

October 12, 2020

Summary

The United States has 7,781,980 confirmed COVID-19 cases and 214,925 reported related deaths. New England Journal of Medicine published a study indicating that hydroxchloroquine is not an effective treatment for hospitalized COVID-19 patients; the study did not evaluate whether hydroxchloroquine is an effective treatment for non-hospitalized patients. Department of Health and Human Services (HHS) and Department of Defense (DOD) announced an agreement with AstraZeneca to provide \$486 million in funding for late-stage development and manufacturing of the company's investigational product AZD7442, a cocktail of two monoclonal antibodies that may help treat or prevent COVID-19. CDC published updated guidance advising that being overweight may be a risk factor for severe COVID-19. Previous versions of the guidance advised that obesity is a risk factor but did not comment on excess weight falling short of obesity. The White House continues to push for a second round of stimulus spending. White House Chief of Staff Meadows and Treasury Secretary Mnuchin sent a letter to Congress requesting legislation permitting President Trump to spend \$130 billion in unused Paycheck Protection Program funds while Congress continues negotiations regarding a broader stimulus package.

Cases continue to rise nationally as uncontrolled outbreaks spread in the Upper Midwest and Rocky Mountains, and the Northeast is seeing early signs of resurgence. Utah, Montana, and Wyoming have all seen new infections at record daily rates. In Wisconsin, a long-dormant field hospital is being readied for COVID-19 patients at the state fairgrounds. Louisiana governor John Bel Edwards announced the state will remain in its current phase of re-opening, including a statewide mask mandate, until at least November 6 following a steep spike in new infections. California cases, conversely, remain low, and the state's seven-day average death rate for the week ending October 10 was the lowest since early July.

New York reported 12 deaths and 878 hospitalizations on Sunday, October 11. Approximately 1,029, or 1.1%, of the 91,793 tests administered in New York on October 11 were positive for COVID-19. On Friday, the United States District Court for the Eastern District of New York denied a Jewish organization's motion for a temporary restraining order to prevent the implementation of restrictions in hot-spot neighborhoods with large Jewish populations ahead of holiday religious observances. Average positivity rates continue to climb in hot-spot neighborhoods currently facing restriction. Governor Cuomo published a book regarding New York's experience combating coronavirus. In New York City, an industry trade group representing Broadway theaters announced that theaters will remain closed until May 30, 2021.

Presidential updates

- [*White House Continues Push for a Second Round of Stimulus Spending*](#), October 11
 - White House Chief of Staff Meadows and Treasury Secretary Mnuchin sent a [letter](#) to Congress requesting legislation allowing President Trump to spend roughly \$130 billion in unused funds from the Paycheck Protection Program (PPP) while Congress continues to negotiate regarding a broader stimulus bill.
 - Meadows and Mnuchin did not explain how President Trump would spend the unused PPP funds. However, the press [reported](#) that Trump would use them to provide additional aid to small businesses.
 - Negotiations regarding a broader stimulus package are ongoing, but Senate Majority leader McConnell [warned](#) that there likely is not enough time to pass legislation before the November elections.
 - Last week, the White House proposed a stimulus package worth \$1.8 trillion that included \$1200 direct payments to most U.S. adults and \$400 per week in federal unemployment benefits. However, lawmakers from both parties rejected the proposal. House Speaker Pelosi said that the package offered too little funding, especially for measures designed to contain the virus. In a [letter](#) to her Democratic colleagues, Pelosi said that, “in terms of addressing testing, tracing and treatment, what the Trump Administration has offered is wholly insufficient.” Meanwhile, Senate Republicans [told](#) White House officials that another large spending bill could jeopardize Republicans’ reelection prospects in November.
 - The Senate is currently conducting confirmation hearings for President Trump’s Supreme Court nominee, Judge Amy Coney Barrett. On October 12, President Trump [urged](#) Senate Republicans to confirm Barrett quickly so Congress can focus on stimulus negotiations.

World Health Organization (WHO)

- [*WHO COVID-19 Updates*](#), October 12
 - In a virtual press conference, Drs. Michael Ryan and Maria Van Kerkhove [emphasized](#) that while lockdowns may be unavoidable at times, countries should strive to avoid widespread lockdowns which are “punishing to communities, to society and to everything else.” Countries should emphasize surveillance, testing, tracking, community empowerment, and education to reduce the need for lockdowns.

U.S. Centers for Disease Control and Prevention (CDC)

- [*CDC Updates List of Severe COVID-19 Risk Factors*](#), October 6
 - CDC maintains a list of underlying medical conditions believed to increase the risk of severe COVID-19, defined as infection resulting in hospitalization, admission to the ICU, intubation, mechanical ventilation, or death.
 - CDC reviews published reports, articles in the press, unreviewed pre-prints, and internal data. Based on this review, CDC identifies underlying conditions that may be risk factors and places them in three categories: (1) strongest evidence that the underlying condition is a risk factor; (2) mixed evidence; and (3) limited evidence.
 - CDC includes obesity, defined as having a body mass index (“BMI”) equal to or greater than 30, on its list of risk factors in the “strongest evidence” category.

- On October 6, CDC added being merely overweight, defined as having a BMI between 25 and 29, to the list of risk factors as well. CDC placed being overweight in the “limited evidence” category.
- In the United States, roughly 40 [percent](#) of adults are obese and another 32 percent are overweight; if CDC is correct that being merely overweight is a risk factor, nearly three quarters of Americans are at an increased risk of severe COVID-19.
- [COVIDView Weekly Surveillance Summary of U.S. COVID-19 Activity](#), October 9
 - CDC summarized key COVID-19 disease indicators for the week ending October 3.
 - The national average of respiratory specimens testing positive for COVID-19 decreased from 5.2% to 4.9% from September 26 to October 3.
 - Regionally, the percentage of respiratory specimens testing positive for COVID-19 declined or remained the same in nine of ten regions, but increased slightly in the Southeast region. The highest percentages of positive specimens were seen in the Southeast (6.7%), South Central (7.7%), and Mountain (7.2%) regions.
 - The overall cumulative hospitalization rate is 183.2 per 100,000, up from 178.2 per 100,000 during the previous week. Following an initial decline of hospitalization rates between the weeks ending July 25 and August 22, weekly hospitalization rates have remained fairly steady among all age groups.
 - Based on death certificate data, the percentage of total deaths attributed to pneumonia, influenza, or COVID-19 increased 0.6 % from September 26 (6.4 %) to October 3 (7%). The percentage remains above the epidemic threshold.

New York State

- [New York State COVID-19 Updates](#), October 12
 - New York reported 12 deaths and 878 hospitalizations on Sunday, October 11.
 - Approximately 1,029, or 1.1% of the 91,793 tests administered in New York on October 11 were positive for COVID-19
 - On Friday, Judge Kiyoo A. Matsumoto of the United States District Court for the Eastern District of New York [rejected](#) Agudath Israel’s request for a temporary restraining order preventing the State’s imposition of new restrictions on hot spot neighborhoods in which large proportions of Orthodox Jews reside. In support of the motion, the religious group argued that the restrictions unfairly targeted Jews ahead of religious observances for three upcoming Jewish holidays. The State argued that the restrictions were necessary to prevent the spread of the virus.
 - Average positivity rates [continue](#) to increase in hot spot neighborhoods, rising from 4.95% on Friday to 5.74% on Saturday. Across the state, there were 118,000 coronavirus tests administered on October 10, with a 0.96% infection rate.
 - Governor Cuomo [released](#) a new book detailing New York State’s efforts to combat the coronavirus. According to the Governor, the quick publication of the book is intended to help governments improve their coronavirus response as the nation prepares for a second wave.

New York City

- [New York City COVID-19 Updates](#), October 12
 - An industry trade group representing Broadway theaters [announced](#) that theaters will remain closed through May 30, 2021 due to the coronavirus pandemic. Theaters have been closed since March 12, 2020.

Other Related Updates

- [Study Finds Hydroxychloroquine Ineffective in Treating Hospitalized COVID-19 Patients](#), October 8
 - New England Journal of Medicine (NEJM) published a study regarding the use of hydroxychloroquine to treat hospitalized COVID-19 patients.
 - 4,700 hospitalized patients were randomized to receive usual care with or without hydroxychloroquine. 1,561 patients received the drug and 3,155 patients did not.
 - The study found that hydroxychloroquine was [not](#) associated with a lower mortality rate in hospitalized COVID-19 patients. At 28 days, mortality rates were statistically similar between groups treated with and without hydroxychloroquine.
 - Patients who received hydroxychloroquine had a longer duration of hospitalization than those in the control group and a lower probability of discharge within 28 days.
 - Among patients who did not begin the study on mechanical ventilation, patients receiving hydroxychloroquine had a higher risk of invasive mechanical ventilation than those who received usual care.
 - The study concluded that hydroxychloroquine is not an effective treatment for hospitalized COVID-19 patients; the study did not address the use of hydroxychloroquine as prophylaxis or as a treatment for non-hospitalized patients.
- [Trump Administration Expands Collaboration with AstraZeneca to Develop and Manufacture an Investigational Monoclonal Antibody to Treat COVID-19](#), October 9
 - As part of Operation Warp Speed, HHS and DOD announced an agreement with AstraZeneca to provide \$486 million in funding for late-stage development and large-scale manufacturing of the company's investigational product AZD7442, a cocktail of two monoclonal antibodies that may help treat or prevent COVID-19.
 - AstraZeneca is one of several companies that have developed monoclonal antibody treatments for COVID-19.
 - Monoclonal antibodies are [distilled](#) from the blood of patients that have recovered from COVID-19, and they are designed to help patients develop an immune response to the virus.
 - Preliminary data indicates that monoclonal antibody therapies may be highly effective at treating COVID-19. A non-peer reviewed [study](#) of Eli Lilly's monoclonal antibody treatment, LY-CoV555, indicated that it may reduce the risk of COVID-19 associated hospitalization by approximately 70 percent.
 - President Trump was recently [treated](#) with REGN-COV2, a monoclonal antibody therapy produced by Regeneron; afterwards, Trump [touted](#) the therapy as a "cure" and promised to distribute the treatment to Americans for free.
 - However, monoclonal antibodies are [difficult](#) and expensive to produce. Regeneron CEO Dr. Leonard Schleifer [said](#) there is not nearly enough of REGN-COV2 and the

country will have to ration it. Currently, there are enough doses of Regeneron's drug to treat 50,000 patients. On October 10, 51,000 new infections were reported in the U.S.

- The government's partnership with AstraZeneca may help to increase the supply of monoclonal antibody therapies. The government estimates that 100,000 doses of AZD7442 may be available for high-risk individuals who will not benefit from a vaccine by December 2020.
 - Eli Lilly is also seeking an emergency use authorization (EUA) for LY-CoV555.
 - If the FDA authorizes the use of AZD7442, the federal government intends to distribute the antibody therapy at no cost to patients. Healthcare providers will be entitled to charge a fee for administering the product.
- [HHS to Nevada: Drop 'unwise, uninformed and unlawful' Ban on Rapid Testing in Nursing Homes](#), October 9
 - Nevada health officials ordered nursing homes to discontinue use of the rapid tests, which have been authorized by the FDA, "until the accuracy of the tests can be better evaluated." Previously, Nevada has argued that up to 60% of the positive antigen tests were false positives. The federal government dismissed such concerns, noting that the quicker tests would inevitably produce false results.
 - Assistant Secretary for Health Giroir said that Nevada's ban on rapid coronavirus tests in nursing homes could "endanger lives" and urged state officials to immediately reverse course. The assistant secretary threatened unspecified enforcement actions if Nevada did not remove the order.
 - HHS has purchased and distributed rapid antigen testing instruments to roughly 14,000 nursing homes nationwide to help prevent nursing home outbreaks. Nursing home deaths represent up to 40% of the total COVID-19 deaths in the United States.
 - [FDA COVID-19 Updates](#), October 12
 - FDA issued two warning letters to two companies for selling fraudulent COVID-19 related products. [Griffo Botanicals](#) and [Prairie Dawn Herbs](#) each offer herbal products with misleading claims that they can mitigate, prevent, treat, or cure COVID-19.

Other recent events covered in detail elsewhere:

- [FDA Announces It Will No Longer Review EUA Requests for COVID-19 Laboratory Developed Tests](#), October 9
- [Expiration of COVID-19 Relief for APs and Principals to Submit Fingerprint Cards](#), October 9
- [HHS Provider Relief Fund Opens Portal for Phase Three General Distribution](#), October 8
- [Keeping Track of the Quacks: Drug and Device Enforcement in the COVID-19 Era](#), October 2

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