

## Update from the Chief Dental Officer of the U.S. Public Health Service



RADM Timothy Ricks, Chief Dental Officer

Here are some recent updates:

- 1. 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](#).
- 2. New Kaiser Brief Shows Disproportionate Impact of COVID-19:** A new Kaiser [issue brief](#) contains some pretty powerful info/statistics on the disproportionate impact of COVID-19 on persons of color.
- 3. 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.
- 4. ADA Webinar, Will COVID-19 Weaken the Dental Care Safety Net?:** The ADA is hosting another webinar on COVID-19 on Tuesday, September 1<sup>st</sup> at 12 p.m. ET. COVID-19 is disproportionately impacting vulnerable populations. This webinar will highlight new data from private practice and public health dentists collected as part of HPI's tracking of the impact of COVID-19. We will share an overview of HPI research related to the dental safety net and discuss emerging concerns as the dental sector recovers. How does patient volume compare in

high and low income areas? Have dentists dropped out of Medicaid since the onset of the pandemic? Is hospital operating room time for high need dental patients being limited due to the hospital “surge”? Panelists include Dr. Monica Hebl, a general dentist in Milwaukee, WI, Dr. Darwin Hayes, the State Dental Director of New Jersey, and Dr. Nicole Weddell, a pediatric dentist in Indianapolis, IN. As always, there will be time for audience Q&A. Register [here](#).

**5. 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.

**6. CDC Updates Travel Guidance:** Yesterday, the CDC updated their [travel guidance](#). This guidance includes different considerations for types of travel (air, train, car, bus, etc.).

**7. 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.

**8. 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.

**9. 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.

**10. 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.

**11. 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.

**12. 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.

Please stay safe and thank you for all you're doing to improve the nation's oral health during this pandemic.

Thanks,

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