

October 5, 2020

Summary

The United States has 7,426,686 confirmed COVID-19 cases and 209,881 reported related deaths. After receiving treatment over the weekend at Walter Reed National Military Center, President Trump announced that he would be discharged on Monday evening. On October 4, President Trump's medical team said that he experienced a high fever on October 2, and that his oxygen saturation level dropped twice over the weekend, at one point dipping below the normal range. Vice President Pence continues to test negative for COVID-19 and he will continue to campaign, but more White House staffers, including Press Secretary Kayleigh McEnany, have tested positive. Biotechnology Innovation Organization, a biotechnology industry trade group associated with several companies designing COVID-19 vaccines, requested that the FDA issue new vaccine guidelines to "add layers of caution to the vaccine vetting process." Labor Secretary Scalia announced that nearly half the jobs eliminated due to the pandemic have returned.

Fears of an autumn surge remain serious as only three states—Texas, Missouri, and South Carolina—reported a decline in new cases for the week ending October 4. Wisconsin continues to face a major spike in cases, as the state reported a 20.5% positivity rate on October 3. The Michigan Supreme Court ruled on October 2 that the Governor does not have authority to issue public health orders without legislative approval, potentially overturning months of emergency orders issued after April 30. Michigan Governor Whitmer said that her orders will remain in effect for 21 days, and then many will continue "under alternative sources" of law. South Carolina Governor Henry McMaster lifted occupancy restrictions on interior dining in restaurants; restaurants can open up for full occupancy dining, but must stop alcohol sales at 11 PM.

New York reported 8 deaths and 636 hospitalizations on Sunday, October 4. Approximately 933, or 1.2%, of the 76,404 tests administered in New York on October 4 were positive for COVID-19. At the urging of Mayor de Blasio, Governor Cuomo ordered several schools located in hot-spot neighborhoods to close beginning Tuesday, October 6. Mayor de Blasio also recommended the closure of nonessential businesses within these neighborhoods, but the Governor rejected the proposal on Monday afternoon. Governor Cuomo also urged local authorities to improve enforcement of COVID-19 safety measures, and threatened to shut down nonessential businesses in communities that did not meet the State's enforcement expectations.

Presidential updates

- [*Trump Says He Will Leave Hospital Monday, as White House Cases Mount*](#), October 5
 - President Trump said that he would leave Walter Reed National Military Center and return to the White House Monday evening, saying that he is feeling “really good” despite concerns about the severity of his condition.
 - Earlier Monday morning, White House Press Secretary Kayleigh McEnany announced that she had tested positive for COVID-19 and that she would begin quarantining. With her positive test result, Ms. McEnany joins First Lady Melania Trump, presidential aide Hope Hicks, former New Jersey Governor Chris Christie, former presidential adviser Kellyanne Conway, and several other staffers who have tested positive within the White House.
 - On October 4, President Trump’s medical team provided an update on his condition. Doctor Sean Conley explained that the president had a “high fever” on October 2, and his blood oxygen levels dropped on October 2 and 3. At one point, President Trump’s oxygen saturation level fell below 94%; 95% is the lower limit of the normal range. President Trump is being treated with the steroid dexamethasone and the antiviral remdesivir; he also received supplemental oxygen on October 2.
 - Vice President Pence continues to test negative and will [continue](#) to campaign; the Vice Presidential debate scheduled for Wednesday, October 7 has not been cancelled.

World Health Organization (WHO)

- [*WHO COVID-19 Updates*](#), October 5
 - Dr. Michael Ryan, head of emergencies at WHO, [told](#) WHO’s executive board that WHO’s best estimates indicate that one in 10 people worldwide have been infected with coronavirus, more than 20 times the number of confirmed cases. WHO warned of surging cases in Southeast Asia, Europe, and the eastern Mediterranean in the same speech.

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

- [*CDC Updates Guidance Regarding COVID-19 Transmission*](#), October 5
 - CDC issued new [guidance](#) acknowledging that COVID-19 can spread by aerosol transmission through respiratory droplets that linger in the air. CDC’s previous guidance advised that COVID-19 spreads primarily via close contact with infected persons.
 - CDC previously issued and then rescinded guidance regarding aerosol transmission of the virus, explaining that the guidance was accidentally published prematurely.
 - In a [statement](#) announcing the release of the updated guidance, CDC explained that it “continues to believe...that people are more likely to become infected the longer and closer they are to a person with COVID-19” and the updated guidance “acknowledges the existence of some published reports showing limited, uncommon circumstances where people with COVID-19 infected others who were more than 6 feet away or shortly after the COVID-19-positive person left an area.”

- [CDC Releases Data Indicating that Adults are Susceptible to Multi-System Inflammatory Syndrome](#), October 2
 - During the course of the pandemic, doctors have observed a new multi-system inflammatory syndrome in children infected with COVID-19 (MIS-C); reports of MIS-C have been increasing in Europe and the United States and have received [media](#) coverage.
 - According to CDC, Children with MIS-C may develop shock, cardiac dysfunction, abdominal pain, and elevated inflammatory markers, without developing the respiratory distress associated with COVID-19.
 - CDC recently collected [reports](#) of 27 adult patients with similar symptoms; these 27 patients tested positive for COVID-19 and developed gastrointestinal, dermatologic, and neurologic symptoms but did not develop severe respiratory distress.
 - These reports indicate that adults infected with COVID-19 are susceptible to multi-system inflammatory syndrome (MIS-C) as well.
- [COVIDView Weekly Surveillance Summary of U.S. COVID-19 Activity](#), October 2
 - CDC summarized key COVID-19 disease indicators for the week ending September 26.
 - The national average of respiratory specimens testing positive for COVID-19 decreased from 5.0% to 4.8% from September 19 to September 26.
 - Regionally, the percentage of respiratory specimens testing positive for COVID-19 declined or remained the same in seven of ten regions, but increased in the Central, Mountain, and Pacific Northwest regions. The highest percentages of positive specimens were seen in the South Central (8.0%), Central (9.1%), and Mountain (7.3%) regions.
 - The overall cumulative hospitalization rate is 178.2 per 100,000, up from 174.8 per 100,000 during the previous week. The highest rates were in people 65 years and older, at 481.5 per 100,000, up from 472.3 per 100,000 during the week of September 19.
 - Based on death certificate data, the percentage of total deaths attributed to pneumonia, influenza, or COVID-19 decreased 0.2% from September 19 (6.6%) to September 26 (6.4%). The percentage remains above the epidemic threshold and will likely increase as more death certificates are processed.

New York State

- [New York State COVID-19 Updates](#), October 5
 - New York reported 8 deaths and 636 hospitalizations, on Sunday, October 4.
 - Approximately 933, or 1.2%, of the 76,404 tests administered in New York on October 4 were positive for COVID-19.
 - Governor Cuomo [urged](#) local governments to more aggressively enforce COVID-19 protection rules, and threatened to close business activities in communities that did not improve their enforcement. The Governor noted that the State's success in re-opening bars and restaurants came only after local government enforced protection measures.

New York City

- [New York City to Close Schools In Areas with COVID-19 Clusters on Tuesday](#), October 5
 - Governor Cuomo ordered certain New York City schools located in neighborhoods experiencing surges in COVID-19 cases to close on Tuesday. Mayor de Blasio

[recommended](#) the action on Sunday, but the plan, which required the Governor's approval, was not approved until Monday.

- Mayor de Blasio also recommended that the City shut down nonessential businesses within the hot-spot neighborhoods; however, Governor Cuomo [rejected](#) the proposal.
- The affected neighborhoods are the Brooklyn and Queens neighborhoods of Far Rockaway, Edgemere, Kew Gardens, Kew Gardens Hills, Pomonk, Borough Park, Gravesend, Homecrest, Midwood, Bensonhurst, Mapleton, Flatlands, Gerritsen Beach, Sheepshead Bay, and Forest Hills.
- Neighborhoods adjacent to the hot-spot neighborhoods are also experiencing an increase in COVID-19 cases, raising concerns about community spread that may require further school and business closures.

Other Related Updates

- [*Secretary of Labor Releases Statement Regarding Unemployment*](#), October 2
 - Labor Secretary Scalia [announced](#) that more than half the jobs eliminated due to the pandemic have returned; at the end of the third quarter, the unemployment rate was 7.9%, half the 15.8% predicted by the Congressional Budget Office in May 2020.
 - In September alone, the private sector added a total of 877,000 jobs with large gains made in lower-wage jobs in retail, leisure, and hospitality. Manufacturing added 66,000 jobs, its largest increase since June.
 - However, some industries continue to see job losses; in September, there was a seasonally-adjusted loss of 350,000 jobs in the education sector.

- [*HHS Assistant Secretary for Health Admiral Brett Giroir to Participate in the World Health Organization Executive Board Special Session on COVID-19*](#), October 5
 - HHS Assistant Secretary Brett Giroir will lead the U.S. delegation to a special session of the Executive Board to the World Health Organization (WHO) that intends to focus on the COVID-19 pandemic response.
 - Representatives of Centers for Disease Control and Prevention (CDC), Department of State, and U.S. Agency for International Development will also participate.
 - The United States plans to participate in the special session despite announcing its intentions to withdraw from WHO earlier this year.

- [*National Academies of Sciences, Engineering, and Medicine Publishes Recommended Vaccine Priority Framework*](#), October 4
 - National Academies of Sciences, Engineering, and Medicine (NAEM) [published](#) recommendations about who should get priority for COVID-19 vaccines when they become available. NAEM proposed a four-phase rollout.
 - Phase 1a includes high-risk health care workers and first responders (estimated 5% of population), and Phase 1b includes people with two or more comorbid conditions that put them at significantly increased risk, in addition to older adults in congregated settings (10% of population).
 - Phase 2 includes teachers, school staff, daycare workers, critical workers in high-risk settings, people with comorbidities that put them at moderately elevated risk, people in homeless shelters, staff and residents of group homes for people with disabilities, and older adults not previously vaccinated (30-35% of population).

- Phase 3 includes workers in essential industries that are at increased risk of exposure, but not included in phase 1 or 2. Phase 3 also includes young adults and children in light of emerging evidence that they play a role in asymptomatic transmission. (40-45% of population).
 - Phase 4 includes everyone else.
 - NASEM recommends that, within phases, access should be prioritized for geographic areas that are more socially vulnerable, as defined by the CDC's Social Vulnerability Index.
- [*Biotech Industry Pushes FDA to Release New Vaccine Guidelines*](#), October 2
 - Biotechnology Innovation Organization (BIO), a biotech industry trade group that includes many of the companies producing coronavirus vaccine candidates, wrote a [letter](#) to DHHS Health Secretary Alex Azar calling to quickly publish new vaccine guidelines drafted by Food and Drug Administration (FDA).
 - The new guidelines should “add layers of caution to the vaccine vetting process,” including specific criteria for clinical trial and safety data.
 - FDA appeared poised to release the new guidelines last week before the process stalled when President Trump announced that he “may or may not” approve the new, stricter criteria.
 - The BIO letter emphasizes that “we cannot allow a lack of transparency to undermine confidence in the vaccine development process.”
 - A recent [survey](#) found that 51% of Americans said they would probably or definitely take a vaccine, down from 72% in May.
 - [*FDA COVID-19 Updates*](#), October 5
 - FDA [issued](#) a warning letter to Nephron Pharmaceuticals Corporation after Nephron sent emails advertising that their product Budesonide Inhalation Suspension could treat symptoms of COVID-19 for which it is not approved.

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
- [*HHS Releases Provider Relief Fund Reporting Requirements*](#), September 25
- [*International Reference Pricing for Medicare Drugs: New Lease on Life or Least Likely to Succeed?*](#), September 16

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