DEPARTMENT OF HEALTH AND HUMAN SERVICES

Witness appearing before the
House Committee on Oversight and Reform

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious nd Response

Dr. Robert R. Redfield, Director, Centers for Disease Control and Prevention

Force on the Novel Coronavirus, which is chaired

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.

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 invest

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

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 optimize

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. We are moving forward aggressively with the hope that we will be able to prevent community

is

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 DemocTf1 0trecent

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.

departments would be severely strained, which is why supporting models such as the Hospital Preparedness Program healthcare

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

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 indds,

Health Emergency Medical Countermeasures Enterprise (PHEMCE), to help advance progress against newly emerging public health threats. In addition, partnerships with academia, the

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

and NIAID-supported investigators are developing PCR-based assays for SARS-CoV-2 to facilitate preclinical

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

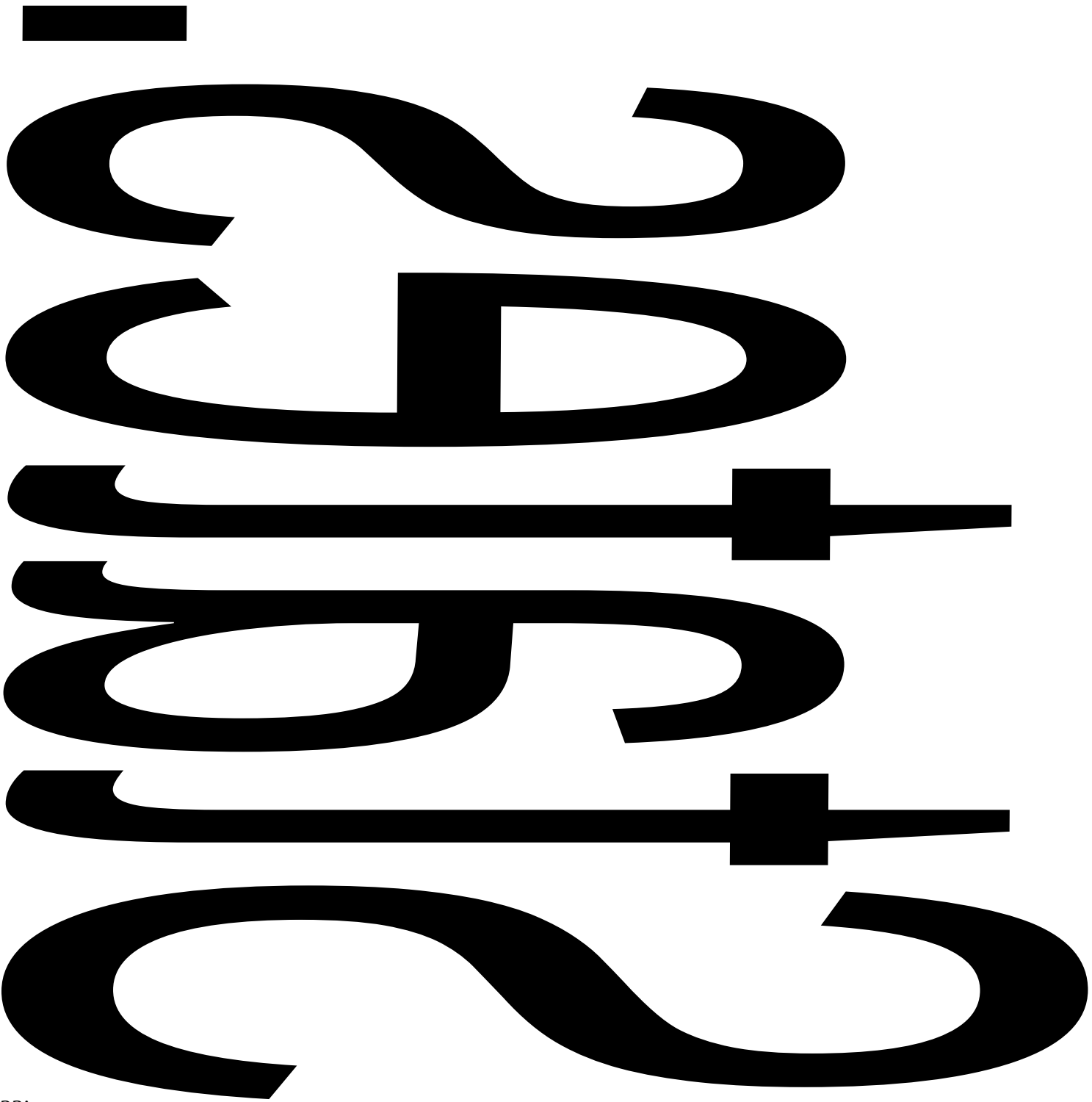
emergencies. Our work primarily

[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

agency, U.S. Custo[illegible] ction (CBP), to [illegible] just our [illegible] d
targeting strategy t[illegible] ure [illegible] ted products [illegible] hen e[illegible] ng the U[illegible] s.

While the out[illegible]



We established a cross-agency task force to closely

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