



LPA

CORONAVIRUS (COVID-19)

UPDATES

August 8, 2020

Some people ask, “If you are making those vaccines so fast, are they really going to be safe?” While I have already flagged the [NIH Director’s conversation](#) on this question, tonight I want to highlight the FDA Commissioner Hahn’s new op-ed:

“No Matter What, Only a Safe, Effective Vaccine Will Get Our Approval”: FDA Commissioner Dr. Stephen Hahn wrote an op-ed that appeared in *The Washington Post* titled, “[No Matter What, Only a Safe, Effective Vaccine Will Get Our Approval](#).” Here is an excerpt:

“While speed is essential in this global emergency, we at the FDA are committed to maintaining strict scientific principles and protection of those who volunteer as vaccine test subjects..... FDA decisions have been, and will continue to be, based solely on good science and data. The public can count on that commitment.”

Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the U.S.: President Donald Trump signed an Executive Order on ensuring that essential medical supplies are produced in the U.S. The White House released the [executive order](#), as well as a [fact sheet](#).

Vaccine Updates

Expanding Domestic Capacity for Fill and Finish Vials for Vaccines: BARDA and the DoD’s JPEO-CBRND are [partnering with Grand River Aseptic Manufacturing, Inc. \(“GRAM”\) to expand the capacity and ensure access for filling and finishing vaccines or therapeutics](#) in the United States. Filling and finishing vials are the last two steps in the manufacturing process for vaccines and drugs. With this award to GRAM, the U.S. government helps ensure that the country will have enough domestic capacity to complete these critical final steps to make vaccines or therapeutics available to the American people. As part of this agreement, the federal government will reserve fill-finish capacity on a commercial filling line for use by federal partners that are developing COVID-19 vaccines or therapeutic treatments.

Funding

HHS Awards Over \$101 Million to Combat the Opioid Crisis: HHS, through HRSA, [awarded over \\$101 million to combat substance use disorders \(SUD\) and opioid use disorders \(OUD\)](#). The awards support 116 organizations in 42 states and the District of Columbia, with many targeting high-risk rural communities. “The [COVID-19] pandemic has created particular stresses for many Americans struggling with substance use disorders, and these HRSA awards will help

strengthen prevention, treatment, and recovery services, especially in rural America, at this difficult time,” said HHS Secretary Alex Azar.

Testing and Treatment

Charting a Rapid Course Toward Better COVID-19 Tests and Treatments: NIH Director Dr. Francis Collins released a blogpost titled, “[Charting a Rapid Course Toward Better COVID-19 Tests and Treatments](#).” NIH last week announced the first RADx projects to come through the deep dive with flying colors and enter the scale-up process necessary to provide additional rapid testing capacity to the U.S. public. As part of the RADx initiative, seven biomedical technology companies will receive a total of \$248.7 million in federal stimulus funding to accelerate their efforts to scale up new lab-based and point-of-care technologies. Four of these projects will aim to bolster the nation’s lab-based COVID-19 diagnostics capacity by tens of thousands of tests per day as soon as September and by millions by the end of the year. The other three will expand point-of-care testing for COVID-19, making results more rapidly and readily available in doctor’s offices, urgent care clinics, long-term care facilities, schools, child care centers, or even at home.

NIH Clinical Trial Testing Remdesivir Plus Interferon Beta-1a for COVID-19 Treatment Begins: A randomized, controlled clinical trial, sponsored by NIAID and NIH, is [evaluating the safety and efficacy of a treatment regimen consisting of the antiviral remdesivir plus the immunomodulator interferon beta-1a](#) in patients with COVID-19 has begun. The study, called the Adaptive COVID-19 Treatment Trial 3 (ACTT 3), is anticipated to enroll more than 1,000 hospitalized adults with COVID-19 at as many as 100 sites in the United States and abroad.

Warning Letter about Distribution of Chloroquine Phosphate Products: The [FDA issued its first warning letter](#) to [New Life International](#) and its second warning letter to [Fishman Chemical of North Carolina, LLC](#), both of which distribute chloroquine phosphate products intended to treat disease in aquarium fish. Chloroquine phosphate intended to treat disease in aquarium fish has not been approved, conditionally approved, or indexed. Although neither company identified in today’s warning letters made claims about these products’ use by people, the agency is [concerned](#) that consumers may mistake, and have mistaken, unapproved chloroquine phosphate animal drugs for the human drug chloroquine phosphate. People should not take any form of chloroquine unless it has been prescribed by a licensed health care provider.

Testing updates: To date, the FDA has currently authorized 203 tests under EUAs; these include 166 molecular tests, 35 antibody tests, and 2 antigen tests.

Reopening Information

General Contact Tracing and Case Investigation Training Modules: CDC updated training modules for public health professionals and members of the general public who are interested in [conducting contact tracing or case investigating](#).

Contact Tracing Resources: CDC updated [resources for conducting contact tracing](#) to stop the spread of COVID-19.

Information for Specific Populations

Toolkit for Young Adults – 15 to 21: CDC updated [resources and tools designed for youth and young adults](#) to keep them healthy as they venture out.

Guidance on Unsheltered Homelessness and COVID-19 for Homeless Service Providers and Local Officials: CDC updated interim guidance on [unsheltered homelessness and COVID-19 for homeless service providers and locals shelters](#). People experiencing unsheltered homelessness (those sleeping outside or in places not meant for human habitation) may be at risk for infection when there is community spread of COVID-19.

COVID-19 in Newly Resettled Refugee Populations: CDC updated information for [refugees to the United States](#), especially those who are recently resettled, may be in living or working conditions that put them at risk of getting COVID-19.

Road Travel Toolkit for Transportation Partners: CDC created this [road travel toolkit for transportation departments](#) and other partners to help reach domestic travelers with COVID-19 prevention messaging during road travel.

Air Travel Toolkit for Airline Partners: CDC created this [communication toolkit for our airline partners](#) to help them reach their travelers and employees with COVID-19 prevention messaging.

Environmental Health Practitioners: CDC updated [information for environmental health practitioners](#) who need information on how to safely provide environmental health services and keep the public protected from environmental hazards during the COVID-19 pandemic

Data on COVID-19 during Pregnancy: CDC updated information on [tracking data on COVID-19 during pregnancy](#) to protect pregnant women and their babies.

As a warning for appropriate hand sanitizer usage -- please use it on your hands and DON'T swallow it!

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