DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Federal Interagency Response to the Coronavirus and Preparing for Future Global Pandemics

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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 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, animal 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 from animals and then spread to people.

The potential global public health threat posed by this virus is high, but right now, the immediate risk to most Americans is low. The greater risk is for people who have recently traveled to an affected country or been exposed to someone with COVID-19.

On January 29, 2020, President Trump announced the formation of the President's Task

Force on the Novel Coronavirus, which is chaired by the Secretary for Health and Human Services and coordinated through the National Security Council. The President's Task Force is composed of subject matter experts from the White House and several United States Government agencies, and it includes some of the Nation's foremost experts on infectious diseases. The Task Force is leading the Administration's efforts to monitor, contain, and mitigate the spread of COVID-19 while ensuring that the American people have the most accurate and up-to-date information to protect themselves and their families.

The President's top priority is the health and welfare of the American people, and his Administration has made it a priority to prepare for infectious disease outbreaks that can cross borders. In 2018, President Trump launched the National Biodefense Strategy, which lays out a framework for coordination among agencies, with the Secretary of the U.S. Department of Health and Human Services (HHS) as Chair of the Biodefense Steering Committee, and helps identify gaps in preparedness and response. As the situation around the new coronavirus evolves, the Administration will continue its coordinated response, in collaboration with state and local governments and the private sector, and adjust its positioning as needed.

Within HHS, the Centers for Disease Control and Prevention (CDC), the Assistant Secretary for Preparedness and Response (ASPR), the National Institute of Allergy and Infectious Diseases (NIAID), and the Food and Drug Administration (FDA) play critical roles in responding to COVID-19 by preventing and slowing the spread of the disease, assisting repatriated Americans, protecting the supply of food, drugs, and devices, and developing diagnostics, therapeutics, and vaccines.

Centers for Disease Control and Prevention

In late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered on a local seafood market in Wuhan, China, with an estimated case

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 to curb the outbreak.

CDC is assisting ministries of health in countries in every region of the globe with their most urgent and immediate needs to prevent, detect, and respond to the COVID-19 outbreak.

CDC's most expert and practiced infectious disease and public health experts are dedicated to this response 24/7 to protect the American people. CDC is a disease preparedness and response agency, and this work is fundamental to our mission both domestically and internationally. The Agency's approach to COVID-19 is built upon decades of experience with prior infectious disease emergencies including responses to SARS, MERS, and Ebola, and to pandemic influenza.

To mitigate the impact of COVID-19 within the United States, CDC is working alongside Federal, state, local, tribal, and territorial partners, as well as public health partners. This public health response is multi-layered and includes aggressive containment and mitigation activities with an objective to detect and minimize introductions of this virus in the United States so as to reduce its spread and impact. It is impossible to catch every single traveler returning from an affected country with this virus – given the nature of this virus and how it's spreading. Our goal continues to be slowing the introduction of the virus into the United States as we work to prepare our communities for more cases and possible sustained spread

To accomplish this, CDC is also working with multiple countries, in collaboration with U.S. Agency for International Development (USAID) and other federal agencies and WHO to

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 system for community spread. These core capabilities and expertise are essential to CDC's comprehensive approach to addressing this outbreak.

While CDC believes that the immediate risk of this new virus to the American public is low, CDC is preparing the nation's healthcare system to respond to identification of individual cases and potential person-to-person transmission of COVID-19 in the community, at the same time ensuring the safety of its patients and workers. CDC has developed guidance on appropriate care and infection control for patients with COVID-19 and is engaging regularly with clinical and hospital associations to confirm that its guidance is helpful and responsive to the needs of the healthcare system.

Furthermore, understanding the current constraints of the global supply of personal protective equipment (PPE), CDC is working with industry and the U.S. health system to comprehend possible effects on facilities' abilities to procure the needed levels of PPE, and to provide strategies to optimize the supply of PPE.

Effective disease surveillance enables countries to quickly detect outbreaks and continuously monitor for new and reemerging health threats. CDC continues to monitor the COVID-19 situation around the world.

CDC has begun working with domestic public health laboratories that conduct community-based influenza-like illness surveillance and leveraging our existing influenza and viral respiratory surveillance systems so that we may begin testing people with flu-like symptoms for the SARS-COV-2 virus. HHS is developing plans to expand this effort.

This collaboration with domestic public health labs is another layer of our response that will help us detect if this virus is spreading in a community. All of our efforts now are to prevent the sustained spread of this virus in our communities, but we need to be prepared for the possibility that it will spread. Results from this surveillance could necessitate changing our response strategy.

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 may have the illness and should be subjected to additional diagnostic testing.

CDC has a demonstrated record of innovative science and evidence-based decision-making, and an experienced and expert workforce that is working 24/7 to combat this public health emergency. The COVID-19 outbreak is evolving rapidly, and the U.S. Government is constantly making adjustments to respond to the changing nature of this public health emergency. Our goal continues to be slowing the introduction of the virus into the United States and preparing our communities for more cases and possible sustained spread. While leaning forward aggressively with the hope that we will be able to prevent community spread, CDC remains vigilant in confronting the challenges presented by this new coronavirus.

Assistant Secretary for Preparedness and Response

Currently, there are no vaccines or therapeutics approved by the FDA to treat or prevent novel coronavirus infections. The Biomedical Advanced Research and Development Authority (BARDA), part of ASPR, is working with counterparts across the government, including within HHS and with the Department of Defense (DOD). The team is reviewing potential vaccines, treatments, and diagnostics from across the public and private sectors to identify promising candidates that could be developed to detect, protect against, or treat people with coronavirus infections. BARDA is working closely across the U.S. Government to assess and identify potential partners and technologies suitable to address the COVID-19 outbreak – both for

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-19 virus to infect human cells.

BARDA is working with Janssen to leverage their Ebola, Zika, HIV vaccine platform to expedite development of vaccines that protect against the SARS-CoV-2 virus. Using existing resources, BARDA will share research and development costs and expertise with Janssen to help accelerate Janssen's investigational COVID-19 vaccine into clinical evaluation. Janssen will also scale-up production and manufacturing capacities required to manufacture the candidate vaccine.

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 practices to help ready healthcare delivery systems for disasters and emergencies and are critical in aiding response and limiting the impact of disaster. As you all are aware, the United States is in the middle of influenza season. Many emergency departments are at 90 percent capacity. If influenza worsens, or if COVID-19 intensifies domestically, emergency

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 about optimization of PPE, to prevent overbuying and overuse of existing supplies

- Engaging private sector partners who manufacture and distribute PPE to share information and concerns, and to explore options to anticipate and meet the needs of the U.S. healthcare sector more effectively. During recent discussions, for example, distributors informed us that they have implemented allocations to help prevent stockpiling at healthcare facilities. The allocation is a percentage of a customer's previous orders and is designed to help protect the healthcare supply chain and ensure the right supplies are available for those who need it.
- We are also partnering with other Federal agencies such as DHS, DOD and the U.S. Department of Veterans Affairs who are large buyers of PPE, to develop acquisition strategies that incentivize industry to expand PPE production while not exacerbating supply challenges.

The Strategic National Stockpile (SNS) holds thousands of deployable face masks, N95 respirators, gloves, and surgical gowns that could be deployed if state and local supplies are diminished due to the current COVID-19 response and commercial supplies are exhausted. The SNS is working hand-in-hand with commercial supply chain partners and other Federal agencies to continue monitoring supply levels and to prepare for a potential deployment of SNS personal protective gear if it is needed.

The National Institutes of Health

The National Institutes of Health (NIH) is the HHS agency leading the research response to the global health emergency of COVID-19. Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19.

NIAID is well-positioned to respond rapidly to infectious disease threats as they emerge by leveraging fundamental basic research efforts; a domestic and international research

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 scientific, technical, and financial risks incurred by industry and incentivizing companies to partner in the development of effective countermeasures including diagnostics, therapeutics, and vaccines.

NIAID also supports the Infectious Diseases Clinical Research Consortium, which includes a network of Vaccine and Treatment Evaluation Units (VTEUs). The VTEUs conduct clinical trials to investigate promising therapeutic and vaccine candidates when public health needs arise. NIAID collaborates with other Federal agencies, including through the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to help advance progress against newly emerging public health threats. In addition, partnerships with academia, the biotechnology and pharmaceutical industries, domestic and international researchers, and organizations such as the World Health Organization (WHO) are integral to these efforts.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has improved our fundamental understanding of coronaviruses and provides a strong foundation for our efforts to address the challenge of SARS-CoV-2, the novel coronavirus that causes COVID-19. NIAID has responded to the newly emerging COVID-19 outbreak by expanding our portfolio of basic research on coronaviruses. NIAID scientists have rapidly identified the human receptor used by SARS-CoV-2 to enter human cells. In addition, NIAID investigators and their collaborators recently identified the atomic structure of the spike protein, an important SARS-CoV-2 surface protein that is a key target for the development of vaccines

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 shared with the domestic and international scientific community as soon as they become available.

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 the release of the SARS-CoV-2 genetic sequence. NIAID is supporting development of several SARS-CoV-2 vaccine candidates, and is utilizing vaccine platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

The NIAID Vaccine Research Center (VRC) is collaborating with the biotechnology company Moderna, Inc., on the development of a vaccine candidate using a messenger RNA (mRNA) vaccine platform containing the gene that expresses the VRC-designed spike protein of SARS-CoV-2. NIAID anticipates the experimental vaccine will be ready for clinical testing in the NIAID VTEUs within the next two months and will conduct preclinical studies as well as a first-in-human study of this COVID-19 vaccine candidate. The Coalition for Epidemic Preparedness Innovations (CEPI) will fund the manufacture of the first clinical production lot of this mRNA-based vaccine candidate using the Moderna rapid manufacturing facility.

NIAID Rocky Mountain Laboratories (RML) scientists are collaborating with Oxford University investigators to develop a chimpanzee adenovirus-vectored vaccine candidate against SARS-CoV-2; in addition, they have partnered with CureVac on an mRNA vaccine candidate. RML investigators also have launched a collaboration with the University of Washington and have begun early-stage testing of an RNA vaccine candidate against SARS-CoV-2. In addition, NIAID-supported scientists at Baylor College of Medicine and their collaborators are evaluating an experimental SARS-CoV recombinant protein vaccine to determine if it also provides protection against SARS-CoV-2. NIAID is exploring additional collaborations with extramural research and industry partners on other vaccine concepts. NIAID also is supporting the development of standardized assays and animal models that will be utilized to evaluate vaccine candidates.

With all these efforts, NIAID is coordinating closely with colleagues at the CDC, BARDA, FDA, DOD, and other federal and international partners.

To achieve the ultimate goal of having a SARS-CoV-2 vaccine available to the public, it is important that NIAID and the entire biomedical research community pursue a range of vaccine strategies in order to be better positioned to overcome the scientific or technical challenges associated with any particular vaccine approach. In this regard, NIAID has dedicated resources toward preclinical research to advance a robust pipeline of vaccine candidates into Phase 1 clinical evaluation. Further vaccine research, including Phase 2 clinical trials, will then be required. Additional research also is needed to better understand the fundamental biology of coronaviruses and to facilitate the design of vaccines that elicit optimal immune responses and protect against infection.

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 research to address COVID-19. As part of its mission to respond rapidly to emerging and re-emerging infectious diseases throughout the world, NIAID is expanding our efforts to elucidate the biology of SARS-CoV-2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIAID is particularly focused on developing safe and effective COVID-19 vaccines. These efforts also help to expand our knowledge base and improve our continued preparedness for the next inevitable emerging disease outbreak.

Food and Drug Administration

The FDA plays a critical role in overseeing our Nation's FDA-regulated products as part of our vital mission to protect and promote public health, including during public health emergencies. Our work primarily focuses on four key areas: first, actively facilitating efforts to diagnose, treat, and prevent the disease; second, surveilling product supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary; third, conducting inspections and monitoring compliance, including of facilities that manufacture FDA-regulated products overseas; fourth, helping to ensure the safety of consumer products.

A key focus area for the FDA is helping to expedite the development and availability of

medical products needed to diagnose, treat, and prevent this disease. We're committed to helping foster the development of critical medical countermeasures as quickly as possible to protect public health. We provide regulatory advice, guidance, and technical assistance to sponsors in order to advance the development and availability of vaccines, therapies, and diagnostic tests for this novel virus.

On February 4, 2020, the FDA issued an emergency use authorization (EUA) to enable immediate use of a diagnostic test developed by the CDC, facilitating the ability for this test to be used in CDC-qualified laboratories.[1] The FDA is dedicated to actively working with other COVID-19 diagnostic developers to help accelerate development programs and requests for EUAs. We have developed an EUA review template for tests to detect the virus, which outlines the data requirements for a Pre-EUA package that is available to developers upon request. To date, we have shared the EUA review template with more than 100 developers who have expressed interest in developing diagnostics for this virus.

The medical product supply chain is always potentially vulnerable to disruption, which makes our surveillance work and collaboration with industry critical and why the Agency takes a proactive stance on any potential impact or disruption to the supply chain. An outbreak of this global scale has an impact on the medical product supply chains, including potential disruptions

[1] FDA. 2019 Novel Coronavirus Emergency Use Authorization. February 4, 2020. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019.
FDA. FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic: Critical Milestone Reached in Response to this Outbreak. https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first.

to supply or shortages of critical medical products in the United States. We are in contact with manufacturers; global regulators, like the European Medicines Agency; health care delivery organizations; and other participants in the medical product supply chains to quickly identify and address any supply concerns that come from issues related to China and other locations in Southeast Asia sourcing raw materials for manufacturing drugs.

We are also tracking reports of increased ordering of some essential medical devices through distributors, such as personal protective equipment (PPE) (e.g., respirators and surgical gowns, gloves and masks). FDA is working proactively to stay ahead of potential shortages or disruptions of medical products. The agency will use all available authorities to react swiftly and mitigate the impact to U.S. patients and health care professionals as these threats arise.

Monitoring the safety of FDA-regulated product supply chains is one of the FDA's highest priorities. The FDA utilizes risk-based models to identify firms for inspection and prioritizes inspections based on specific criteria. Because of travel restrictions to China, the Agency has postponed planned inspection activities in China. However, we are currently continuing inspection and enforcement activities as normal for the rest of our operations. Inspections of facilities in China remain prioritized in our site selection model and, when travel restrictions are lifted, inspections of facilities in China will resume. Any travel to China that is deemed to be mission-critical is being assessed on a case-by-case basis in close coordination with other HHS components and with the Department of State. FDA is committed to maintaining its scheduled inspections around the globe to the extent possible, while maintaining the safety of the staff involved. We will revisit this approach and adjust as necessary as this outbreak continues to unfold. In the meantime, FDA is working with our partner government

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 products, including those from China, continues.

Inspections are one of many tools that the Agency uses to inform its risk strategy for imported FDA-regulated products and to help prevent products that do not meet the FDA's standards from entering the U.S. market. Other tools include: import alerts, increased import sampling, and screening. Inspections are also part of, among other things, the new and generic drug approval process. While such pre-approval inspections are on hold in China, we are working to mitigate the impact on new and generic drug approval decisions by requesting records that may be used in lieu of an inspection, depending on the circumstances. Based on our evaluation of previous FDA inspection history, a firm's previous compliance history and information from foreign health authorities with which we have mutual recognition agreements, we determine if the totality of the information would suffice in lieu of such a pre-approval inspection.

All products offered for entry into the United States, including items for personal use, are subject to the regulatory requirements of CBP. Imported shipments of FDA-regulated products referred by CBP, including those from China, are then reviewed by the FDA and must comply with the same standards as domestic products. At this time, we want to reassure the public that there is no evidence to support transmission of COVID-19 associated with imported goods, including food and drugs for people or pets, and there have not been any cases of COVID-19 in the U.S. associated with imported goods.

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 is utilizing all our existing authorities to address COVID-19 and we welcome the opportunity to work with Congress to strengthen our response capabilities. There are four specific proposals included in the President's Budget that would better equip the Agency to prevent or mitigate medical product shortages.

(1) Lengthen Expiration Dates to Mitigate Critical Drug Shortages

Shortages of critical drugs can be exacerbated when drugs must be discarded because they exceed a labeled shelf-life due to unnecessarily short expiration dates. By expanding FDA's authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate, submit studies to FDA, and label a product with the longest possible expiration date that FDA agrees is scientifically justified, there could be more supply available to alleviate the drug shortage or the severity of a shortage.

(2) Improving Critical Infrastructure by Requiring Risk Management Plans

Enabling FDA to require application holders of certain drugs to conduct periodic risk assessments to identify the vulnerabilities in their manufacturing supply chain (inclusive of contract manufacturing facilities) and develop plans to mitigate the risks associated with the identified vulnerabilities would enable the Agency to strengthen the supply chain by integrating contingencies for emergency situations. Currently, many applicants lack plans to assess and address vulnerabilities in their manufacturing supply chain, putting

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

(3) Improving Critical Infrastructure Through Improved Data Sharing: Requiring More Accurate Supply Chain Information

Empowering FDA to require information to assess critical infrastructure, as well as manufacturing quality and capacity, would facilitate more accurate and timely supply chain monitoring and improve our ability to recognize shortage signals.

(4) Device Shortages

FDA does not have the same authorities for medical device shortages as it does for drugs and biological products. For instance, medical device manufacturers are not required to notify FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States, nor are they required to respond to inquiries from FDA about the availability of devices. Enabling FDA to have timely and accurate information about likely or confirmed national shortages of essential devices would allow the Agency to take steps to promote the continued availability of devices of public health importance. Among other things, FDA proposes to require that firms notify the agency of an anticipated meaningful interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and authorize the temporary importation of certain devices where the benefits of the device in mitigating a shortage outweigh the risks presented by the device that could otherwise result in denial of importation of the device into the United States.