

October 7, 2020

### Summary

The United States has 7,512,319 confirmed COVID-19 cases and 211,192 reported related deaths. President Trump has been released from Walter Reed National Military Hospital where he was being treated for COVID-19. On October 6, President Trump said that he is feeling great and plans to attend the next presidential debate on October 15. COVID-19 continues to spread among White House staff; top White House aide Stephen Miller announced that he has tested positive for the virus. FDA updated its guidance for drug makers seeking emergency use authorizations (EUAs) for COVID-19 vaccines. The updated guidance is designed to ensure that drug makers collect adequate safety data before applying for an EUA; the guidance will likely extend the timeline for approval of a COVID-19 vaccine. On October 6, President Trump instructed Senate Republicans and Treasury Secretary Mnuchin to cease negotiations regarding a second round of stimulus spending until after the November elections; later, the President expressed support for additional narrow stimulus spending. Members of the Joint Chiefs of Staff, including Chairman General Mark Milley, are quarantining after they were exposed to the virus during a meeting at the Pentagon; a military spokesperson said that there has been no degradation to the country's national defense.

Concerns about a fall surge remain as cases spike throughout the Midwest. North Dakota reported more cases per capita than any other state in the past week; North Dakota hospitals have had to send patients to faraway cities or even across state lines. Montana set a new state record for daily positive tests as 230 health care organizations signed a letter asking the public to "do its part" to once again flatten the curve. Washington governor Jay Inslee loosened COVID-19 restrictions for restaurants, movie theaters, and outdoor sports despite the fact that the state is seeing an uptick in new cases. In Massachusetts, Governor Charlie Baker announced he will not impose state-wide trick-or-treating rules but discouraged indoor Halloween parties.

New York reported 9 deaths, 705 hospitalizations, and 158 COVID-19 patients in intensive care on Tuesday, October 6. Approximately 1,360, or 1.26% of the 108,246 tests administered in New York on October 6 were positive for COVID-19. Governor Cuomo approved a new "cluster action" which imposed restrictions of varying degrees in certain hot spot neighborhoods, predominantly in Brooklyn and Queens. Red zones, or the areas under the most severe restrictions, must close nonessential businesses, restrict access to places of worship to 10 people, and shut down schools. Several Orthodox Jewish leaders have objected to the new restrictions—the first new restrictions imposed since New York began lifting its initial restrictions in May—as unfairly singling out the Orthodox community.

## Presidential updates

- [President Trump Leaves Walter Reed National Military Hospital, Plans to Resume Campaigning](#), October 7
  - President Trump was discharged from Walter Reed National Military Hospital on October 5 and has returned to the White House.
  - On October 6, the President said that he is feeling great and plans to attend the next presidential debate, scheduled to occur on October 15 in Miami.
  - CDC [recommends](#) that individuals diagnosed with COVID-19 quarantine for 10 to 20 days from the onset of symptoms, depending on the severity of their infection. The President's symptoms reportedly started around October 1.
  - White House aid Stephen Miller [announced](#) that he tested positive for the virus; he joins a growing list of President Trump's contacts that have contracted COVID-19, including First Lady Melania Trump, President Trump's Campaign Manager Bill Stepien, and White House Press Secretary Kayleigh McEnany.
- [President Trump Halts Stimulus Negotiations, Later Expresses Support for Limited Aid](#), October 6
  - On October 6, President Trump instructed Senate Republicans and Treasury Secretary Mnuchin to cease negotiations regarding a second round of stimulus spending; Trump indicated that Senate Republicans should instead focus on confirming his Supreme Court nominee, Judge Amy Coney Barrett.
  - Members of Congress began discussing a second round of stimulus spending months ago; though talks stalled in August, House Speaker Pelosi and Treasury Secretary Mnuchin recently [restarted](#) negotiations.
  - Later on October 6, President Trump expressed support for providing \$1200 stimulus checks to the American people and aid for airlines and small businesses.
  - White House Chief of Staff Meadows said that he and President Trump have spoken to Secretary Mnuchin regarding the possibility of passing narrow stimulus spending; on October 7, Mnuchin also spoke with Speaker Pelosi regarding a standalone bill providing aid to struggling airlines.
  - On October 6, Federal Reserve Chair Jerome Powell [warned](#) that insufficient stimulus spending could lead to a slow economic recovery. Powell noted that "fiscal and monetary policy actions have so far supported a strong but incomplete recovery in demand," and even as the labor market recovers, "there is still a long way to go."

## World Health Organization (WHO)

- [WHO COVID-19 Updates](#), October 7
  - A WHO survey [found](#) that the pandemic has disrupted or halted "critical mental health services" in 93% of countries worldwide, while the demand for mental health care is increasing. Some countries have used telemedicine to overcome disruptions in in-person service, but there are significant disparities in access to telemedicine. According to WHO, more than 80% of high-income countries report deploying telemedicine to provide mental health services, compared with less than 50% of low-income countries.
  - WHO Director-General Tedros [told](#) the WHO Executive Board that there is hope for a vaccine by the end of 2020 without elaborating further. His remarks called for

solidarity and political commitment by all leaders to ensure equal distribution of vaccines when they become available.

### **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 that results in hospitalization, admission to the ICU, intubation, mechanical ventilation or death.
  - CDC reviews published reports, un-reviewed pre-prints, articles in the press, and internal data to identify conditions that may increase the risk of severe COVID-19; based on this review, CDC classifies medical conditions into one of three categories: (1) strongest and most consistent evidence that the condition is a risk factor; (2) mixed evidence; and (3) limited evidence.
  - CDC updated the list, moving smoking from the “mixed evidence” category to the “strongest evidence” category. Other conditions in the “strongest evidence” category include cancer, type 2 diabetes, and chronic obstructive pulmonary disease,
  - CDC also expanded the definition of some risk factors. The updated version of the list includes obesity and chronic kidney disease as risk factors; a prior version listed only extreme obesity and chronic kidney disease requiring dialysis as risk factors.

### **New York State**

- [New York State COVID-19 Updates](#), October 1
  - New York reported 9 deaths, 705 hospitalizations, and 158 COVID-19 patients in intensive care on Tuesday, October 6.
  - Approximately 1,360, or 1.26% of the 108,246 tests administered in New York on October 6 were positive for COVID-19.
  - Governor Cuomo [announced](#) that New Mexico has been added to New York State’s COVID-19 travel advisory. No states were removed from the list. Travelers arriving from states on the travel advisory list must quarantine for 14 days after arrival.

### **New York City**

- [New York Sets New Lockdown Restrictions Where Coronavirus Has Resurged](#), October 6
  - Governor Cuomo announced plans to impose additional restrictions on large swaths of New York City, as well as nearby Rockland and Orange counties, in the first set of such restrictions since New York began to emerge from its initial lockdowns in May. The lockdowns are set for two weeks, at which time the State will decide whether they must be renewed.
  - The lockdowns [deploy](#) a tiered approach. Red zones, which are areas with the highest positivity rates, face a near total shutdown; schools will be closed, worship services will be limited to 10 people, and only essential businesses will be permitted to operate. Restaurants will be limited to providing takeout service. Orange and yellow zones face lighter restrictions. Covered communities have until October 9 to implement these restrictions.
  - Governor Cuomo [ordered](#) schools in yellow zones to conduct random weekly testing of students and teachers; schools in orange and red zones will close and students will continue learning remotely. Previously New York State and New York City had agreed

to perform random monthly testing in schools. City Department of Education officials questioned whether weekly or even monthly tests were feasible or necessary to ensure student safety. At \$70 per test, the city will likely spend millions of dollars each month on its school testing programs.

- The lockdowns have [sparked](#) protests by members of the Orthodox Jewish community, who feel unfairly targeted by the new restrictions. Though Governor Cuomo said that he had a “good conversation” with Orthodox leaders about the new restrictions, a group of Orthodox Jewish leaders contradicted that assertion, saying that the Governor had not warned them about the imposition of new restrictions.
- Positivity rates in the hot spots have climbed above 3% for at least the last seven days. Across New York City, however, positivity rates remain relatively low, at 1.65% over an average of seven days.

### **Other Related Updates**

- [Members of the Joint Chiefs of Staff Were Exposed to COVID-19](#), October 6
  - Members of the Joint Chiefs of Staff, including Chairman General Mark Milley and Army Chief of Staff General James McConville, are quarantining after attending meetings at the Pentagon with Vice Commandant of the Coast Guard Admiral Charles Ray, who has since tested positive for the virus.
  - A Pentagon spokesperson said that no Pentagon contacts have exhibited symptoms or tested positive for COVID-19 since meeting with Admiral Ray but are quarantining “out of an abundance of caution.”
  - A military spokesperson said that General Milley and the rest of the Joint Chiefs have full operational capacity from where they are working and there has been no degradation to the country’s national defense.
- [NIH RADx Initiative Advances Six New COVID-19 Testing Technologies](#), October 6
  - National Health Institute [announced](#) a third round of contract awards for scale-up and manufacturing of new COVID-19 testing technologies through their Rapid Acceleration of Diagnostics ([RADx](#)) initiative.
  - The contracts total \$98.35 million for point-of-care and other novel test approaches that provide new modes of sample collection, processing, and return of results. These six new technologies are expected to increase U.S. testing capacity by 500,000 tests per day by the end of 2020 and 1 million tests per day by early 2021.
  - The new tests include innovations such as integration with smart devices, mobile-lab processing that can be deployed to COVID-19 hotspots, and an antigen test that will provide results within 15 minutes.
  - [RADx Tech](#) program, a subset of the RADx initiative focused on rapidly advancing early testing technologies, and RADx Advanced Technology Platforms (RADx-ATP), a subset of RADx initiative focused on late-stage scale-up projects, are now supporting a combined portfolio of 22 companies for a total of \$476.4 million in manufacturing expansion contracts.

- [\*American College of Physicians Provide Practice Points for Use of Remdesivir\*](#), October 5
  - American College of Physicians (ACP) [advises](#) that doctors use remdesivir for five days in patients with moderate COVID-19 and in those with severe illness who do not need mechanical ventilation or extracorporeal membrane oxygenation (ECMO).
  - For patients with severe illness who end up requiring mechanical ventilation or ECMO during the five days of remdesivir, ACP advises that doctors consider extending treatment to 10 days.
  - The practice points are based on evidence collected through August 2020.
  
- [\*Frequent Neurologic Manifestations and Encephalopathy-Associated Morbidity in COVID-19 Patients\*](#), October 5
  - A [study](#) of 509 consecutive patients admitted to hospitals in the Chicago area for COVID-19 revealed that 42% had neurologic manifestations at illness onset, 63% at hospital admission, and 82% at some time during their illness.
  - The most common conditions were myalgias (muscle aches), headaches, encephalopathy (altered brain function), dizziness, dysgeusia (loss of taste), and anosmia (loss of smell).
  - Younger patients and those with severe illness were generally more likely to develop neurologic symptoms, but older patients were more likely to develop encephalopathy.
  - Encephalopathy was more common in severe than non-severe patients (84% vs. 13%).
  - Encephalopathy was an independent predictor of worse outcomes and mortality within 30 days after hospitalization.
  
- [\*FDA Issues Guidance on Emergency Use Authorization for COVID-19 Vaccines\*](#), October 6
  - With public confidence in the vaccine approval process declining, Food and Drug Administration (FDA) updated [guidance](#) for drug makers seeking emergency use authorizations (EUAs) for COVID-19 vaccines.
  - The updated guidance is designed to ensure that drug makers collect adequate safety data before seeking an EUA, including by following trial participants for a median of two months after they receive the final vaccine dose.
  - Pharmaceutical Research and Manufacturers of America, the drug industry’s largest trade group, [announced](#) that it supports the new guidance, noting that it brings “greater transparency to the review process for COVID-19 vaccines.”
  - The White House budget office [approved](#) the new guidance after spending weeks reviewing it; the White House initially [indicated](#) that it might reject the guidance, citing concerns that it would needlessly extend the timeline for approving a COVID-19 vaccine.
  - Despite the fact that the White House budget office approved the guidance, President Trump [expressed](#) anger that the guidance may delay approval of a vaccine until after the November elections, calling the update a “political hit job.”
  
- [\*FDA COVID-19 Updates\*](#), October 7
  - FDA [launched](#) a webpage to highlight new information about COVID-19 vaccines as it becomes available.

- FDA [awarded](#) a new research contract to Stanford University School of Medicine to perform an in-depth analysis of tissue samples to learn more about how COVID-19 affects different systems of the body and to identify immunity correlates.

Other recent events covered in detail elsewhere:

- [House Funding Bill Proposes Repayment Relief for Medicare Accelerated and Advance Payment Programs Participants](#), October 1
- [COVID-19: Non-Binding Guidance: Real-World Evidence in Drug Development and the Impact of the Pandemic](#), September 30
- [Non-Binding Guidance: Real-World Evidence in Drug Development and the Impact of the COVID-19 Pandemic](#), September 30

Send questions to:

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