

September 25, 2020

Summary

The United States has 6,997,468 confirmed COVID-19 cases and 203,147 reported related deaths. Johnson & Johnson and Novavax began Phase 3 clinical trials of their COVID-19 vaccine candidates. Dr. Fauci warned that a COVID-19 vaccine will not eliminate the need for social distancing and face masks because a vaccine will not be 100 % effective. Fauci also warned about aerosole transmission of COVID-19, meaning transmission via viral particles that linger in the air. Fauci expressed that “there’s good enough data that aerosol transmission does occur.” Earlier this week, CDC rescinded guidance acknowledging the threat of aerosol transmission of COVID-19. HHS announced that CDC will provide \$200 million to help state and local governments prepare to distribute COVID-19 vaccines. Media outlets reported that FDA may raise the standard for granting emergency use authorizations for vaccines to shore up flagging public confidence in the federal government’s COVID-19 vaccine approval process. Treasury Secretary Mnuchin said that he and House Speaker Pelosi have agreed to resume negotiations regarding a second round of stimulus spending.

COVID-19 case counts are rising in many states, sparking fears of a fall surge; according to an analysis by Washington Post, 27 states and Puerto Rico have seen an increase in their seven-day average of new cases since the end of August. In Texas and South Carolina, official case counts spiked after government employees finished processing data backlogs caused by reporting errors and technological problems; Texas county official Dr. Shah expressed “we’re never going to get ahead of this unless we work on data reconciliation and automation.” Missouri Governor Parson and Virginia Governor Northam tested positive for COVID-19.

New York reported seven deaths, 511 hospitalizations, and 154 COVID-19 patients in intensive care on Thursday, September 24. Approximately 908, or 0.95%, of the 94,818 tests administered in New York on September 24 were positive for COVID-19. Governor Cuomo announced New York will independently review COVID-19 vaccines approved by the federal government, citing politicization of the federal government’s vaccine approval process. The State panel may delay distribution of any vaccine it considers unsafe or ineffective. Attorney General James announced recipients of the COVID-19 Tenant Legal Assistance Initiative Grants. The grantees will develop and manage volunteer attorney programs across the state to provide support for tenants facing eviction due to the pandemic. In New York City, Mayor de Blasio announced expanded furloughs for managerial and non-represented city employees.

Presidential updates

- [*President Trump Updates the Public on Operation Warp Speed*](#), September 23
 - During a press [briefing](#), President Trump discussed the status of Operation Warp Speed, the federal government’s COVID-19 vaccine acceleration initiative.
 - President Trump noted that Johnson & Johnson recently began Phase 3 trials of its COVID-19 vaccine candidate, ahead of the company’s projected timeline.
 - Trump noted, “earlier this year, Johnson & Johnson anticipated that they would reach phase one trials by September. But due to our support under Operation Warp Speed, and to some of the incredible scientists involved, they’ve reached phase three trials by September — far ahead of schedule.”
 - Trump explained that “we’re seeing promising results [from] our monoclonal antibody treatments – which help the immune system fight the virus and help very significantly – we’re finding [it] can reduce hospitalizations now by more than 70 percent.”
 - Last week, drug maker Eli Lilly [released](#) clinical trial results indicating that its monoclonal antibody treatment, LY-CoV555, may reduce the risk of COVID-related hospitalization by approximately 70%. Lilly’s clinical trial results have not yet been peer reviewed.
 - President Trump addressed media reports that FDA is considering tightening rules governing emergency use authorizations (EUAs) for vaccines to shore up flagging public confidence in the federal government’s COVID-19 vaccine approval process, stating that revising the rules governing EUAs is “a political move” and the White House “may or may not approve it.”
 - According to media reports, vaccine makers seeking EUAs under the revised rules would be required to monitor late-phase clinical trial participants for a median of two months after they receive the final vaccine dose.

World Health Organization (WHO)

- [*WHO COVID-19 Updates*](#), September 25
 - WHO, United Nations, and various partners released a joint [statement](#) calling on member states to develop and implement action plans to manage misinformation and disinformation about the COVID-19 pandemic that undermines the global response.
 - The statement calls for the timely dissemination of accurate information based on science and evidence, particularly in high-risk communities.

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

- [*CDC Provides Funding for COVID-19 Vaccine Distribution*](#), September 23
 - Department of Health and Human Services (HHS) announced that CDC will allocate \$200 million in Coronavirus Aid, Relief, and Economic Security Act (CARES Act) funding to help state and local governments prepare to distribute COVID-19 vaccines.
 - CDC will divide the funds between 64 jurisdictions based on population size.
 - HHS Secretary Azar [expressed](#) “With these \$200 million in new funds, jurisdictions can develop and update plans for the eventual distribution and administration of the safe and effective vaccines that will help bring this pandemic to an end.”

- [CDC Interpretation of Forecasts of New Deaths and Hospitalizations](#), September 24
 - 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 214,000 and 226,000 by October 17.
 - CDC [consolidated](#) data from nine models projecting the number of daily COVID-19 hospitalizations. Two models predict an increase in daily hospitalizations over the next four weeks, two models predict a decrease, and five models are uncertain about the direction of the trend or predict stable numbers. The forecasts estimate 1,500 to 5,000 new COVID-19 hospitalizations per day by October 19.

New York State

- [New York State COVID-19 Updates](#), September 25
 - New York reported seven deaths, 511 hospitalizations, and 154 COVID-19 patients in intensive care on Thursday, September 24.
 - Approximately 908, or 0.95%, of the 94,818 tests administered in New York on September 24 were positive for COVID-19.
 - Governor Cuomo and State University of New York (SUNY) Chancellor Jim Malatras [announced](#) that a saliva swab diagnostic test for COVID-19, developed at SUNY Upstate Medical University, received an emergency use authorization (EUA) from Food and Drug Administration (FDA).
 - Attorney General James [announced](#) recipients of the COVID-19 Tenant Legal Assistance Initiative grants, a program launched this year to support tenants during the pandemic. The grantees will “develop and manage regional volunteer attorney programs across the state to provide support for tenants facing eviction due to the COVID-19 pandemic.”
- [New York Will Review COVID-19 Vaccines Independently, Citing Politicization of the Federal Government’s Approval Process](#), September 24
 - Governor Cuomo [announced](#) that New York State will form an independent Clinical Advisory Task Force comprised of scientists, doctors, and health experts to independently review every COVID-19 vaccine approved by the federal government.
 - The group will advise New York on the vaccines’ safety and efficacy.
 - Cuomo explained that, “the federal government’s response to COVID ... raises serious questions about whether or not the vaccine has become politicized. Frankly, I’m not going to trust the federal government’s opinion and I wouldn’t recommend [it] to New Yorkers based on the federal government’s opinion.”
 - While New York officials cannot play a formal role in the approval of a vaccine, they could delay distribution throughout the state if they determine a vaccine is not safe.
 - Cuomo established a Vaccine Distribution and Implementation Task Force charged with developing a plan for distributing and administering COVID-19 vaccines in New York.

New York City

- [*New York City COVID-19 Updates*](#), September 25
 - Mayor de Blasio [announced](#) the City will expand furloughs to all managerial and non-represented city employees. The expanded furloughs will impact 9,000 employees and save \$21 million. The City faces a revenue loss of \$9 billion as a result of the pandemic, and has already cut \$7 billion from the budget between February and the Fiscal Year 2021 Adopted Budget announced in June.
 - Mayor de Blasio [extended](#) Executive Order 148, prohibiting certain outdoor events to minimize crowding, facilitate COVID-19 testing and treatment sites, and allow use of streets and parks for recreation, learning, and dining, through December 31.
 - Mayor de Blasio [announced](#) the New York City Recovery Agenda, a series of policy proposals based on four principles focused on making the City stronger, healthier, and fairer: continuing the fight against COVID-19, making the City a hub for public health research, creating high quality jobs, and making New York fairer by focusing service and action in the neighborhoods that bear the heaviest burden of economic and health inequities.
 - New York City Department of Health and Mental Hygiene (NYCDOH) published [guidance](#) on dermatologic issues and COVID-19. The guidance indicates that skin manifestations such as redness and swelling, especially in the toes, appear in COVID-19 patients and “may provide insights for early diagnosis or severity of disease.”
 - Metropolitan Transportation Authority is [adding](#) service in preparation for City students’ return to school, including nearly one thousand additional bus trips planned to begin on October 1.

Other Related Updates

- [*Department of Labor Unemployment Insurance Weekly Claims Report*](#), September 24
 - Department of Labor (DOL) [reports](#) that another 870,000 workers filed initial claims for unemployment benefits last week, up slightly from 866,000 the week prior.
 - The number of new claims has been trending downward since March, when nearly seven million people filed for unemployment insurance in a single week. Last week was the fourth consecutive week with new claims below one million.
 - 630,080 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.
- [*Johnson & Johnson and Novavax COVID-19 Vaccine Candidates Advance to Phase 3 Clinical Trials*](#), September 23
 - Johnson & Johnson (J&J) [announced](#) on September 23 that it has begun Phase 3 clinical trials for its COVID-19 vaccine candidate. On September 24, Novavax [announced](#) that it has entered Phase 3 trials as well.
 - There are now five late-stage COVID-19 vaccine trials supported by Operation Warp Speed. There are 11 total late-stage COVID-19 vaccine trials worldwide.
 - Neither J&J nor Novavax’s vaccine need to be frozen during transport, a significant logistical advantage over some competitors. Also, J&J’s candidate may only require one dose instead of two; the company is testing both single and double dose courses of the vaccine.

- Following the lead of Pfizer, Moderna, and AstraZeneca, J&J published its clinical trial [protocol](#) to increase transparency. J&J’s Phase 3 trial will include 60,000 participants, significantly more than Moderna or Pfizer’s clinical trials. Participants will be recruited from the U.S., Argentina, Brazil, Chile, Colombia, Mexico, Peru, and South Africa.
- Novavax will begin its trials in the United Kingdom before launching a trial in the United States next month.
- Novavax has never brought a vaccine to market before, but its COVID-19 vaccine candidate showed promising results in early clinical trials. Phase 1 and 2 results, [published](#) in the New England Journal of Medicine on September 2, showed that the vaccine candidate produced “strikingly high levels of antibodies against the virus.”
- [Scientists Discover Genetic and Immunologic Underpinnings of Some Severe COVID-19 Cases](#), September 24
 - National Institute of Health (NIH) researchers and their collaborators [discovered](#) that more than 10% of people who develop severe COVID-19 have “misguided antibodies - autoantibodies - that attack the immune system rather than the virus that causes the disease.”
 - Another 3.5% of people who develop severe COVID-19 infection carry a specific kind of genetic mutation that affects immunity.
 - Both groups consequently lack effective immune responses that “depend on type I interferon, a set of 17 proteins crucial for protecting cells and the body from viruses.” Their absence appears “to be a commonality among a subgroup of people who suffer from life-threatening COVID-19 pneumonia.”
 - The discoveries come after researchers examined nearly 1,000 patients with life-threatening COVID-19 pneumonia. 10% had autoantibodies against interferons after the onset of infection, and 95% of those were men, possibly pointing to a molecular reason that COVID-19 affects men more severely than women overall.
 - These findings are the first results published from the COVID Human Genetic Effort, an international project spanning more than 50 genetic sequencing facilities and hundreds of hospitals.
- [FDA COVID-19 Updates](#), September 25
 - Food and Drug Administration [re-issued](#) an emergency use authorization (EUA) for the Assure COVID-19 IgG/IgM Rapid Test Device, the first authorized serology (antibody) test that can be used at the point of care.
 - FDA developed new health education [materials](#) that are culturally and linguistically tailored for diverse consumers. The materials are intended for health care professionals to share with patients to stimulate dialogue and answer pressing questions about FDA’s response to COVID-19.

Send questions to:

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