

Big news announced last night by President Trump, Secretary Azar, and FDA Commissioner Hahn on issuing an EUA (Emergency Use Authorization) for use of convalescent plasma from people who have recovered from COVID-19 in treating hospitalized COVID patients. More below.

Monday COVID Snapshot

New Cases:

- 82% of jurisdictions are in a downward trajectory (was 80% last week)
- 9% are in plateau (was 7% last week)
- 9% are in upward trajectory (was 13% last week)

National Positivity Rate

- 5.5% positive test rate (was 6.3% last week)

Hospitalizations from COVID

- 10% of inpatients have COVID (was 11% last week, down from a high in April of 24%)

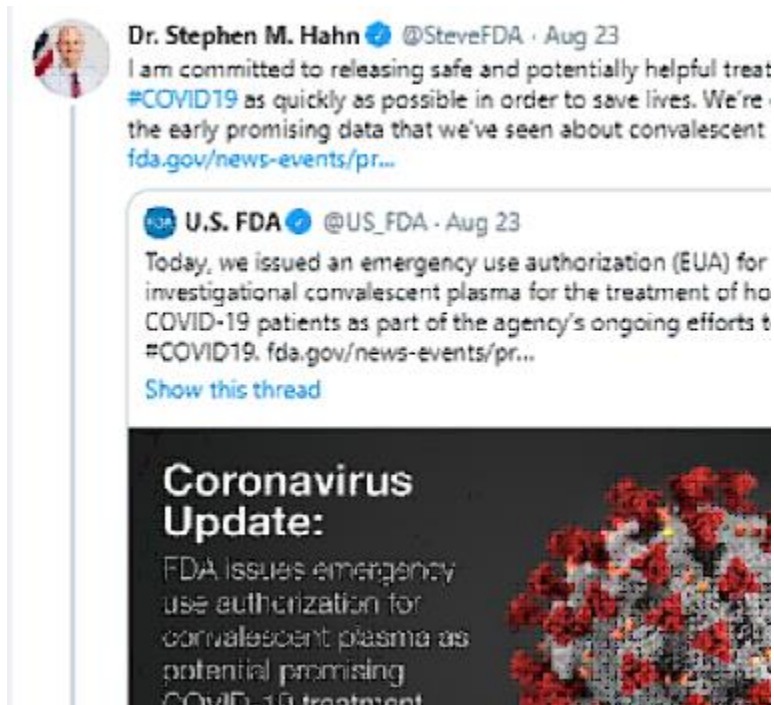
Deaths

- 8.5% decrease in new deaths from previous week

FDA Issues EUA for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration’s Fight Against Pandemic: FDA issued an [emergency use authorization \(EUA\) for investigational convalescent plasma for the treatment of COVID-19](#) in hospitalized patients as part of the agency’s ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product. Today’s action follows the FDA’s extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. President Trump, HHS Secretary Azar, and FDA Commissioner Hahn [delivered remarks on this EUA in a press briefing](#).

Secretary Azar had a great quote from the event emphasizing the significance of the data:

“The data we gathered suggests that patients who were treated early in their disease course — within three days of being diagnosed — with plasma containing high levels of antibodies benefited the most from treatment. We saw about a **35 percent better survival in the patients who benefited most from the treatment** — which were patients under 80 who were not on artificial respiration. I just want to emphasize this point because I don’t want you to gloss over this — this number. **We dream, in drug development, of something like a 35 percent mortality reduction. This is a major advance in the treatment of patients. This is a major advance.**”



For more information on donating convalescent plasma, visit [coronavirus.gov](https://www.coronavirus.gov).

Testing

COVID-19 Electronic Laboratory Reporting Implementation by State: CDC updated information on rapidly onboarding state and jurisdictional health departments to a more detailed form of [COVID-19 electronic laboratory reporting \(CELR\)](#). As of Monday, August 24, 40 jurisdictions have converted to electronic laboratory reporting, representing more than 75% of the total laboratory testing volume in the country.

Overview of Testing for SARS-CoV-2 (COVID-19): CDC updated a summary of considerations and current [CDC recommendations regarding SARS-CoV-2 testing](#) and a [brief overview of SARS-CoV-2 testing](#). The guidance also emphasizes how negative tests should be interpreted and acted on, and fully supports public health surveillance testing, done in a proactive way through federal, state, and local public health officials.

Test for Current Infection: CDC updated a guide to help you make decisions on when it is [appropriate to test for COVID-19 infection](#).

Testing Updates: To date, the FDA has currently authorized 218 tests under EUAs; these include 176 molecular tests, 39 antibody tests, and 3 antigen tests.

Treatment

Trump Administration Adds Health Plans to June 2020 Plasma Donation Guidance: Today, under the leadership of President Trump, the Office for Civil Rights (OCR) at the HHS issued amended guidance on how the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule permits

covered health care providers (e.g., hospitals, pharmacies, laboratories) and health plans to [contact their patients and beneficiaries who have recovered from COVID-19 to inform them about how they can donate their plasma containing antibodies](#) (known as “convalescent plasma”) to help treat others with COVID-19. OCR added health plans to the June 2020 guidance that explains how HIPAA permits covered health care providers and health plans to identify and contact patients and beneficiaries who have recovered from COVID-19 for individual and population-based case management or care coordination. The guidance also emphasizes that, without individuals’ authorization, the providers and health plans cannot receive any payment from, or on behalf of, a plasma donation center in exchange for such communications with recovered individuals.

Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19: The FDA has released a temporary industry guidance entitled, “[Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers](#).” The FDA recognizes the COVID-19 pandemic is not only impacting public health, but also drug development programs, ongoing manufacturing operations and the FDA’s ability to conduct inspections. The questions and answers in the guidance provide information regarding inspections for facilities that manufacture pharmaceutical products and sites involved in the conduct of clinical, analytical and nonclinical studies.

Warning Letter for Fraudulent COVID-19 Products: As part of the FDA’s effort to protect consumers, the agency issued a joint warning letter with the Federal Trade Commission to [Living Senior, LLC](#) for selling fraudulent COVID-19 related products. Living Senior, LLC, sells cannabidiol (CBD) products with misleading claims that the products can mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Currently, there are no FDA-approved products to prevent or treat COVID-19. FDA has requested that Living Senior, LLC, immediately stop selling these unapproved and unauthorized products. Consumers concerned about COVID-19 should consult with their health care provider.

Unapproved COVID-19 Product: The FDA has issued a [warning letter to Predictive Biotech, Inc., for marketing CoreCyte](#), an unapproved umbilical cord-derived product claiming to mitigate, prevent, treat diagnose and/or cure COVID-19. Additionally, the FDA, in conjunction with the Federal Trade Commission, issued a separate letter to PA Green Wellness, LLC, for offering CoreCyte for sale to patients in the U.S. to prevent COVID-19.

Media Telebriefing Transcript – Update on COVID-19: CDC hosted a media telebriefing to provide an update to media on the COVID-19 response and [released a transcript of the briefing](#).

CDC COVID-19 Response Health Equity Strategy: CDC updated their [COVID-19 response health equity strategy](#) on accelerating progress towards reducing COVID-19 disparities and achieving health equity.

CMS Updates

CMS Issues Informational Bulletin on Medicaid Reimbursement Strategies to Prevent Spread of COVID-19 in Nursing Facilities: CMS released a [Medicaid Informational Bulletin \(CIB\)](#) that provides guidance to states on flexibilities that are available to [increase reimbursement for nursing facilities that implement specific infection control practices](#), such as designating a quarantine or isolation wing for COVID-19 patients. Nursing facilities are particularly vulnerable to the prevalence and spread of COVID-19 and states must take proactive steps to enhance infection control policies, including establishing practices to limit potential transmission, and prevent widespread outbreaks within these

facilities. Today's guidance highlights specific steps some states have taken to better support nursing facilities' ability to safely care for all residents, including COVID-19 positive residents, and how enhanced reimbursement supported those efforts.

PPE

EUA to NovaSterilis: The FDA issued an [emergency use authorization](#) (EUA) to NovaSterilis, Inc. for its Nova2200, which uses the NovaClean decontamination process. Nova2200 can be used to decontaminate compatible N95 respirators for single-user reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering respirators (FFRs) during the COVID-19 pandemic.

Protective Barrier Enclosures Without Negative Pressure Used During the COVID-19 Pandemic May Increase Risk to Patients and Health Care Providers: The FDA issued a [letter to health care providers](#) (HCP) and health care facilities alerting them of the potential that passive protective barriers (those without negative pressure) pose an increased health risk to patients and HCPs when treating patients who are known or suspected to have COVID-19.

Reopening Information

Employee Health and Food Safety Checklist for Human and Animal Food Operations: FDA, in partnership with OSHA, developed the [Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic](#). The checklist will assist the food industry with operational changes it may have as a result of COVID-19. The checklist pulls guidance from the FDA, CDC, and OSHA; and serves as a quick reference in the areas of employee health, social distancing, and food safety for food operations that have been impacted during the pandemic.

Operating schools during COVID-19 – CDC's Considerations: CDC updated information on [how schools can protect health during COVID-19](#).

Staffing Resources: CDC updated [staffing resources and guidance](#) to enhance frontline public health capacity in state, local, tribal, and territorial health departments to intensify the coordinated response to COVID-19.

Worker Safety and Support: CDC updated information on [worker safety and support](#) to plan, prepare, and respond to COVID-19.

Schools and Childcare Programs: CDC updated information on [schools and childcare programs](#) to plan, prepare, and respond to COVID-19.

Considerations for Schools: CDC updated considerations for [operating schools during COVID-19](#).

Businesses and Workplaces: CDC updated information for [businesses and workplaces](#) to plan, prepare, and respond to COVID-19.

Information for Specific Populations

COVID-19 Guidance for Shared or Congregate Housing: CDC updated the following guidance was created to help owners, administrators, or operators of [shared \(also called “congregate”\) housing facilities](#) – working together with residents, staff, and public health officials – prevent the spread of COVID-19.

Outpatient Hemodialysis Facilities: CDC updated interim additional guidance for infection prevention and control recommendations for patients with suspected or confirmed COVID-19 in [outpatient hemodialysis facilities](#).

Caring for Children: CDC updated information on [caring for children and teens during COVID-19](#).

Travel during the COVID-19 Pandemic: CDC updated information on [what should be considered before traveling](#) during the COVID-19 pandemic.

Food and COVID-19: CDC updated information on the [risk of getting sick with COVID-19 from eating or handling food](#). Currently, there is no evidence that food is associated with spreading the virus that causes COVID-19.

COVID-19 and Animals: CDC updated information on the risk of [animals spreading the COVID-19 virus](#).

Research Updates

Limited Secondary Transmission of SARS-CoV-2 in Child Care Programs: CDC released an MMWR on [Limited Secondary Transmission of SARS-CoV-2 in Child Care Programs](#) in Rhode Island from June 1 through June 31, 2020. Rhode Island reopened child care programs in the context of low SARS-CoV-2 transmission relative to other U.S. states. Possible secondary transmission was identified in four of the 666 programs that had been allowed to reopen, all in the last 2 weeks of July, when community transmission in Rhode Island increased. The apparent absence of secondary transmission within the other 662 child care programs was likely the result of RIDOH response efforts to contain transmission and child care programs’ adherence to RIDHS requirements, in particular maximum class sizes and use of face masks for adults (1). However, case ascertainment among children is challenging, given high rates of asymptomatic infection or mild disease (2,3), and SARS-CoV-2 infections were likely undetected. Despite limited identified secondary transmission, the impact on child care programs was substantial, with 853 children and staff members quarantined, which highlights the importance of community mitigation efforts to safeguard child care programs.