



April 2, 2020

COVID-19: Issues Related to Vaccines and Treatment

COMMITTEE ON ENERGY & COMMERCE

PURPOSE

- This document addresses issues related to the development of therapies to treat COVID-19 patients and vaccines to prevent infection and the spread of COVID-19. The information in this document is based on information provided by the Trump Administration and outside sources. This document is intended to provide Members with the latest reported information during this unprecedented pandemic. The Committee continues to receive updates from Administration officials and will update Members as new information becomes available.

TREATMENT FOR COVID-19

- Although there are ongoing clinical trials, **there are currently no FDA-approved therapies to treat COVID-19.**
- Through the Coronavirus Preparedness and Response Supplemental Appropriations Act and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress provided nearly \$1.8 billion of supplemental funding to the National Institutes of Health (NIH). With this support, NIH is working with researchers to improve our scientific understanding of the virus and develop therapeutics.
- In partnership with the University of Nebraska Medical Center, NIH is [actively testing](#) an antiviral drug, **remdesivir**, in adults with COVID-19. Since its launch on February 21, the clinical trial has [40 participating sites](#) across the country, including the NIH Clinical Center. [Remdesivir](#) was initially developed by Gilead Sciences Inc. as a broad-spectrum antiviral treatment and was previously tested to treat Ebola, Middle East respiratory syndrome (MERS), and severe acute respiratory syndrome (SARS). The Food and Drug Administration (FDA) has allowed the use of this drug under the agency's [expanded access program](#) for those unable to enroll in a clinical trial.
- Trials have also begun to test the safety and effectiveness of **hydroxychloroquine and chloroquine** in COVID-19 patients. Hydroxychloroquine and chloroquine are generic drugs approved to prevent or treat other conditions, including rheumatoid arthritis, lupus, and malaria.
- [FDA has issued an emergency use authorization \(EUA\) for hydroxychloroquine and chloroquine](#) to allow the drugs to be donated to the Strategic National Stockpile (SNS) to be distributed and prescribed to COVID-19 patients under certain conditions when a clinical trial is not available or feasible.
 - As part of the EUA, FDA noted there is limited in-vitro and anecdotal data about the use of these products for COVID-19; however, hydroxychloroquine phosphate and chloroquine sulfate have been recommended for treatment in several countries and there are some

national guidelines. The EUA issued on March 28 concluded that the known and potential benefits of hydroxychloroquine and chloroquine, when used for the treatment of COVID-19 within the scope of the EUA, outweigh the potential risks of the products. FDA has not made an assessment of the overall safety or effectiveness of the drugs in patients with COVID-19.

- Prior to this decision, leadership within NIH's National Institute for Allergy and Infectious Diseases (NIAID) noted that after looking at the available human data, there did not seem to be [“anything in the literature that appears to show any benefit.”](#) Immediately following this EUA, [HHS announced](#) that it would accept a donation of 30 million doses of hydroxychloroquine and one million doses of chloroquine from manufacturers to the SNS.
- Antiviral drugs that might treat host targets, such as interleukin-6 (IL-6) receptor inhibitors that might reduce lung inflammation and improve lung function, are also [under investigation](#) to determine whether these can be used to treat COVID-19 symptoms.
- FDA has also [begun](#) looking into whether **antibody-rich blood products** taken from blood donated by people who have recovered from COVID-19 can be used to shorten the length or lessen the severity of illness in patients with the disease.

VACCINES TO PREVENT INFECTION AND THE SPREAD OF COVID-19

- Multiple manufacturers have begun efforts to work with federal partners to develop a vaccine that can be used to prevent COVID-19 infection and stop its spread. Although several are moving to clinical trial far faster than a typical investigational vaccine, establishing safety and effectiveness in vaccines requires high standards and study over time, as the vaccines are intended to be used in otherwise healthy patients, and must not harm them.
- On March 16, [NIH began a Phase I clinical trial](#) on a COVID-19 vaccine at Kaiser Permanente Washington Health Research Institute in Seattle, WA. The science behind this vaccine was developed by researchers at NIAID's Vaccine Research Center and Moderna Therapeutics.
 - In a Phase I trial, FDA assesses the safety and initial effectiveness in a small sample of patients before determining whether it is safe to proceed to a Phase II study, which evaluates the drug's effectiveness. Moderna has stated that its goal is to have patient safety data back in April and initial efficacy data by June.
 - As an additional goal, Moderna [has said to investors](#) that it hopes to seek an EUA to provide the vaccine to certain health care workers as soon as this fall. That authorization will be determined by FDA based on available safety and efficacy data, the coronavirus situation, and a determination that the benefits would outweigh the potential risks. However, even if finally approved under a faster-than-usual timeline, the vaccine is unlikely to be commercially available for 12 to 18 months.
- Johnson & Johnson has also [announced](#) that it identified a vaccine candidate for a Phase I trial, which the company expects to begin in September, with hopes of receiving safety and initial

effectiveness data by the end of 2020.

- Both of these trials are moving more rapidly than would be typical for a vaccine, which usually requires years of study before even identifying a candidate for a trial.

HOW PATIENTS CAN ACCESS POTENTIAL THERAPIES AND VACCINES

- **Clinical Trials:** Individuals and health care providers can visit clinicaltrials.gov to see whether they or their patients are eligible to enroll in a clinical trial to assess the safety or effectiveness of a particular vaccine or treatment.
- **Expanded Access:** Under certain conditions and with the supervision of a patient's physician, FDA and manufacturers may allow a patient to use an investigational drug or medical product under [expanded access](#). This will only be allowed when enrollment in a clinical trial is not possible, where the benefit justifies the potential risk of using a product, and providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.
 - Patients should know that investigational drugs, biologics, or medical devices have not yet been approved or cleared by FDA and FDA has not found these products to be safe and effective for their specific use. Furthermore, the investigational medical product may, or may not, be effective in the treatment of the condition, and use of the product may cause unexpected serious side effects. Expanded access use also depends on the manufacturer agreeing to make the medical product available.
- **A Note About Fraud:** FDA and law enforcement officials have [reported](#) that some people and companies have sought to fraudulently prey on the fears of the public and profit from the COVID-19 pandemic by illegally selling products that claim to prevent, treat, or cure COVID-19. These [products, which include](#) colloidal silver, teas, salt therapies, essential oil and herbal products, and "corona cure" nasal sprays, have not been evaluated by FDA, are not known to have any benefit to prevent, treat, or cure COVID-19, and may cause harm to those who use them. Consumers and health professionals can report suspected cases of fraudulent sales of coronavirus therapies to FDA's [Health Fraud Program](#) or the agency's [Office of Criminal Investigations](#).