

November 25, 2020

Summary

The United States has 12,642,245 confirmed COVID-19 cases and 260,591 reported related deaths. On November 24, the country had 2,100 reported deaths, the highest daily death count since May. Government Services Administration (GSA) approved President-elect Biden and his transition team to begin accessing non-public government data. GSA previously refused to ascertain Biden as the President-elect; in recent weeks, Biden and others expressed concern that the delay might hamper the Biden administration's COVID-19 response. Operation Warp Speed official Perna said the federal government and Pfizer expect to ship 6.4 million doses of Pfizer's COVID-19 vaccine to the states within 24 of hours of FDA approval, which could come as early as mid-December. This initial batch of 6.4 million doses will not be enough to vaccinate even the country's 20 million health care workers, but additional doses will soon become available as manufacturing ramps up. CDC is reportedly planning to shorten the length of time it recommends people quarantine after potential exposure to the virus; it is anticipated that the revised time-period will be dependent on receiving a negative COVID-19 test result.

Holiday travel is below typical numbers year over year, but millions of Americans are still travelling for Thanksgiving despite CDC warnings to stay home. After initially faring well in the current surge, California reported 17,694 new cases on November 23, more than any state has reported on a single day. Texas immediately broke that record, reporting 20,300 new cases on November 24. 11 states had more COVID-19 related deaths in the last week than in any other week since the pandemic began. Pennsylvania banned alcohol sales at bars and restaurants after 5 p.m. on November 25, freezing sales on the night before Thanksgiving – the biggest day of the year for bar sales – before reopening sales at 8 a.m. November 26. Arizona's state hospital system will stop accepting out of state transfers as hospitals throughout the state reached 90% ICU capacity over the weekend.

New York reported 47 deaths, 2,856 hospitalizations, and 263 COVID-19 patients in intensive care on Monday, November 23. Approximately 4,881, or 2.96% of the 164,761 tests administered in New York on November 23 were positive for COVID-19. A Siena College Research Institute poll found that a quarter of New Yorkers are unlikely to take a vaccine, while about two-thirds will "definitely" or "probably" take the vaccine. On Monday, Mayor de Blasio said that he expected Governor Cuomo to impose tougher lockdown restrictions on New York after Thanksgiving. The New York City Police Department and the New York City Sheriff's Department said that they would not enforce the 10-person indoor gathering limit on Thanksgiving Day, instead focusing on larger gatherings that have a greater potential to become superspreader events.

Presidential updates

- [GSA Recognizes Biden as President-Elect, Allowing Formal Transition to Begin](#), November 23
 - Government Services Administration (GSA) approved President-elect Biden and his transition team to begin accessing non-public government data.
 - GSA had previously refused to ascertain Biden as the President-elect; as a result, Biden and his transition team were unable to access non-public government data, including data regarding the pandemic, or work with current government officials.
 - In recent weeks, Biden and others [expressed](#) concern that the delay might hamper the Biden administration's pandemic response.
 - Now that GSA has approved Biden to begin accessing non-public data, Biden and his transition team have begun [working](#) with members of the current White House Coronavirus Task Force, such as Dr. Fauci.
 - Biden and his transition team are also preparing to [dispatch](#) groups of staffers known as "landing teams" to Department of Health and Human Services (HHS), Center for Disease Control (CDC), and Food and Drug Administration (FDA) to begin getting up to speed on issues like the government's plan for distributing COVID-19 vaccines.

World Health Organization (WHO)

- [WHO COVID-19 Updates](#), November 25
 - WHO Secretary-General Tedros [emphasized](#) the need for another \$4.3 billion in funding this year and \$23.8 billion next year to support the COVAX program, which aims to provide equitable access to COVID-19 vaccines to countries throughout the world, most importantly by funding procurement and distribution in poorer countries.
 - WHO [published](#) technical guidance to help health facilities assess present and surge capacities for treatment of COVID-19, in particular by identifying areas of need with regard to critical medicine and supplies.

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

- [CDC Releases Guidance Instructing Health Departments to Prioritize Certain Cases for Contact Tracing](#), November 23
 - CDC released [guidance](#) instructing health departments to focus their contact-tracing efforts on certain groups, including contacts of individuals that tested positive or developed symptoms within the past six days.
 - The guidance says that health departments should not spend resources tracing the contacts of individuals that tested positive more than 14 days ago, unless there are extenuating circumstances (e.g., the infected individual is part of an outbreak associated with a congregate living facility).
 - Early in the pandemic, public health workers attempted to trace the contacts of all infected persons, but surging cases are outstripping health departments' resources.
 - Prior to the release of the CDC guidance, some states had already begun scaling back their contact-tracing efforts.
 - For example, last week, New Hampshire announced that it will trace only cases connected to outbreaks or in specific at-risk age or racial groups. Last month, North Dakota instructed most residents to notify their own contacts if they become infected,

explaining that the state would focus its contact-tracing efforts on cases associated with schools and health care facilities.

New York State

- [*New York State COVID-19 Updates*](#), November 25
 - New York reported 47 deaths, 2,856 hospitalizations, and 263 COVID-19 patients in intensive care on Monday, November 23.
 - Approximately 4,881, or 2.96% of the 164,761 tests administered in New York on November 23 were positive for COVID-19.
 - According to a poll by the Siena College Research Institute, nearly a quarter of New Yorkers are [unlikely](#) to take a coronavirus vaccine when one becomes available. Thirty-five percent would “definitely” take the vaccine, and 34% said they would “probably take the vaccine.”

New York City

- [*New York City COVID-19 Updates*](#), November 25
 - On Monday, Mayor de Blasio [said](#) that he believed Governor Cuomo would impose tougher lockdown measures on the entire city, designating it as an orange zone. As a result, schools, which are already closed, would be required to remain closed for another four days. Following that, Mayor de Blasio said, schools could reopen following testing in advance of re-openings and “constant testing throughout the school year, much more than we’ve been doing already.”
 - While Governor Cuomo issued an order limiting indoor gatherings to 10 people on Thanksgiving, the New York City Police Department and the New York City Sheriff’s Office do [not](#) plan to make enforcement of that order a priority. Instead, law enforcement will focus on larger superspreader events that have a greater potential to harm the public.
 - Governor Cuomo [imposed](#) tighter coronavirus restrictions on Staten Island, where portions of the borough have been declared “orange” micro-cluster zones. Most of the rest of Staten Island is classified as a “yellow” micro-cluster zone.

Other Related Updates

- [*Pfizer to Distribute 6.4 Million Doses to U.S. in First Push*](#), November 24
 - Pfizer will ship out 6.4 million doses of its COVID-19 vaccine within 24 hours of Food and Drug Administration (FDA) granting an expected emergency use authorization (EUA).
 - The first doses will be allocated to all 50 states and eight territories, as well as six major metropolitan areas. Governors and other local leaders will be responsible for deciding who receives the initial vaccinations.
 - The first doses are expected to go to health care workers and potentially other highly vulnerable groups, such as seniors in assisted living facilities.
 - Pfizer will ship doses of the vaccine via UPS and FedEx in special coolers packed with dry ice that hold a minimum of 975 doses. The doses must be used up within a few weeks or stored in an ultra cold freezer for up to six months.

- An FDA advisory committee will meet on December 10 to discuss Pfizer’s clinical trial data and vote on whether to recommend authorization. It is not clear how long that decision will make, and FDA Commissioner Dr. Stephen Hahn [said](#) it may take “days.”
- However, Moncef Slaoui, head of Operation Warp Speed, [said](#) during an appearance on CNN that the first doses could be administered as soon as December 11.
After the initial distribution push, vaccine shipments will go out to states and other jurisdictions weekly. Federal officials expect to have 40 million doses of vaccines (from Pfizer and Moderna) available in the United States by the end of 2020. That would be enough to vaccinate 20 million people.
- [*Study Shows Convalescent Plasma Ineffective to Treat Severe COVID-19*](#), November 24
 - A double-blinded, placebo-controlled, multicenter [trial](#) conducted at 12 clinical sites in Argentina found no significant differences in clinical status or mortality at 30 days between patients treated with convalescent plasma and those who received placebo.
 - The trial enrolled 333 hospitalized adult patients with severe COVID-19 pneumonia, 228 of whom received convalescent plasma treatment, and examined a primary endpoint of clinical status 30 days after intervention.
 - Convalescent plasma has been used for treatment of infectious disease for more than a century under the assumption that it can “jump start” the immune system, but has only been proven effective in treatment of Argentine hemorrhagic fever.
 - A series of non-randomized studies have alleged that convalescent plasma was effective and safe for treatment of SARS, MERS, influenza A (H1N1), avian influenza (H5N1), and Ebola, but conclusive data from randomized trials was lacking.
 - Researchers note that their results were consistent with findings in another recent randomized trial of convalescent plasma used to treat patients with moderate COVID-19.
 - In the United States, FDA granted an EUA for convalescent plasma treatments for COVID-19 in August.
- [*NIH Announces Fourth Iteration of ACCT-4 Trial for COVID-19 Treatments*](#), November 25
 - National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH), announced Adaptive COVID-19 Treatment Trial (ACCT-4), the fourth iteration of trials to study potential treatments for COVID-19.
 - ACCT-4 will enroll up to 1,500 hospitalized adults who require supplemental oxygen at approximately 100 sites in the United States and other countries. Participants will be randomly assigned to one of two treatment arms of equal size.
 - One group will receive both dexamethasone, a corticosteroid widely available as a generic drug and [approved](#) by the FDA for compounding in treatments for COVID-19, and remdesivir.
 - The second group will receive both baricitinib, a modulator of inflammation for treatment of rheumatoid arthritis that was recently [granted](#) an EUA by FDA for treatment of COVID-19 in hospitalized adults, and remdesivir.
 - Redmesivir became the first treatment approved by FDA for treatment of COVID-19 on October 22. However, WHO guidance on remdesivir conflicts with FDA guidance, as WHO [recommends](#) against the use of remdesivir to treat hospitalized patients.
 - The trial is blinded for dexamethasone and baricitinib components.

- To date, dexamethasone and baricitinib are the only two therapies that reduce inflammation that have demonstrated efficacy for treatment of hospitalized adults with COVID-19 in large, randomized trials.
- ACCT-4 aims to determine whether baricitinib or dexamethasone, administered with remdesivir, is more effective at preventing hospitalized adults on supplemental oxygen from progressing to requiring mechanical ventilation or death, or if they are similar.
- [*FDA COVID-19 Updates*](#), November 25
 - FDA [published](#) a comprehensive page on FDA.gov with answers to frequently asked questions about facemasks, surgical masks, and respirators.
 - FDA published two [templates](#) with recommendations on what to include in EUA requests for serology tests. The templates provide current recommendations on what data and information to submit to FDA in support of a request for EUA or pre-EUA submission.
 - FDA [approved](#) an abbreviated drug application for succinylcholine chloride injection USP 200 mg/19 mL, which is indicated for general anesthesia, and to facilitate tracheal intubation and provide skeletal muscle relaxation during surgery or mechanical ventilation.
 - FDA [approved](#) an abbreviated drug application for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive-care setting, and sedation of non-intubated patients prior to and/or during surgical or other procedures.
- [*Modified Thanksgiving Day Parade Will Take Place Despite Pandemic*](#), November 24
 - Macy’s Thanksgiving Day Parade will take place this year despite the pandemic, albeit in a modified form.
 - The parade will still feature balloons, floats, and musical performances, but to avoid attracting crowds, much of the parade was pre-taped this year.
 - For the portion of the parade that will be performed on Thanksgiving Day, instead of following its normal route, the parade will be confined to a small “set” near Macy’s flagship store in Manhattan, which will be patrolled by police officers to disperse any crowds that might form.
 - The parade staff has also been reduced from 8,000 people to only 960, with the majority of the balloon handlers being replaced with utility vehicles.
 - High school and college marching bands scheduled to perform will appear in the 2021 parade instead.

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
- [*Ethical Challenges in Clinical Research During the COVID-19 Pandemic*](#), November 10

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