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MEMORANDUM

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*May 28, 2020*

To: Governors' Offices  
From: National Governors Association  
Subject: Update on COVID-19 Treatment Development

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COVID-19 treatment development is moving at an unprecedented pace across the world and resulting therapeutics may be critical to reducing disease burden and pressure on the health system. This memo provides a brief review of accelerated development efforts, the types of treatments being studied, and information about outcomes of select studies.

### **Accelerated Development**

An array of activities are underway across sectors to accelerate the development of effective COVID-19 therapeutics. A recent [report](#) from Duke's Margolis Center for Health Policy outlines key steps to accelerating development of therapeutics for COVID-19 many of which are being implemented. The Food and Drug Administration (FDA) established the [Coronavirus Treatment Acceleration Program](#) to expedite the development of COVID-19 treatments. The emergency program triages requests to get new studies launched quickly and utilizes processes such as ultra-rapid review protocols. The FDA is also [coordinating](#) a national effort to spur development of antibody-rich blood products made from blood donated by people who have recovered from the virus.

Additionally, several high-profile efforts are underway to collaboratively engage governments, industry and academia to spur development and vet findings. On May 15, the Trump Administration announced [Operation Warp Speed](#), a new public-private partnership across multiple federal agencies and programs and private firms to facilitate accelerated development, manufacturing and distribution of COVID-19 countermeasures including diagnostics, therapeutics and vaccines. Other efforts including the National Institutes of Health (NIH) public-private partnership Accelerating Covid-19 Therapeutic Interventions and Vaccines ([ACTIV](#)), which will coordinate with Operation Warp Speed, the World Health Organization's (WHO) [Solidarity Trial](#), the Centers for Disease Control and Prevention's Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance ([SPHERES](#)) consortium, and [Scientists to Stop COVID-19](#), a self-described Manhattan Project. Payers and health systems are also [collaborating](#) to collect and exchange real world data on COVID-19 treatment efforts. These efforts and others are supported by substantial financial investments from governments, philanthropists, and industry. In the United States, Congress has directed almost [\\$10 billion](#) to research and countermeasure development through supplemental funding. Federal agencies have also leveraged existing research to inform COVID-19 response and have shifted investments and priorities to support COVID-19 efforts.

### **Number and Types of Treatments**

As of May 20, there are between [219](#) and [346](#) reported treatments in various stages of development, with approximately [138](#) in trial phases. Development is largely focused on redirecting or repurposing existing therapeutics for COVID-19 and there are more than [2,700](#) studies underway globally (inclusive of therapeutics and vaccines). Investigational treatments typically fall into two broad buckets: (1) those that directly interact with the virus or disrupt its ability to replicate; and (2) those for supportive care, such as treating respiratory

symptoms or overactive immune response that can result from COVID-19 infection. Specific types of treatments in development include: antivirals, antimalarials, vasodilators, anticoagulants, antibodies, anti-inflammatory therapies, immunotherapies, and blood-related treatments, such as convalescent plasma and immunoglobulin.

## **Emergency Use Authorizations and Preliminary Outcome Data**

To date, no treatment has been approved for COVID-19. However, the FDA has issued Emergency Use Authorizations (EUAs) for [chloroquine/hydroxychloroquine](#) and [remdesivir](#) for hospitalized COVID-19 patients with severe disease.\* [EUAs are not equivalent to an FDA approval](#), but rather allow distribution and use for certain patients in emergency situations.

*Chloroquine and Hydroxychloroquine* are immunosuppressive and anti-parasitic drugs FDA-approved for treatment and prevention of malaria. Hydroxychloroquine is also used to treat lupus and rheumatoid arthritis. Thus far, studies have shown limited or no benefit for COVID-19 patients and, in some cases, increased risk of cardiovascular events particularly when used in combination with other therapies. On April 24, the FDA issued a [safety warning](#) related to the use of chloroquine or hydroxychloroquine outside of the hospital or clinical trial setting due to risk of heart rhythm problems. On May 22, a multinational registry analysis of patients across multiple geographic regions [published findings](#) on the use of chloroquine or hydroxychloroquine with or without a macrolide (a class of antibiotics) for treatment of COVID-19. The observational study found no benefit on in-hospital outcomes and that each of the drug regimens, used alone or in combination with a macrolide, was associated with an increased hazard for clinically significant occurrence of ventricular arrhythmias and increased risk of in-hospital death with COVID-19. On May 25, the WHO [announced](#) the temporary suspension its study of hydroxychloroquine as part of its [Solidarity Trial](#) to review safety concerns.

*Remdesivir* is an intravenously-administered, broad-spectrum, antiviral medication first examined as a potential treatment for Ebola and not yet FDA-approved for any indication. Preliminary data, including an [NIH clinical trial](#) and a [smaller study out of China](#), have shown that severely ill, hospitalized patients treated with remdesivir experienced reduced time to recovery but no difference in mortality rate. Remdesivir's manufacturer, Gilead, has committed to donating 1.5 million doses worldwide and has taken other steps to bolster the drugs availability. Doses are currently being [distributed](#) to hospitals across the states through the U.S. Department of Health and Human Services, Assistant Secretary for Preparedness and Response and processes are still being updated. State feedback on success of federal distribution efforts has been mixed and should inform process improvement of distribution protocols going forward.

## **Availability and Affordability of COVID-19 Treatments**

Early results and expedited regulatory pathways have already sparked discussions about availability of effective treatments as they emerge. The promise of reducing mortality, morbidity, and burden on the health care system while awaiting a vaccine is driving unprecedented partnerships and global investments. Questions remain as to what demand, access and costs may look like. In the short term, all sectors are investing “at risk” to collectively address the crisis with uncertainties about which treatments may ultimately prove safe and effective. As the crisis wanes, the balance of access and affordability in the context of new and likely harsh economic realities will be revisited. In its recently announced Operation Warp Speed initiative, the Trump Administration underscored the unprecedented taxpayer investments and a commitment to affordability of any resulting treatments and vaccines. To date, quantitative frameworks to guide the discussion around access, affordability and the nature and source of investments (including federal taxpayer funds) are lacking. One effort to provide such a framework was recently released by the Institute for Clinical and Economic Review (ICER). ICER, a non-profit organization that evaluates the clinical and economic value of treatments, is adapting their methodology to examine alternative pricing models for potential COVID-19 treatments, including both cost recovery and cost-effectiveness approaches. ICER recently released a [report](#) outlining cost recovery and cost effectiveness pricing models for remdesivir. The cost recovery model estimates a price for remdesivir that would



compensate the manufacturer for costs of production without additional profit and factors in federal investment in development and production. The cost effectiveness model looks at health-based price benchmarks versus standard of care. The ICER report has been [the focus of much debate](#). For example, there is concern that an unaffordable drug will limit access and on the other hand if the price is too low drug companies will not invest in development. Additional cost, value and affordability frameworks are needed to continue to inform the debate.

Additional data on chloroquine, hydroxychloroquine, remdesivir and other potential therapeutics are expected on a rolling basis over the next several months. As new data are released, it will be increasingly important to monitor potential access issues related to supply, treatment indications, and cost to ensure robust and equitable supply of effective new treatments and avoid shortages. Shortages have already developed for chloroquine and hydroxychloroquine, which has been particularly [concerning](#) for individuals with lupus and rheumatoid arthritis that rely on these drugs to manage their conditions.

\*The FDA also issued an EUA for [Fresenius Kabi Propoven 2%](#) to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an intensive care unit (ICU). Sedatives are among several ICU drugs that have been in short supply due to increased demand associated with COVID-19.

