U.S.

Centers for Disease Control and Prevention

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America from health, safety and security threats, both abroad and in the United States. CDC has a key role in preparedness and response, and addressing infectious diseases like COVID-19 is central to our mission. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and the H1N1 pandemic influenza, to meet new challenges presented by COVID-19. These

our respiratory disease experts in the CDC Country Office in China, which were shared with HHS, and reaching out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response structure to facilitate staffing and communications. On January 21, 2020, CDC officially activated its Emergency Operations Center for COVID-19. Using the IM structure, CDC immediately set up task forces to address key needs, reach out to our state and local partners, and deploy staff where needed to support state and local screening and investigation efforts. CDC is an integral part of the COVID-19 response and coordinates with other agencies through the Joint Coordination Center (JCC) led by Secretary Azar. Addressing COVID-19 is an all-of-government effort.

Congress has addressed the urgent need to respond to this pandemic at home and abroad DQG KDV DOORFDWHG VXEVWDQWLDO UHVRXUFHV IRU &'&¶V activities through the statutes mentioned above. This funding supports a federally guided, state managed, and locally implemented response to COVID-19 in the United States. With support provided by Congress for global disease detection and emergency response through COVID-19 appropriations, CDC is supporting prevention, preparedness, and response efforts in partnership with public health agencies, health ministry counterparts, and multilateral and non-governmental agencies worldwide. Here in the United States, CDC is working with STLT partners to focus use of these resources to establish and enhance case identification; conduct contact tracing; implement appropriate containment and community mitigation measures; improve public health surveillance; enhance testing capacity; control COVID-19 in congregate settings, protect vulnerable and high-risk populations; and work with healthcare systems to manage and monitor capacity. As of June 22, 2020, CDC has announced or obligated $12.1 billion in direct awards to jurisdictions across America from the funds provided by Congress, including $10.25 billion from the Paycheck Protection Program and Health Care Enhancement Act.

CDC is providing direct technical assistance and support to STLT partners as they consider appro

Puerto Rico and the District of Columbia to identify state capacities and needs. The federal government has committed to ensuring that states can meet testing objectives for the month of June, as identified by each state. Through these calls and other outreach efforts, CDC has worked with jurisdictions to identify needs and develop plans to enhance testing capacity, state surveillance, contact tracing, and surge staffing. These discussions and plans for action will emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

In addition, CDC has launched a multifaceted approach to enhance and complement STLT efforts and expand support to communities during the current public health emergency, including deploying over 1,500 individuals to over 100 locations across the United States. These support staff will augment health department teams and engage in core public health functions including contact tracing, testing, infection prevention and control, call center activities, COVID-19 education, and public health surveillance.

CDC relies on timely and accurate public health surveillance data to guide public health action and inform the nationwide response to COVID-19. This crisis has highlighted the need to continue eff

case investigation and contact tracing plan, digital contact tracing tools, and a Contact Tracing Communications Toolkit for Health Departments.

CDC is also working to understand the impact of COVID-

S X E O L F ¶ The test is currently not designed to test individuals who want to know if they

CDC has developed a new laboratory test that checks for three viruses at the same time, two types of influenza viruses (A and B) and SARS-CoV-2, the virus that causes COVID-19. Testing for all three viruses simultaneously will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find co-infections of influenza and SARS-COV-2, which is important for doctors to diagnose and treat people properly. CDC requested emergency use authorization (EUA) for this combined laboratory test from the U.S. Food and Drug Administration (FDA) on June 18, 2020. CDC expects that private sector laboratory test developers may be creating similar multiplex assays to meet clinician needs during influenza season. The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID-19. CDC develops and disseminates guidance for a range of audiences, individuals and communities, including business, schools, and healthcare professionals. These recommendations include actions that every American should take, such as following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. CDC guidance is available here https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick-prevention.html.

CDC released consideration documents to help businesses and community organizations operate as safely as possible during the COVID-19 pandemic, including K-12 schools and universities. These documents complement other CDC resources, including interim guidance documents that are posted online and the decision tools that help communities make decisions about resuming and gradually scaling up operations. These decision tree tools quickly walk through some key questions that should be answered in preparation for phased opening of schools, businesses, mass transit, and other settings. These suggestions are updated as we learn more about COVID-19 and as state and local leaders continue to decide how to adjust mitigation strategies in their communities. School administrators and officials can consult with state and local health officials to determine how to put these considerations into place. In addition, schools may need to make adjustments to meet their unique needs and circumstances.

First responder and healthcare guidance documents cover a range of topics - from addressing potential work-related exposures, implementing infection prevention and control measures in health facilities, and optimizing the supply of personal protective equipment to clinical evaluation, testing, and clinical care. CDC is providing these recommendations to support communities, and each community is unique and will need to consider these in the context of their community-level data and circumstances. CDC teams on the ground and those aiding from Atlanta are and will continue working with state and local officials to integrate these recommendations into COVID-19 plans. CDC offers a framework for providing non-COVID-19 clinical care that outlines key considerations for healthcare systems and health care providers. Key considerations include monitoring trends in local cases and deaths, consulting with state or local health departments for region-specific information and recommendations, following recommended infection control practices, screening all patients for COVID-19 symptoms and expanding services gradually.

Mitigation and containment of COVID-19 are the key to public health strategies, and CDC is committed to using our expertise and partnering with others on the frontlines. While surveillance, testing, contact tracing, and community mitigation interventions are the best tools we have right now to bend the curve and private health systems to deliver effectively a COVID-19 vaccine once it is available. This includes working with CDC's immunization program to ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking.

While it remains unclear how long the pandemic will last, COVID-19 activity will likely continue for some time. It is also unclear what impact the ongoing COVID-19 pandemic will have on health care and public health systems during the upcoming influenza season. If there is COVID-19 and flu activity at the same time, this could place a tremendous burden on the health care system related to bed occupancy, laboratory testing needs, personal protective equipment and health care worker safety. In the context of likely ongoing COVID-19 activity, getting a flu vaccine is more important now that ever. Getting a flu vaccine will help keep you and your loved ones out of a doctor's office and help conserve scarce medical resources to care for COVID-19 patients.

CDC works with public health and clinical partners each year to increase the number of people who get the flu vaccine and eliminate barriers to vaccination. Ongoing COVID-19 activity may affect where and how flu vaccines are given. CDC is working with manufacturers to maximize flu vaccine supply and with providers and health departments to develop contingency plans so that people can be vaccinated in a safe environment.

,Q DGGLWLRQ RQ -XQH &'& DZDUGHG PLOOLRQ WI existing immunization cooperative agreement to enable state health departments to launch an initial scale up for influenza season, given the increased risk of COVID-19. Funds will, among other activities, begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for these vulnerable populations. Due to the risk of COVID-19, the goal is to increase flu coverage for vulnerable populations during the 2020-21 flu season, ensure Americans are aware of the importance of getting vaccinated this flu season, and increase access

the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by product developers and incentivizing companies to partner with us in developing safe and effective countermeasures including vaccines, therapeutics, and diagnostics.

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 enhanced our fundamental understanding of coronaviruses in general and provides a strong foundation for our accelerated efforts to address the specific challenge of COVID-19 by developing vaccines, therapeutics, and diagnostics.

Developing Vaccines to Prevent SARS-CoV-2 Infection

A safe and effective vaccine for SARS-CoV-2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks. NIAID is supporting development of several SARS-CoV-2 vaccine candidates, including vaccines based on platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

As part of a longstanding collaboration, the NIAID Vaccine Research Center worked with the biotechnology company Moderna, Inc., to develop a vaccine candidate using a messenger RNA (mRNA) vac vaccines based

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clinical trials to assess hyperimmune intravenous immunoglobulin (IVIG) and mAbs for treatment of COVID-19 in hospitalized adults.

On April 6, 2020, the National Heart, Lung, and Blood Institute (NHLBI) launched a clinical trial of HCQ in hospitalized COVID-19 patients through its Prevention and Early Treatment of Acute Lung Injury (PETAL) clinical trials network. NHLBI also sponsored the addition of a U.S. site for a Canadian Institutes for Health Research-funded trial of colchicine ² an anti-inflammatory drug commonly used to treat gout ² for treating COVID-19 in the outpatient setting. Additionally, NHLBI is leveraging the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID-19, can help reduce the progression of COVID-19 in patients with mild symptoms.

The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection, a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS-CoV-2 therapeutics for further investigation. Other Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the development and testing of mAbs, antiviral, and anti-thrombotic drugs for potential treatment of COVID-19. NIAID, NCI, NHLBI, NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke (NINDS) are all engaged in this critical effort.

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID-19 therapeutics and vaccines. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership brings together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. Other federal partners include BARDA, DOD, the Department of Veterans Affairs, CDC, and FDA. NIAID has been a pn4-3(on. Ot)-9A6d2

NIH also has convened the COVID-19 Treatment Guidelines Panel, comprised of representatives of NIH and five other federal agencies along with representatives of eight professional organizations, academic experts, and treating physicians including providers from high COVID-19 incidence areas. On April 21, 2020, the panel issued the first release of COVID-19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments currently available and address considerations for special populations, including pregnant women and children. On May 12, 2020, in response to the preliminary analysis of ACTT-1, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation. The

to increase national capacity for high-quality serological testing with return-of-results to subjects. In addition, they will conduct research to increase the understanding and application of those results and support related clinical efforts, including clinical trials of convalescent serum and the creation of registries of tested subjects for sero-protection studies.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the United States without a confirmed history of infection with SARS-CoV-2 have antibodies to the virus, indicating prior infection. In addition, NIH is supporting COVID-19 natural history studies to understand the incidence of infection in specific populations, including children and their household contacts, and aspects of the clinical course of infection, including incidents of thrombosis, strokes, heart attacks, and other sequelae of infection. Some of these studies will examine the quality and durability of the immune response to SARS-CoV-2 and evaluate whether unique immune responses may be associated with clinical disease trajectories; this information may be leveraged to develop SARS-CoV-2 therapeutics or vaccines. Natural history studies also will inform our understanding of COVID-19 pathogenesis, including factors that may predict disease progression and help to identify individuals or groups at high risk.

In order to improve understanding of neurological consequences of SARS-CoV-2 and inform potential treatment strategies, NIND(e)90 613(ip)-3(vn0 g(0 612 7(f1 0 i alt.000912 0 612 792 reW*nBT/

Office of the Assistant Secretary for Health

Diagnostics and Testing

Testing for the presence of SARS-CoV- L V D Q H V V H Q W L D O F R P S R Q H Q W F 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

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. Point-of-care (POC) tests are an exception in that they are low complexity; however, this class of test still represents a minority of available testing capability and has a defined role because of its low throughput and relatively limited sensitivity especially early or late in the infection. Finally, the pandemic caused an unprecedented demand for all supplies and materials, such that overall demand in a single month approximated total annual demand of some essential supplies and materials. This reality represented substantial challenges, but federal leadership has guided efforts to combat these challenges in close collaboration with states, local jurisdictions, and the private sector. Our overall strategy for testing includes:

- Assuring that those who need testing, receive testing;
- Prioritizing testing to meet the stage of the pandemic;
- Increasing the number, diversity, and quality of tests;
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  drive-through community-based testing sites;
- Organizing and galvanizing the industry on an unprecedented scale;
- Enhancing testing to underserved communities;
- Providing surge testing capacity during local outbreaks;
- Supporting critical infrastructure and national security needs; and
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

Stage 1: Launch: Engaging the Emerging Crisis

In the early stages of the COVID-19 pandemic, the 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 p R V W H G L W V D V V D \ I R U W K H & ' & ¶ V Q H Z C 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 Food and Drug Administration (FDA) issued an EUA on February 4, just 24 hours after receiving the F R P S O H W H S D F N D J H H Q D E O L Q J X V H R I W K H & ' & ¶ V & 2 9 , ' 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 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 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.

the testing scale and capacity in our country, while providing enough oversight to assure patients can depend on the results of these tests.

Throughout the COVID-19 outbreak, the Administration has encouraged and worked collaboratively with diagnostic test manufacturers, commercial laboratories, public health laboratories, and professional societies to expand capacity and scale for existing nucleic acid testing platforms. 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-

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 DQG UDSLG UHVSRQVH SURJUDPV FDOOHG IRU LQ WKH 3UHV

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-19ribeP72.024 59i,W*n3tg plans,la

these centers offer COVID-19 testing. As of June 26, health centers have reported testing nearly 1.3 million individuals in total and racial and/or ethnic minority patients represent 55 percent of those tested in the past week.

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 4,532 officers as of June 24, 2020, with many of them undertaking multiple or consecutive

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.

Food and Drug Administration

provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA has announced several policies to facilitate oversight. These include engaging in rolling reviews of EUA submissions, and authorizing tests that have the necessary data to support that the criteria for issuance are met. To date, we have authorized more than 150 EUAs for COVID-19 tests. States that have the capacity and expertise to do so have been authorizing tests for use within a laboratory in that state.

COVID-19 infection; however, they can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have overcome an infection in the past and may have developed an immune response. These tests may also aid in identifying individuals with antibodies to the virus that causes COVID-19 so they may donate convalescent plasma as a possible treatment for severely ill COVID-19 patients, which is a potential treatment currently being researched.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serological tests to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable, without FDA authorization and as further recommended in the policy. The policy was intended to allow for early patient access and flexibility for developers, with appropriate transparency regarding the limitations of these tests. At the time FDA issued this policy, flexibility was important to allow for early use of antibody tests to begin to answer some of the critical population-level questions about the prevalence of COVID-19 infections in different communities, whether the presence of antibodies conveys immunity and, if so, for how long, while also encouraging test developers to seek an EUA, as many did. Answering these questions is critical for informing how best to use these tests, but we could not answer these questions without tests being available.

FDA authorization. These templates can help facilitate the preparation and submission of an EUA request and can be used by interested developers. Also,

Since the beginning of the COVID-19 pandemic, FDA has been working tirelessly to facilitate the development and availability of therapeutics for use by patients, physicians, and health systems as expeditiously and safely as possible. FDA announced on March 31, 2020 the creation of an emergency review and development program for possible therapies for COVID-

eligibility criteria. To that end, FDA continues to work with blood collectors to facilitate the collection of convalescent plasma, and to work with developers of these therapies to move forward with clinical evaluations. Thousands of COVID-19 patients have received investigational COVID- F R Q Y D O H V F H Q W S O D V P D X Q G H U) ' $ ¶ V S D W K Z products, including expanded access and clinical trials.

Medical Product Supply

FDA monitors and proactively adjusts to the worldwide demand and supply chain disruptions for medical products caused by the COVID-19 pandemic. We are working closely with manufacturers to help ensure they continue to notify the Agency of any permanent discontinuance or interruption of drug, biological product, and device manufacturing in a timely manner. In addition to our usual communication with drug manufacturers, we are work closely with healthcare and pharmacy systems, hospitals, providers, and others on the frontlines of COVID-19 patient care to identify current or emerging regional shortages of critical care drugs used to treat COVID-19.

FDA understands the significant impact shortages can have on patient care and is doing everything within our authorities to help prevent and alleviate this impact. For example, we issued temporary policies under which outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or federal facilities can compound certain drugs used to treat patients with COVID-19 under particular conditions explained in FDA guidance.

In addition, when we identify a shortage, we react swiftly to mitigate the impact to U.S. patients and health care professionals, and quickly share that information with the public. For example, the Agency quickly identified the need for making hand sanitizers available as demand spiked. FDA has published and updated three guidances to facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. As another example, the Agency granted an EUA to authorize use of propofol approved in the European Union, thus alleviating a shortage of this critical drug for COVID-19 patients who need to be on a ventilator.

We are working to increase the supply of personal protective equipment (PPE) and other critical devices that patients and those on the front lines of the U.S. response rely upon. FDA has

reached out to over 1000 manufacturers since January and has helped facilitate an increase of the availability of PPE while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them. FDA has issued several EUAs to help make more respirators available to health care personnel and ease burdens on the health care system. These allow for the emergency use of NIOSH-approved respirators in health care settings for healthcare personnel and the importation of non-NIOSH approved respirators that meet certain specified criteria, as set forth in the various EUAs. FDA has also issued several guidances to provide flexibility for those manufacturing PPE for the COVID-19 response, and we have published conservation strategies for gloves and masks and gowns. To support these efforts further, FDA has issued several EUAs for devices used to decontaminate respirators for reuse by health care workers in hospital settings, where appropriate.lp ma

FDA has also issued guidances for several other critical devices including ventilators, clinical electronic thermometers, and imaging systems, as well as remote digital pathology and remote monitoring devices intended to help facilitate remote care that puts patients and healthw27-10rs at l12 0 61
care providers at less risk for exposure to COVID-19.

FDA has worked steadily to support those manufacturing PPE, as well as those who are dealing with limited supplies and shortages, to provide alternatives when there are no other options avail

Although food production and manufacturing in the United States remains strong, resilient, and is for the most part dispersed throughout the United States, some components are under stress. We are monitoring these situations closely and identifying mitigation strategies.

There has been a significant shift in where consumers are buying food, because of the pandemic. We have taken steps to provide temporary guidance to provide flexibility in packaging and labeling requirements to help industry divert products manufactured for food service and institutional use to retail grocery stores.

)'$ UHFRJQL]HV WKDW WKH IRRG VXSSO\ FKDLQ LV GHSH and agricultural workforce. Along with our federal partners, we have provided best practices for food and agricultural workers, industry, and consumers on how to stay safe, and help ensure the continuity of operations in the food and agriculture critical infrastructure sector during the pandemic and as retail establishments begin to reopen.)'$¶V &RRUGLQDWHG 2XWEUHD and Evaluation team has been working throughout the pandemic, is fully staffed, and on-the-job looking for signs of foodborne illness outbreaks. FDA continues to monitor closely the overall VDIHW\ RI WKH Supply. Importantly, we continue to work with CDC, the U.S. QDWLRQ¶V IRRG Department of Agriculture, and our state and local partners to protect consumers from foods contaminated with pathogens. For example, in March, FDA found and detained *Salmonella* contaminated tahini products at the port of entry; products that were already in U.S. distribution were recalled. Earlier this month FDA started investigating a multistate outbreak of Cyclospora illnesses potentially linked to store brand garden salads; three retailers have recalled the product.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from firms and individuals selling unproven products with false or misleading claims to prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil and criminal enforcement actions, where appropriate. For example, FDA has sent hundreds of abuse complaints to domain name registrars and internet marketplaces, which in most instances have voluntarily removed listings for products that fraudulently claim to diagnose, cure, mitigate, treat, or prevent COVID-19. The Agency also has sent more than 50 warning letters to sellers of such fraudulent products. Working with the Department of Justice, FDA has sought and obtained several preliminary injunctions that require defendants to halt the sale of fraudulent

products claiming to treat or prevent COVID-19, including one product that, when used as directed, is equivalent to industrial bleach.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining, reviewing, and sampling import entries, and refusing admission where appropriate. We protect the supply chain in two equally critical ways: first, we help ensure safe products are coming in and second, that illegal, dangerous and fraudulent products do not get into the country. As FDA import staff screen medical products entering our country, we also find and block the entry of fraudulent products that falsely claim to prevent, treat, mitigate, diagnose, or cure COVID-19. For example, in March, at the border, FDA intercepted fraudulent COVID-19 ³WUHDWPHQW NLWV´ WKDW ZHUH IDOVHO\ GHFODUHG DV ³Z VKLSPHQWV IRXQG PLVEUDQGHG at SARS-CoV-2. ³NLWV´ This joint investigation, LQWHUFHSWHG WR WU ZKLFK LQFOXGHG)'$¶V 2IILFH RI &ULPLQDO ,QYHVWLJDWLR to an arrest in the UK by law enforcement partners there. In addition, in April, FDA intercepted a bulk shipment of hydroxychloroquine coming from China going to a physician in California. The physician was charged with smuggling hydroxychloroquine from China to make his own pills and conce4(s).dA1.95 Tm0 gr