

November 12, 2020

### Summary

The United States has 10,500,259 confirmed COVID-19 cases and 242,436 reported related deaths. Moderna announced it is preparing to submit preliminary data from Phase 3 clinical trials of its COVID-19 vaccine candidate to an independent review board. The news comes days after Pfizer announced that initial, non-peer reviewed data indicates its vaccine candidate may be 90% effective. Dr. Fauci said Moderna and Pfizer's vaccine candidates employ similar technologies, and he "would be surprised if we didn't see a similar degree of efficacy" in both. Dr. Fauci also said a COVID-19 vaccine could be widely available in the United States by April 2021. CDC updated its guidance regarding face masks. Earlier versions of the guidance indicated masks are intended to block viral particles emitted by the mask wearer; the updated guidance notes there is growing evidence that masks also protect the wearer from viral particles emitted by others.

United States COVID-19 hospitalizations broke a record high of 61,964 on November 10. San Diego and ten other counties across California moved into more restrictive tiers of the state's COVID-19 re-opening system. California nurses held rallies at hospitals across the state calling for better staffing. Ohio governor Mike DeWine announced that Ohio's state of emergency would continue and encouraged Ohioans to limit social interactions to a small "bubble," two days after a group of doctors overseeing the state response said hospital staffs were becoming overburdened. City leaders across North Dakota, which has the highest COVID-19 rate per capita of any state, have issued mask mandates as Governor Doug Burgum declines to take statewide action. In Pennsylvania, the Philadelphia public school district delayed plans to bring students back for in-person learning. In Chicago, the Mayor, concerned about Thanksgiving, issued a stay-at-home advisory and imposed restrictions on gatherings of more than 10 people.

New York announced a statewide 10 p.m.–5 a.m. curfew, effective November 13, for bars, restaurants and gyms. New York will also limit indoor and outdoor private gatherings to 10 people. On November 11, Governor Cuomo modified micro-cluster designations: Port Chester was elevated to an "orange" zone, Staten Island and Tioga County were designated new yellow zones, and the yellow zone designation was removed from Steuben County. Long Island businesses have increased sales this fall as City residents remain in their summer homes or new residences past the traditional summer season, but the businesses have not completely offset losses from the non-essential business closures last spring. New York City is focusing much of its coronavirus efforts in certain Staten Island neighborhoods, where positivity rates are nearly three times the citywide positivity rate. Popular holiday celebrations, such as the Macy's Thanksgiving Day Parade, the Rockefeller tree lighting, and theatrical performances have been modified or cancelled.

## Presidential updates

- [White House Coronavirus Task Force Warns States of “Accelerating Community Spread.”](#)  
November 8
  - The White House Coronavirus Task Force sends weekly reports to the states regarding the pandemic. The reports are not public but the [media](#) sometimes gains access to and reports on their contents.
  - CNN reported that this week the Task Force warned states of “accelerating community spread” in parts of the country. The Task Force’s reports noted that cases are rising across the top half of the country as temperatures cool, and the Sunbelt is experiencing its “most diffuse spread to date.”
  - The reports admonished some states to expand testing, including testing of asymptomatic people. The Task Force wrote to some states that “the silent community spread that precedes and continues throughout surges can only be identified and interrupted through proactive and increased testing and surveillance.”
  - The federal government has heretofore declined to create a national COVID-19 testing plan, leaving states to create their own individual plans, though Democrats in Congress have [proposed](#) funding for a national testing initiative.
  - President-Elect Biden has [said](#) that he plans to scale up testing when he takes office.
- [Election Lawsuits Hamper Launch of Biden Administration’s Coronavirus Response,](#)  
November 10
  - President Trump’s refusal to concede the election may hamper the launch of the Biden Administration’s pandemic response.
  - Biden’s Health and Human Services transition team is not able to take important steps towards preparing to manage the crisis, like working with current government officials or accessing non-public government data, until the Government Services Administration (GSA) certifies Biden as the President Elect.
  - GSA Administrator Emily Murphy is [refusing](#) to certify Biden, pending the outcome of a series of legal challenges launched by the Trump campaign regarding the results of the election.
  - Members of Biden’s transition team told the press that Murphy’s refusal to certify Biden is also hampering Biden’s plan to create a special coronavirus transition team responsible for coordinating pandemic response work across the government.
  - On November 9, members of Biden’s transition team called on Murphy to certify Biden and [told](#) the media they are considering “all options,” including possible legal action, to push Murphy to allow the transition to begin.
  - White House officials have pointed out the delay is not unprecedented—in 2000, the transition between presidential administrations was delayed pending the outcome of a legal battle between the Gore and Bush campaigns regarding election results in Florida.

## World Health Organization (WHO)

- [WHO COVID-19 Updates,](#) November 12
  - WHO published technical [guidance](#) on Immunization as an Essential Health Service, which provides guiding principles to support country’s decision-making regarding provision or resumption of immunization services during severe disruptive events such as COVID-19, natural disasters, or humanitarian emergencies.

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

- [CDC Publishes Data Regarding Hospital Re-Admissions Among COVID-19 Patients](#), November 9
  - CDC published data regarding the percentage of hospitalized COVID-19 patients that are re-admitted to the hospital within two months of discharge for any purpose.
  - CDC followed 126,137 patients hospitalized with COVID-19 between March and July 2020. Roughly 85% (106,543) of those patients survived and were discharged from the hospital.
  - CDC found that 9% (9,504) of the surviving patients were readmitted to the hospital within two months of discharge and 1.6% (1,667) were re-admitted to the hospital more than once during that time.
  - During re-admission, the most common diagnoses were diseases of the circulatory, digestive, or respiratory systems.
  - Risk factors for re-admission included age ( $\geq 65$ ), certain chronic conditions, hospitalization within the three months *preceding* the first COVID-19 hospitalization, and discharge to a skilled nursing facility or home health care.
  - CDC noted that, “evidence suggests that potential health complications after COVID-19 illness might require ongoing clinical care,” and “understanding frequency of, and potential reasons for, readmission after a COVID-19 hospitalization can inform clinical practice, discharge disposition decisions, and public health priorities, such as health care resource planning.”

## New York State

- [New York State COVID-19 Updates](#), November 12
  - New York reported 29 deaths, 1,677 hospitalizations, and 308 COVID-19 patients in intensive care on Thursday, November 11.
  - Approximately 4,797, or 2.94% of the 162,627 tests administered in New York on November 11 were positive for COVID-19
  - On November 11, Governor Cuomo [announced](#) a statewide 10 p.m.–5 a.m. curfew for most bars, restaurants, and gyms, and will limit indoor and outdoor gatherings at private residences to 10 people. The curfew will take effect on Friday, November 13. Food delivery and pick-up [may](#) continue after 10 p.m. if the bar or restaurant does not serve alcohol with the meal. Governor Cuomo said that bars, restaurants, gyms, and private gatherings were driving the increased spread of the virus throughout the state.
  - Also on November 11, Governor Cuomo [announced](#) that several micro-cluster zones had been modified. Port Chester was elevated from a “yellow” zone to an “orange” zone, Staten Island and Tioga County were designated as new yellow zones, and the yellow zone was removed from Steuben County. On November 9, Governor Cuomo [announced](#) that Erie, Monroe and Onondaga Counties would be designated as yellow zones, while Brooklyn would be reduced from a “red” zone to an orange zone.
  - The pandemic has [extended](#) the traditional summer business season in areas of Long Island, as New York City residents who would normally return to the city following summer vacations have remained in their summer homes. Long Island communities are reporting increased sales, school enrollments and home sales, and businesses are extending their hours to meet rising demand. For most businesses however, the

extended season has not completely erased losses at the beginning of the year, when most stores were closed during the initial lockdown.

### **New York City**

- [\*New York City COVID-19 Updates\*](#), November 12
  - New York City has [focused](#) much of its coronavirus prevention efforts in Staten Island, where positivity rates in some neighborhoods are 6.57%, or roughly three times the citywide positivity rate.
  - New York City will [reduce](#) its holiday festivities as a result of the pandemic. The Macy's Thanksgiving Day parade will occur as a televised program, with floats passing by Macy's flagship store in Herald Square. The Rockefeller Christmas tree lighting will also be staged for television only, and protocols will be put in place for in-person viewing of the tree. Holiday theatrical productions, such as the Rockette's "Christmas Spectacular" and "The Nutcracker" have been cancelled.

### **Other Related Updates**

- [\*HHS Allocates Eli Lilly Therapeutic to Treat Patients with Mild to Moderate COVID-19\*](#), November 10
  - Department of Health and Human Services (DHHS) announced that it would allocate initial doses of Eli Lilly's investigational monoclonal antibody therapeutic, bamlanivimab, for the treatment of non-hospitalized patients with mild to moderate confirmed cases of COVID-19.
  - Food and Drug Administration (FDA) [issued](#) an emergency use authorization (EUA) for mild-to-moderate COVID-19 patients 12 years or older at increased risk for severe COVID-19, including adults over 65 and patients with comorbidities.
  - HHS Assistant Secretary for Preparedness and Response Robert Kadlec mentioned that the administration would coordinate with Eli Lilly to ensure the equitable and efficient distribution of the therapeutic. Weekly allocations of the drug to state and territory partners will be proportionate to the number of confirmed COVID-19 cases in each state or territory over the previous seven days.
  - The infusion takes approximately one hour to complete, and must be performed in a setting in which medical providers have access to medications that would treat a severe infusion reaction, such as anaphylaxis, and have the capability to activate EMS as necessary. Providers must also have sufficient space to administer the medication in a socially distanced manner.
- [\*HHS Secretary: Coronavirus "General Vaccination" Programs By Spring\*](#), November 10
  - On November 10, DHHS Secretary Alex Azar predicted that there would be enough of Pfizer's and other companies' vaccines available for general public vaccination campaigns by the end of March or early April 2021.
  - Azar predicted that there would be enough vaccine to inoculate at-risk nursing home residents, health care workers, and first responders by the end of January.

- Secretary Azar said that Pfizer is ramping up manufacturing capacity to deliver 20 million doses of its vaccine by the end of November. Pfizer plans to distribute up to 1.3 billion doses of the vaccine in 2021.
- [\*Department of Labor Unemployment Insurance Weekly Claims Report\*](#), November 12
  - Department of Labor (DOL) [reports](#) that another 709,000 workers filed initial claims for unemployment benefits last week.
  - The number of new claims had been trending downward since March, when nearly seven million people filed for unemployment insurance in a single week.
  - 298,154 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.
- [\*Moderna Says Data from COVID-19 Vaccine Trials Will Be Available Soon\*](#), November 11
  - Drug maker Moderna [announced](#) that it is preparing to submit preliminary data from Phase 3 clinical trials of its COVID-19 vaccine candidate to an independent review board for analysis.
  - Moderna [told](#) the press the board will be able to release the data “in days, not weeks.”
  - The news comes a few days after Pfizer announced that initial data indicates its COVID-19 vaccine is 90% effective.
  - Dr. Fauci [told](#) the press that the Moderna and Pfizer vaccines employ similar technologies, and he “would be surprised if we didn’t see a similar degree of efficacy” in the two vaccines.
- [\*Hydroxychloroquine Does Not Benefit Adults Hospitalized with COVID-19\*](#), November 9
  - A National Institutes of Health clinical [trial](#) evaluating the safety and effectiveness of hydroxychloroquine for treating adults with COVID-19 has concluded that the drug provides no clinical benefit to hospitalized patients.
  - The trial began in April at 34 hospitals across the United States, and enrolled 479 adult patients with a median age of 57. Participants were randomly assigned to a treatment group and received 10 doses of either hydroxychloroquine or placebo over five days.
  - Researchers assessed each patients clinical status 14 days after being assigned a treatment group using a seven-category scale ranging from one (death) to seven (discharged and able to perform normal activities), as well as 12 other outcomes.
  - At day 14, the two groups had a similar health status. Mortality rate was similar between the groups at days 14 and 28.
  - The study did not find hydroxychloroquine causes significant harm.
- [\*NIH Focus on Treatment for Early COVID-19 Infection\*](#), November 11
  - Dr. Anthony Fauci and colleagues [wrote](#) that “COVID-19 treatments for people with early infection are needed urgently,” and that “treating people early in the course of infection . . . would speed their recovery, reduce the likelihood that they develop severe outcomes and reduce demand on the healthcare system.”
  - Several treatments such as remdesivir and dexamethasone are available or in development for severe COVID-19, but treatments that can be administered early in the course of infection are urgently needed.

- Researchers are exploring early treatments using convalescent plasma and monoclonal antibodies, as well as the possibility of repurposing existing antivirals for early treatment. FDA granted the first EUA for a monoclonal antibody treatment this week.
- The writers emphasize that robust support is needed from the medical community and the public to ensure success of these critical areas of research.
- [Reducing Occupancy at Select Venues would Limit Transmission More than Limiting Mobility Overall](#), November 10
  - A [study](#) published in Nature found that reducing maximum occupancy at certain public venues will do more to limit COVID-19 transmission than reducing mobility overall.
  - Researchers used cell phone data to track people’s movements to over 550,000 locations (e.g. restaurants and religious venues) in 10 large metropolitan areas between March and May, then incorporated the data into a transmission model.
  - Researchers found that a minority of locations accounted for a majority of predicted infections, leading researchers to suggest that reopening plans should emphasize restricting capacity at these super spreader locations, such as gyms, hotels, cafes, religious organizations, and especially full service restaurants.
  - Researchers also found that lower-income people are more likely to become infected because they are less able to reduce their mobility - likely due to less ability to work from home - and because the locations they visit tend to be smaller and more crowded.
  - Researchers made five policy suggestions: 1) more stringent caps on occupancy at high-risk locations, 2) emergency food distribution centers to reduce densities in high-risk stores, 3) free and widely available testing in high risk neighborhoods, 4) improved paid leave policy or income supports, and 5) improved workplace infection prevention for essential workers, such as high-quality PPE, ventilation, and distancing.
- [FDA COVID-19 Updates](#), November 12
  - Food and Drug Administration (FDA) [approved](#) an abbreviated new drug application for cisatracurium besylate USP 10 mg/5mL, which is indicated as an adjunct to traditional anesthesia to facilitate tracheal intubation by providing skeletal muscle relaxation during surgery, or for mechanical ventilation in adults.

Other recent events covered in detail elsewhere:

- [SBA Proposes Detailed New Questionnaire to Evaluate Post-Hoc the Good Faith of PPP Applicants’ Prior Certifications of Loan “Necessity”](#), November 11
- [New HHS Advisory Opinions Support Broad Application of PREP Act Immunity for COVID-19 Response](#), November 3

Send questions to:

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