETEC and the regional Ebola and other special pathogen treatment centers have been used to support recent quarantine efforts. Should the coronavirus infections increase domestically, these centers will become critical in isolating infected persons and providing adequate treatment.

ASPR and CDC also work to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for federal responses to public health emergencies. NDMS was originally created during the Cold War to take care of military casualties from overseas in U.S. civilian hospitals. Today, NDMS teams are deployed to strategic locations across the country, caring for U.S. citizens who may have been exposed to SARS-CoV-2, effectively providing medical care and limiting the potential spread of the disease.

Recently, to assist in the repatriation effort, ASPR stood up a National HHS Incident Management Team (IMT) located in Washington, DC. The IMT serves as the national command and control element, deploying Public Health Service Commission Corps Officers and NDMS personnel.

In addition, HHS provided cache equipment, (e.g., medical supplies and resources) to Travis AFB, Marine Corps Air Station Miramar, Lackland, Air Force Base, and Camp Ashland to support evacuees quarantined at these facilities. HHS deployed one Disaster Medical Assistance Team (DMAT) and one IMT on February 12, 2020, to support American citizens in Japan on the Diamond Princess cruise ship, as well as the
U.S. Embassy, to provide medical care, prescriptions, and behavioral health support.

Many active pharmaceutical ingredients and medical supplies, including auxiliary supplies such as syringes and gloves, come from China and India. This outbreak demonstrates why ASPR is seeking innovative solutions and partnerships to better protect national security. ASPR is working to increase access to personal protective equipment (PPE) by:

- Coordinating with CDC and other Federal agencies to share information

- Engaging private sector partners who manufacture and distribute PPE to share

infrastructure that can be quickly mobilized; and collaborative and highly productive partnerships with industry. NIAID provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research for emerging and re-emerging infectious diseases. These research resources are designed to bridge gaps in the product development pipeline, thereby lowering the

and therapeutics. NIAID scientists also are evaluating the stability of SARS-CoV-2 on various ordinary surfaces and in aerosols to better understand the potential for viral spread throughout the community.

NIAID-supported researchers are assessing the risk of emergence of bat coronaviruses in China, including the characterization of bat viruses and surveys of people who live in high-risk communities for evidence of bat coronavirus infection. Such research is necessary to better understand this emerging infection and to investigate optimal ways to diagnose, treat, and prevent COVID-19.

The NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS), which conduct influenza risk assessments in multiple sites throughout the world particularly in Asia, have responded rapidly to the COVID-19 outbreak. CEIRS researchers at the University of Hong Kong are evaluating the epidemiology, transmission dynamics, and severity of COVID-19. These scientists also have performed environmental sampling of the Wuhan market where the first COVID-19 cases were reported.

NIAID is working with CEIRS collaborators and the CDC to obtain additional virus and biological samples from patients to further advance research efforts on COVID-19. Recently, the NIAID-funded BEI Resources Repository made samples of SARS-CoV-2 available for distribution to domestic and international researchers at Biosafety Level 3 laboratories. In addition, CEIRS researchers and other NIAID-supported scientists are developing reagents, assays, and animal models that can be used to evaluate promising therapeutics and vaccines. These research resources also will be

On February 6, 2020, NIAID issued a Notice of Special Interest regarding the Availability of Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus. This notice encourages existing NIAID grantees to apply for supplements for research project grants focused on the natural history, pathogenicity, and transmission of the virus, as well as projects to develop medical countermeasures and suitable animal models for preclinical testing of COVID-19 vaccines and therapeutics.

NIAID has responded to public health concerns about COVID-19 by increasing ongoing coronavirus research efforts to accelerate the development of interventions that could help control current and future outbreaks of COVID-19. These activities build on prior NIAID research addressing other coronaviruses, such as those that cause SARS and MERS.

The CDC has developed a real-time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) test that can detect COVID-19 using respiratory samples from clinical specimens. NIAID is accelerating efforts to develop additional diagnostic tests for COVID-19, and NIAID-supported investigators are developing PCR-based assays for SARS-CoV-2 to facilitate preclinical studies and aid in the development of medical countermeasures. NIAID scientists also are developing reagents for an enzyme-linked immunosorbent assay for SARS-CoV-2. CEIRS researchers at the University of Hong Kong have developed a separate RT-PCR test and made their protocol publicly available through the WHO. These NIAID-supported investigators also have distributed assay reagents to 12 countries to facilitate the diagnosis of COVID-19.

NIAID is pursuing the development of antivirals and monoclonal antibodies for potential use against SARS-CoV-2. NIAID has launched a multicenter, randomized controlled clinical trial to evaluate the safety and efficacy of the antiviral drug remdesivir for the treatment of

COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 illness. The adaptive design of this trial will enable the evaluation of additional promising therapies. NIAID plans to assess other existing antivirals for activity against SARS-CoV-2, and NIAID scientists are working to identify monoclonal antibodies with therapeutic potential from COVID-19 patient samples as well as historical SARS patient samples. NIAID-funded scientists also aim to delineate new viral targets to facilitate the development of novel therapeutics with broad activity against coronaviruses. Finally, NIAID is expanding its suite of preclinical services to add assays that investigators can use to accelerate research and development of therapeutics for COVID-19.

A safe and effective vaccine for SARS-CoV-2 would be an extremely valuable tool to stop the spread of infection and prevent future outbreaks. Public and private entities across the globe have announced plans to develop SARS-CoV-2 vaccine candidates following

While ongoing SARS-CoV-2 vaccine research efforts are promising, it is important to realize that the development of investigational vaccines and the clinical testing to establish their safety and efficacy take time. Although we plan to begin early-stage clinical testing of an NIAID-supported vaccine candidate in the next few months, a safe and effective, fully licensed SARS-CoV-2 vaccine will likely not be available for some time. Currently, the COVID-19 outbreak response in the United States remains focused on the proven public health practices of containment – identifying cases, isolating patients, and tracing contacts.

NIH is committed to continued collaboration with other HHS agencies and additional partners across the U.S. government and international community to advance rese( )Tj it2

medical products needed to diagnose, treat, and prevent this disease. We're

agency, U.S. Customs and Border Protection (CBP), to evaluate and adjust our risk-based targeting strategy to ensure FDA-regulated products are safe when entering the United States.

While the outbreak is impacting our ability to conduct inspections in China, it's important to underscore that the FDA's regular risk-based process of surveillance testing of imported productChina)-4(,)(s)-150.40 Td [(o)-3(w)]0(c)-6(n)-10(e)-2(i)-12n(u)-10(e)-6sf.

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We established a cross-agency task force to closely monitor for fraudulent FDA-regulated products and false product claims related to COVID-19 and we have already reached out to major retailers to ask for their help in monitoring their online marketplaces for fraudulent products with coronavirus and other pathogen claims.

FDA

them, and American patients, at risk for drug supply disruptions following disasters (e.g., hurricanes) or