

October 9, 2020

Summary

The United States has 7,620,052 confirmed COVID-19 cases and 213,016 reported related deaths. President Trump's physician announced the president has completed his COVID-19 treatment and should be able to resume public engagements on October 10. The Commission on Presidential Debates announced plans to hold the next presidential debate virtually to protect the health and safety of those involved. President Trump said he would not attend a virtual debate; on October 9, the Wall Street Journal reported that the Commission plans to cancel the debate. New England Journal of Medicine (NEJM) published an editorial criticizing the federal government's pandemic response and urging the American people to vote their current leaders out of office; the editorial did not refer to President Trump by name. Operation Warp Speed Chief Slaoui said efficacy data from clinical trials of Pfizer and Moderna's COVID-19 vaccine candidates will likely be available in November or December. Moderna announced that it will not enforce seven patents related to its COVID-19 vaccine candidate during the pandemic. The media reported that the White House plans to propose a \$1.8 trillion stimulus package to address the economic damage caused by the pandemic.

The FBI announced 13 men were arrested in Michigan for plotting to kidnap Governor Gretchen Whitmer of Michigan. Governor Whitmer has been the subject of criticism from right-wing protestors for the measures she imposed to control the spread of COVID-19. In Massachusetts, Boston Mayor Marty Walsh announced the district will pause its plan to bring back public school students for in-person lessons after the city's coronavirus positivity rate climbed over 4%. Nevada instructed nursing homes in the state to immediately suspend use of two rapid virus tests after a spate of false-positive results.

New York reported 10 deaths, 754 hospitalizations, and 172 COVID-19 patients in intensive care on October 8, 2020. Approximately 1,410, or 1.01% of the 145,811 tests administered in New York on October 8 were positive for COVID-19. The 145,811 tests marked a record high number for New York State. State Liquor Authority officials conducted 2,327 compliance checks at bars and restaurants in New York during the week of October 5, observing 19 social distancing violations. Religious groups representing the Catholic and Jewish faiths sued State and City governments, alleging that lockdown restrictions capping the number of worshippers in houses of worship violates the U.S. Constitution. New York City parents protested the shutdown of schools within hot spot neighborhoods. Today, New York City began imposing \$15,000 fines per day for offenders of mass gathering restrictions. On October 8, City officials announced they would be unable to pay teachers \$900 million owed in back pay, the issue is expected to enter arbitration as the City struggles to meet budget obligations.

Presidential updates

- [*President Trump Completes COVID-19 Treatment, Plans to Resume Public Engagements*](#), October 8
 - On October 8, President Trump's physician Dr. Conley [said](#) that the president has completed his COVID-19 treatment and should be able to safely resume public engagements on October 10; President Trump told the media that he hopes to hold campaign rallies on October 10 and 11.
 - On October 6, President Trump [said](#) that he would attend the next presidential debate scheduled for October 15. However, on October 8, the Commission on Presidential Debates ("the Commission") [announced](#) plans to hold the debate virtually "in order to protect the health and safety of all involved." President Trump said he would not attend a virtual debate, calling the idea "ridiculous." On October 9, the Wall Street Journal [reported](#) that the Commission plans to cancel the debate.
 - CDC recommends that individuals diagnosed with COVID-19 quarantine for 10 to 20 days from the onset of symptoms, depending on the severity of the infection. President Trump's symptoms reportedly began around October 1.

World Health Organization (WHO)

- [*WHO COVID-19 Updates*](#), October 9
 - China [agreed](#) to join COVAX, the WHO-backed vaccine distribution program that was rejected by President Trump. The government statement did not detail what specific support China will provide to the program, which aims to deliver at least 2 billion doses of vaccine by the end of 2021.

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

- [*CDC Interpretation of Forecasts of New Deaths and Hospitalizations*](#), October 8
 - CDC [consolidated](#) data from 41 models projecting the COVID-19 death rate. Predicted rates of increase differ among the forecasts, depending on assumptions about the prevalence and rigor of social distancing behaviors.
 - CDC's national ensemble forecast indicates an uncertain trend in new COVID-19 deaths over the next four weeks. CDC predicts that the number of cumulative COVID-19 deaths will be between 224,000 and 233,000 by October 31.
 - CDC [consolidated](#) data from nine models projecting the number of daily COVID-19 hospitalizations. Three models predict an increase in daily hospitalizations over the next four weeks and four models are uncertain about the trend or predict stable numbers. The forecasts estimate 2,300 to 5,700 new COVID-19 hospitalizations per day by November 2.

New York State

- [*New York State COVID-19 Updates*](#), October 9
 - New York reported 10 deaths, 754 hospitalizations, and 172 COVID-19 patients in intensive care on October 8, 2020.
 - Approximately 1,410, or 1.01% of the 145,811 tests administered in New York on October 8 were positive for COVID-19. The 145,811 tests marked a record high number of total tests for New York State.

- State Liquor Authority officials conducted 2,327 compliance checks at bars and restaurants in New York during the week of October 5, 2020, observing 19 social distancing violations. Officials did not immediately suspend any licenses.
- [Religious Groups Sue to Block New York Lockdown Restrictions in Parts of New York Seeing Covid-19 Surges](#), October 8
 - On October 8, 2020, the Diocese of Brooklyn and Agudath Israel of America sued the City in two separate lawsuits challenging the constitutionality of Governor Cuomo’s order limiting the size of gathering in houses of worship in hot spot neighborhoods primarily located in New York City. The Diocese represents the Roman Catholic faith, and Agudath Israel represents the Jewish faith.
 - Earlier this week, Governor Cuomo limited the maximum capacity at houses of worship based on the severity of the outbreaks. The strictest restrictions limited houses of worship to 25% capacity or no more than 10 people, whichever is less. Houses of worship within neighborhoods with fewer cases were limited to 33% capacity or no more than 25 worshippers.
 - The Orthodox Jewish population around New York City has complained that it has been unfairly targeted by the City and State’s restrictions. Governor Cuomo claimed to have a “good conversation” with Jewish leaders earlier this week, but some Jewish leaders [contradicted](#) his claim.

New York City

- [New York City COVID-19 Updates](#), October 9
 - New York City will [begin](#) issuing \$15,000 fines per day to residents who violate mass gathering rules throughout the City as part of an effort to increase enforcement of new coronavirus-related restrictions. As noted previously, the New York State imposed tiered restrictions on red, orange, and yellow zones throughout several Brooklyn and Queens neighborhoods. The twenty hot spot ZIP codes have a 5.8% positivity rate, more than five times the statewide average.
 - On October 8, 2020, New York City officials [announced](#) that they would be unable to pay a lump sum back payment of \$900 million to teachers due to budget constraints caused by the pandemic. The City faces a \$9 billion budget deficit over the next two year, driven by dwindling tax revenue. The City and the teachers’ union appear headed towards arbitration.
 - Last week, 66,700 new unemployment claims were [filed](#) in New York according to the State Department of Labor, slightly lower than the State’s monthly average of 67,000 applications a week over the last month. New York City residents make up more than 50% of jobless claims. Almost two million City residents have filed for unemployment benefits since mid-March, compared with 200,000 over the same period last year.
 - Starting on October 7, several groups of parents of New York City schoolchildren [protested](#) Governor Cuomo’s decision to close schools, alleging that the schools are safe and that their children need in-person classes. The governor ordered schools closed in certain New York City neighborhoods experiencing a surge in coronavirus cases after Mayor de Blasio recommended the action last weekend. Governor Cuomo and Mayor de Blasio characterized the order as an effort to reduce community spread to avoid further school closures throughout the school year.

Other Related Updates

- [*Department of Labor Unemployment Insurance Weekly Claims Report*](#), October 8
 - Department of Labor (DOL) [reports](#) that another 840,000 workers filed initial claims for unemployment benefits last week.
 - The number of new claims has been trending downward since March, when nearly seven million people filed for unemployment insurance in a single week. This week's report marks the lowest weekly total since March.
 - 464,437 new claims were filed for Pandemic Unemployment Assistance, the federal program intended to help freelancers, gig workers, the self-employed, and others not normally eligible for state jobless benefits.

- [*HHS Secretary Azar Says U.S. Could Have Enough Coronavirus Vaccine Does for Every American by March*](#), October 8
 - HHS Secretary Alex Azar claimed that the Trump Administration's coronavirus vaccine program Operation Warp Speed expects to have up to 100 million doses by the end of the year, and projects to have enough doses of the vaccine for every American who wants one by March or April 2020.
 - Secretary Azar further stated that the United States is currently manufacturing vaccines developed by Moderna, Pfizer, AstraZeneca, and Johnson & Johnson, all of which are in late-stage testing. The United States is also obtaining needles, syringes, bottles, and other supplies that will be necessary to administer and distribute the immunizations throughout the country.
 - The HHS Secretary delivered the remarks on Thursday at the Goldman Sachs Healthcare virtual event on coronavirus.

- [*NEJM Publishes Editorial Criticizing the Federal Government's Pandemic Response*](#), October 8
 - New England Journal of Medicine (NEJM) [published](#) an editorial by 34 of its editors criticizing the federal government's response to the pandemic and urging the American people to vote their current leaders out of office; the editorial did not name President Trump or former Vice President Biden by name.
 - The editors opined that the United States had "enormous advantages" relative to other countries in confronting the virus, including "tremendous manufacturing capacity" and "enormous expertise in public health, health policy, and basic biology."
 - Nevertheless, the United States leads the world in COVID-19 cases and deaths; the editors noted that "the [United States] death rate...is more than double that of Canada, exceeds that of Japan...by a factor of almost 50, and even dwarfs the rates in lower-middle-income countries, such as Vietnam, by a factor of almost 2000."
 - The editors explained that, instead of using the United States' significant expertise to its advantage, the federal government repeatedly undermined experts; they highlighted that CDC "has been eviscerated and suffered dramatic . . . policy failures;" NIH has been "excluded from much crucial government decision making;" and FDA has been "shamefully politicized."
 - The editors noted that, due to the federal government's failures, the United States has been slow and inconsistent in its efforts to develop its testing capacity, distribute PPE,

and implement social distancing and mask wearing. The United States also remains behind the curve in testing. Though the absolute rate of testing has increased, the editors explained that a “more useful metric is the number of tests performed per infected person.” On that score, United States trails behind countries like Zimbabwe and Ethiopia.

- The editors closed by calling the country’s current leaders “dangerously incompetent” and opining that the American people should not “abet them and enable the deaths of thousands more Americans by allowing them to keep their jobs.”
- [Moderna Won’t Enforce COVID-19 Patents During Pandemic](#), October 8
 - Moderna announced it will not enforce its patents related to COVID-19 vaccines during the pandemic, in an effort to not deter other companies and researchers from making similar shots.
 - The move is unusual in an industry where holding a drug patent usually assures a company of an extended period of exclusivity and the attendant profits.
 - Numerous companies, including Pfizer, are pursuing vaccines based on similar messenger RNA technology.
 - Moderna said it is open to licensing its patents for use in COVID-19 after the pandemic ends.
- [Remdesivir Confers Shorter Recovery Time in COVID-19 Patients](#), October 8
 - A [study](#) on use of the antiviral remdesivir to treat COVID-19 found that patients who took remdesivir required a median of 10 days recovery time, vs. 15 days for patients treated with a placebo.
 - The randomized trial enrolled nearly 1,100 adults to receive 10 days treatment of either remdesivir or a placebo.
 - Results were not significant for patients requiring mechanical ventilation or extracorporeal membrane oxygenation (ECMO) at study entry.
 - Mortality estimates at 15 days also favored remdesivir, 7% vs. 15% for placebo groups.
 - Researchers concluded that “[g]iven high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient.”
- [National Health Institute \(NIH\) Clinical Trial Testing Hyperimmune Intravenous Immunoglobulin Plus Remdesivir to Treat COVID-19 Begins](#), October 8
 - NIH began a clinical trial to [test](#) safety, tolerability, and efficacy of a combination treatment regimen for COVID-19 consisting of the antiviral remdesivir plus a highly concentrated solution of antibodies that neutralize SARS-CoV-2, the virus that causes COVID-19.
 - The study will enroll over 500 hospitalized adults with COVID-19 in the United States, Mexico, and 16 other countries on five continents. National Institute of Allergy and Infectious Disease (NIAID), part of NIH, is sponsoring and funding the Phase 3 trial.
 - The antibody solution being tested is anti-coronavirus hyperimmune intravenous immunoglobulin, or hIVIG. The antibodies come from plasma donated by healthy people who have recovered from COVID-19.

- Investigators hypothesize that giving people anti-coronavirus hIVIG at the onset of COVID-19 symptoms, before the body makes an immune response of its own, could augment the natural antibody response, reducing the risk of more serious illness.
- Four companies are collaborating to provide hIVIG for the trial: Emergent Biosolutions, Grifols S.A., CSL Behring, and Takeda Pharmaceuticals.
- [*NIH to Launch Serological Sciences Network for COVID-19*](#), October 8
 - The National Cancer Institute (NCI) has [launched](#) the Serological Sciences Network for COVID-19 ([SeroNet](#)), an initiative aimed at quickly increasing the nation’s antibody testing capacity and engaging the US research community to understand the immune response to COVID-19. NCI is part of NIH.
 - SeroNet will engage top academic, government, and private sector biomedical research institutions to study the immune response to COVID-19 and speed delivery of testing, treatments, and vaccine development.
 - Congress authorized \$306 million for NCI to develop serological testing and associated technologies as part of the Paycheck Protection Program and Health Care Enhancement Act.
- [*FDA COVID-19 Updates*](#), October 9
 - FDA [issued](#) a letter to health care providers recommending that health care providers give clear, step-by-step [instructions](#) to patients who, in a health care setting, are self-collecting anterior nasal samples for COVID-19 testing. Without proper instruction, patients may not collect adequate samples for testing.
 - FDA [issued](#) a warning letter to Battelle Memorial Institute for failure to follow Medical Device Report requirements in the EUA issued for their Critical Care Decontamination System. The system is authorized to decontaminate certain filtering face piece respirators for reuse by healthcare personnel.

Other recent events covered in detail elsewhere:

- [FDA Announces It Will No Longer Review EUA Requests for COVID-19 Laboratory Developed Tests](#), October 9
- [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:

- COVID-19-Implications@ropesgray.com
- COVID-19RecoveryPolicies@ropesgray.com