

Outbreak Breakdown

October 9, 2020

This weekly report is provided as an informal information resource for certain AdvaMed member work groups. Content is provided by staff and is not to be construed as conveying AdvaMed viewpoints or endorsement. Newsletter Editors: [Andy Fish](#), Chief Strategy Officer and [Kristina Shultz](#), Manager, Strategy & Policy. Inquiries about AdvaMed's COVID-19 response can be directed to [Chris White](#), AdvaMed COVID Action Team Leader, COO & General Counsel.

AdvaMed Notes

MedTech Conference: AdvaMed's annual MedTech Conference was live this week with three days of virtual programming and networking events. Keynote events included discussions with pollster and author Kristen Soltis Anderson; retired NBA star and businessman Earvin "Magic" Johnson; FDA Commissioner Dr. Stephen Hahn; HHS Assistant Secretary for Preparedness and Response Dr. Robert Kadlec; and epidemiologist Michael Osterholm. Sessions can be rewatched until October 23. Visit the [conference website](#) for more information.

FDA Review of LDT EUAs: The FDA [announced this week](#) that it will no longer review requests for emergency use authorizations for SARS-CoV-2 laboratory developed tests (LDTs), a further policy change building on the recent [HHS announcement](#) that FDA would no longer require premarket review for LDTs.

AdvaMed Resources:

[COVID Testing Supply Registry](#)

[PPE Sourcing Program](#)

[MedTech Responds](#)

Something Completely Different

An [emerging understanding](#) of the [intellectual capacity of avian crania](#) took [big leaps forward](#) recently with the identification of [avian self-consciousness](#) and further elucidation of a [feature of avian neuroarchitecture](#) that explains why birds (and [dinosaurs?](#)) can hold their own against mammalian cognition and it's no flight of fancy to think that your [fowl-mouthed](#) parrot [really is talking](#) to you.

Pandemic Snapshot

Global: Current Cases: [36,567,300](#) Deaths: [1,062,200](#)

- India's daily incidence is decreasing after it hit a peak in mid-September of nearly 100,000 cases per day.
- Cases in Europe continue to surge, with many countries implementing new restrictions and lockdowns. The [U.K. and France](#) both reported their highest numbers of daily new cases this week. Europe recently surpassed North America in terms of per capita daily incidence. Its outbreak is now twice as large as its initial peak in April.
- A report released by the World Bank Wednesday estimates that [between 88 and 114 million people](#) have been pushed into extreme poverty because of the pandemic and resulting economic recession. This number is expected to rise.

United States: Current Cases: [7,639,600](#) Deaths: [212,700](#)

- Cases nationwide increased for the fourth consecutive week. Hospitalizations are now also increasing in 41 states.
- Deaths continued to decline, although they are likely to eventually begin to tick up again (following the increase in hospitalizations observed this week and last).
- The surge in the Midwest continued this week. Wisconsin and North Dakota have both reported dwindling hospital capacity and shortages of healthcare workers. Some hospitals are turning patients away or [sending them to neighboring states](#) for care.
- Concerns are growing that New York City may be [headed for a second wave](#) after suppressing the virus for the past few months.

[Johns Hopkins Daily COVID-19 Situation Reports](#)
[AdvaMed COVID-19 Modeling & Data Visualization Resources](#)

News & Insights

CDC Guidance on Aerosol Transmission: On Monday, CDC [published a new guidance](#) on the transmission of SARS-CoV-2 that include [aerosols as a mode of transmission](#). CDC published similar guidance several weeks ago, but quickly rescinded it. The new guidance distinguishes between droplet and aerosol transmission and notes that aerosols “can remain suspended for many minutes to hours and travel far from the source.” The guidance states that most SARS-CoV-2 infections are spread through “close contact” – e.g. respiratory droplet transmission within a short range – rather than airborne transmission, but that there are certain conditions where airborne transmission is more likely to occur (e.g. enclosed spaces with poor ventilation).

COVID-19 in Young Adults: CDC’s Morbidity and Mortality Weekly Report (MMWR) published an [analysis of COVID-19 cases among young adults](#) aged 18-22 years, which increased by 55% nationally in August and early September. The increase seems to be driven primarily by increased incidence in non-Hispanic white young adults, in which cases rose by nearly 150% (incidence in other racial and ethnic groups remained steady or decreased). The increase coincides with many college students returning to campuses around the country, although the researchers note that there are likely additional factors contributing to the rise in cases. The researchers also noted that the increases could not be explained solely by an increase in testing.

Antibody Treatments: Antibody treatments for COVID-19 found themselves in the spotlight this week after President Trump was treated with an antibody cocktail made by Regeneron last week. The experimental treatment is still in clinical trials, although following the publicity it received this week, [Regeneron submitted](#) a request for an emergency use authorization (EUA) for one of its treatments on Wednesday. [Eli Lilly also submitted](#) a request for an EUA this week after announcing the results of a Phase II trial of its own antibody treatment. Monoclonal and polyclonal antibody treatments are composed of laboratory-produced proteins designed to act like human antibodies against specific pathogens in the immune system. Early trials of these treatments have shown that when administered early in the course of illness, they may be effective in reducing the likelihood of severe illness and the need for hospitalization.

FDA Vaccine Standards: On Tuesday, the White House [approved new guidelines](#) for coronavirus vaccine manufacturers seeking an EUA. The new, stricter FDA standards will bring the guidelines for an EUA more in line with the requirements for a traditional approval. Among other recommendations, FDA suggests that participants in late-stage clinical trials be followed for at least two months after they

receive their final dose of the vaccine (or placebo), making it highly unlikely – though not impossible – that any of the companies with vaccine candidates currently in Phase III trials will have data ready to submit to FDA prior to the U.S. election on November 3. The recommendations are nonbinding.

[The Coronavirus Unveiled](#) | New York Times, October 9

[Moderna Vows to Not Enforce COVID-19 Vaccine Patents During the Pandemic](#) | Wall Street Journal, October 8

[COVID-19 Is Now the Third Leading Cause of Death in the U.S.](#) | Scientific American, October 8

[Coronavirus Hit the U.S. Long Before We Knew](#) | Wall Street Journal, October 8

[After a Hospital Stay for COVID, Patients May Face Months of Rehabilitation](#) | Washington Post, October 8

[What's Special About Bat Viruses? What We Don't Know Could Hurt Us](#) | Washington Post, October 8

[Hospitals That Don't Report COVID-19 Data Daily Will Get Warning Letter](#) | NPR, October 7

[What We Dream When We Dream About COVID-19](#) | New York Times, October 6

[Face Masks: What the Data Say](#) | Nature, October 6

[Race for COVID-19 Vaccine Slows As Regulators, Top Warp Speed Officials Tap the Brakes](#) | STAT News, October 6

[Charting a COVID-19 Immune Response](#) | New York Times, October 5

[Charting a Coronavirus Infection](#) | New York Times, October 5

[Why Some People Are Still Getting Sick – but Not with COVID](#) | Scientific American, October 2

[How To Combat COVID-19 Apathy](#) | Forbes, October 1

[This Overlooked Variable Is the Key to the Pandemic](#) | The Atlantic, September 30

More News

[MIT Technology Review Coronavirus Coverage](#)

[Tulane Outbreak Daily](#)

[Prevent Epidemics Weekly Science Review](#)

[Helio COVID-19 Resource Center](#)

[Johns Hopkins Novel Coronavirus Research Compendium](#)