

September 18, 2020

Summary

The United States has 6,705,114 confirmed COVID-19 cases and 198,197 reported related deaths. CDC revised its COVID-19 testing guidance clarifying that asymptomatic individuals who have been exposed to the virus should be tested; CDC previously published controversial guidance that asymptomatic individuals do not necessarily need to be tested. Departments of Health and Human Services and Defense released a strategic plan for distributing COVID-19 vaccines when they become available. The plan contemplates a phased distribution starting with high-priority populations. Dr. Fauci predicted that the United States will be able to start vaccinating high-priority populations in late 2020 or early 2021. Pew Research released poll results indicating that more than half of Americans are skeptical of COVID-19 vaccines. Dr. Fauci warned that a COVID-19 vaccine will not effectively stop the spread of the virus unless there is broad uptake. President Trump expressed support for a second round of stimulus spending.

A paper published in Health Affairs estimated that at least 40% of individuals working in American schools are at a high risk of developing severe COVID-19. Senators Warren and Shumer called on President Trump to take executive action to cancel up to \$50,000 in federal student loan debt per borrower; Warren and Shumer argue that the nation's \$1.5 trillion in outstanding student loan debt is exacerbating the economic damage caused by the pandemic. There are now more than 88,000 COVID-19 cases on college campuses. The "Big Ten" college athletic conference announced that it will hold its regularly scheduled football season, after previously voting to postpone due to safety concerns related to COVID-19.

New York reported 10 deaths, 478 hospitalizations, and 141 COVID-19 patients in intensive care on Thursday, September 17. Approximately 790, or 0.88%, of the 89,727 tests administered in New York on September 17 were positive for COVID-19. State Budget Director Robert Mujica indicated New York has no plans to create or increase taxes on millionaires and billionaires. New York State Department of Health (NYSDOH) announced nursing homes in New York can resume visitation with certain health restrictions. In New York City, public schools will further delay the start of in-person learning for most students. Mayor de Blasio announced a rolling schedule for reopening by age group. K-3 students can return to school starting Monday, September 21. Students in other grades will not start in-person learning until later this fall. Mayor de Blasio announced the opening of a dedicated Pandemic Response Lab (PRL) responsible for processing diagnostic tests for city hospitals. PRL is expected to ramp up to processing 20,000 tests per day by November. The New York City Council voted to permit restaurants to impose up to a 10% surcharge for COVID-19 recovery on in-person diners.

Presidential updates

- [*President Trump Comments on Stimulus Negotiations*](#), September 16
 - During a press [briefing](#), President Trump expressed support for a second round of stimulus spending to address the economic damage caused by the pandemic.
 - The House of Representatives is currently negotiating a stimulus package. Republicans recently put forth a \$350 billion stimulus bill, and Democrats, lead by Speaker Pelosi, are proposing a \$2.2 trillion package. A bipartisan group of 50 members of the House, who call themselves the “Problem Solvers Caucus,” proposed a compromise bill worth \$1.5 trillion.
 - When asked if he supports the Problem Solvers’ bill, President Trump said he was in favor of something similar. He explained, “I like the larger amount...Some of the Republicans disagree, but I think I can convince them to go along with it because I like the larger number.”

World Health Organization (WHO)

- [*WHO COVID-19 Updates*](#), September 18
 - Dr. Hans Kluge, WHO Director for Europe, issued a [statement](#) to the press regarding surging COVID-19 cases throughout Europe. Describing a “very serious situation unfolding before us,” Kluge noted that “more than half of European countries have reported a greater than 10 per cent increase in cases in the past two weeks.”
 - Dr. General Tedros called for more funding for the Access to COVID-19 Tools (ACT) Accelerator in his remarks to member states this week, explaining “[s]o far, 3 billion US dollars has been invested . . . it is only a tenth of the remaining 35 billion dollars needed.” The ACT accelerator is a partnership to speed up COVID-19 vaccine development.

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

- [*CDC Director Testifies Before Senate Regarding Coronavirus Guidance*](#), September 16
 - CDC Director Redfield [testified](#) before the Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies regarding his agency’s response to the pandemic.
 - Redfield responded to questions regarding reports that HHS spokesperson Caputo and Caputo’s science advisor, Professor Paul Alexander, pressured CDC to alter its Morbidity and Mortality Weekly Reports (MMWRs) to make them consistent with White House messaging regarding COVID-19.
 - Redfield said that, “the scientific integrity of the MMWR has not been compromised; it will not be compromised on my watch.”
 - HHS announced that Caputo will take a 60-day leave of absence to focus on the health and well-being of his family, and Professor Alexander will permanently leave the department.
 - After Redfield’s testimony, news outlets [reported](#) that HHS also pressured CDC to revise its guidance regarding COVID-19 testing and school re-openings, citing conversations with anonymous health officials.

- [CDC Interpretation of Forecasts of New Deaths and Hospitalizations](#), September 17
 - CDC [consolidated](#) data from 40 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 207,000 and 218,000 by October 10.
 - CDC [consolidated](#) data from six models projecting the number of daily COVID-19 hospitalizations. Two models predict an increase in daily hospitalizations over the next four weeks, one model predicted a decrease, and three models are uncertain about the direction of the trend. The forecasts estimate 1,300 to 5,500 new COVID-19 hospitalizations per day by October 12.

New York State

- [New York State COVID-19 Updates](#), September 18
 - New York reported 10 deaths, 478 hospitalizations, and 141 COVID-19 patients in intensive care on Thursday, September 17.
 - Approximately 790, or 0.88%, of the 89,727 tests administered in New York on September 17 were positive for COVID-19.
 - State Liquor Authority officials conducted 1,495 compliance checks at bars and restaurants in New York on September 17, observing four social distancing violations.
 - Governor Cuomo [announced](#) that the Special Enrollment Period for uninsured New Yorkers will be extended through December 31, 2020. New Yorkers can apply for coverage through NY State of Health, the state’s online insurance marketplace, or directly through their insurers.
 - State Budget Director Robert Mujica [indicated](#) New York has no plan to change the tax rate on millionaires after New Jersey Governor Phil Murphy announced a plan to raise taxes on income of more than \$1 million from 8.97% to 10.75%. Mujica noted “the combined state and city income tax rate is already 12.6% -- which is higher than New Jersey’s new top rate or a proposed 12 percent ‘billionaire/millionaire tax rate.’”
 - New York State Department of Health (NYSDOH) Commissioner Dr. Zucker [announced](#) that nursing homes in New York will be allowed to resume limited visitation in facilities that are COVID-19 free for at least 14 days.

New York City

- [New York City COVID-19 Updates](#), September 18
 - The City Council [voted](#) to let restaurants impose a temporary COVID-19 recovery charge on bills. Restaurants can impose a surcharge up to 10% to each bill for in-person dining, but not for takeout or delivery, as long as it is clearly noted on menus. The vote was met with [mixed](#) responses from restauranteurs.
 - Mayor de Blasio [released](#) the annual Mayor’s Management Report (MMR), which serves as a public account of the performance of City agencies to measure whether they are delivering effective and efficient services. This year’s report includes a chapter on the City’s COVID-19 response.

- [*New York City Schools Again Delay Start of In-Person Learning*](#), September 17
 - Mayor de Blasio [announced](#) an updated schedule for the 2020-2021 school year, pushing back the scheduled opening of Monday, September 21 for most “blended learning” students. “Blended learning” describes students who will learn partially online and partially in school classrooms.
 - Students in New York City this year can choose to enroll in full remote learning or in blended learning.
 - The youngest blended learning students, ages three through kindergarten, will still begin attending physical schools on Monday, September 21. Students enrolled in K-5 and K-8 schools will begin Tuesday, September 29. Students in middle schools, high schools, and secondary schools spanning 6-12 will begin on Thursday, October 1.
 - All students in full remote programs will continue as planned, starting full-day instruction on Monday, September 21.
 - The move is a blow to Mayor de Blasio’s push to reopen in-person learning, and leaves New York amongst a long list of big cities that will begin the school year online for most students.

- [*New York City Announces Its Own Dedicated COVID-19 Lab*](#), September 17
 - Mayor de Blasio [announced](#) the launch of the Pandemic Response Lab (PRL), a facility dedicated to processing COVID-19 tests within 24-48 hours for NYC Health and Hospitals.
 - PRL is up and running, and will scale up its capacity to process approximately 20,000 tests per day by November.
 - PRL will also create good-paying jobs such as clinical lab technologists, customer success representatives, automation engineers, and scientists. PRL expects to employ 150 people by November.
 - After months of long delays in testing results, the City has improved its turnaround times, with over 80% of tests coming back within 72 hours or less.

Other Related Updates

- [*Department of Labor Unemployment Insurance Weekly Claims Report*](#), September 17
 - Department of Labor (DOL) [reports](#) that another 860,000 workers filed initial claims for unemployment benefits last week.
 - The number of new claims had been steadily declining since March, when nearly seven million people filed for unemployment insurance in a single week. The numbers spiked for two weeks in July, briefly marking a reversal of that trend. This week’s report marks the lowest weekly total since March.
 - 658,737 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 and DoD Release Plan for Distributing COVID-19 Vaccine*](#), September 17
 - Department of Health and Human Services (HHS) and Department of Defense (DoD) released a strategic [plan](#) for distributing COVID-19 vaccines when they become

available. HHS and DoD also released a [handbook](#) outlining steps state and local governments should take to prepare for distribution.

- The plan outlines three phases of distribution. During phase 1, the plan predicts that there will be limited quantities of the vaccines available and doses will be distributed to high-priority populations that have yet to be defined. During phase 2, vaccine production will ramp up and doses will be distributed to the general public. During phase 3, the vaccines will be integrated into routine vaccination programs, if necessary.
 - The plan does not include a timeline for the phases but predicts that 100 million doses will be available by January 2021.
 - CDC's Advisory Committee on Immunization Practices (ACIP) will recommend priority groups for phase 1, drawing on past experience, a prioritization framework developed by the National Academy of Medicine, and research regarding COVID-19 epidemiology, vaccine safety, and implementation issues. ACIP meetings and records will be public.
 - Vaccines will be distributed by private contractor McKesson to state, local, and tribal health departments, federal entities, and some commercial partners. DoD will provide logistical support.
- [Eli Lilly Releases Promising Data on Potential COVID-19 Treatment](#), September 16
 - In a non-peer reviewed study, drug maker Eli Lilly [announced](#) the results of a clinical trial of LY-CoV555, a possible treatment for COVID-19.
 - LY-CoV555 is a monoclonal antibody, which is a manufactured copy of an antibody produced by patients who recovered from COVID-19, administered to patients via a transfusion.
 - During the clinical trial, more than 450 newly diagnosed COVID-19 patients received either LY-CoV555 or a placebo infusion.
 - LY-CoV555 lowered the amount of the virus present in trial participants' bodies, alleviated symptoms, and reduced risk of hospitalization by 72%.
 - 1.7% of trial participants who received LY-CoV555 were hospitalized, compared with 6% who received a placebo.
 - LY-CoV555 did not produce significant side effects.
 - The results of the trial have not yet been peer-reviewed. However, Eli Lilly said it intends to publish the results in a peer-reviewed journal and may seek an emergency use authorization for LY-CoV555.
 - Monoclonal antibodies have been used to treat other diseases, including cancer and eczema, but are difficult and expensive to manufacture.
- [Health Officials, President Trump Disagree Regarding COVID-19 Vaccine Timeline](#), September 17
 - While testifying before the Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, CDC Director Redfield [predicted](#) that a COVID-19 vaccine will not be widely available until the second or third quarter of 2021.
 - In a press [briefing](#), President Trump said that Redfield was mistaken; Trump expressed that, "under no circumstance, will it be as late as [Dr. Redfield] said... We will have rapid distribution. We're set up — our military and others are set up to do it, and we

think it could even start taking place in October, but certainly during November, December would be the latest.”

- In a media interview, Dr. Fauci [said](#) that Redfield and Trump were “both right.” Fauci explained, “The president was saying is that it is entirely conceivable that we will have an answer by October.”
- Dr. Fauci predicted that the United States will have an effective COVID-19 vaccine by November or December 2020 and will be able to begin distributing it to high-priority populations at the end of 2020 or the beginning of 2021. However, Fauci agreed with Redfield that a vaccine will not be broadly available until later in 2021.
- [*According to Pew Research Poll, Many Americans Skeptical of COVID-19 Vaccine*](#), September 18
 - Pew Research conducted a poll to determine how many Americans are willing to receive a COVID-19 vaccine when they become available.
 - The poll surveyed 10,093 American adults from September 8 through September 13.
 - 51% of survey respondents said that they would get a COVID-19 vaccine, down from 72% in a similar poll conducted in May. 49% of survey respondents said they would “probably” or “definitely” not get it.
 - 78% of survey respondents said that the COVID-19 vaccine development process has been rushed, and 77% said they believed a COVID-19 vaccine will be approved before its safety or efficacy is full understood.
 - In a media interview, Dr. Fauci [explained](#) that “if too few Americans get a COVID-19 vaccine when it becomes available, it won’t help reduce the spread of the deadly virus.” Fauci expressed that even a third of Americans getting vaccinated will be insufficient to stop the spread of the virus.
- [*New COVID-19 Diagnostic Test Can Return Results in One Hour*](#), September 16
 - Researchers at Harvard and MIT [published](#) results in the New England Journal of Medicine showing a new diagnostic test that can be performed in “less than an hour and with minimal equipment.”
 - The test uses a simplified method of viral RNA extraction along with isothermal amplification and clustered regularly interspaced short palindromic repeats (CRISPR)-mediated detection.
 - Blinded testing at an external laboratory at the University of Washington showed a sensitivity (correctly identifying positives) of 93.1% and a specificity (correctly identifying negatives) of 98.5%, comparable to the widely used PCR tests.
- [*National Institute of Health \(NIH\) Awards Contracts to Develop Digital Health Technologies*](#), September 15
 - NIH [awarded](#) seven contracts to companies and academic institutions to develop digital health solutions that help address the COVID-19 pandemic.
 - The work may lead to user-friendly tools like smartphone apps, wearable devices, and software that can trace contacts of infected individuals, keep track of verified COVID-19 test results, and monitor the health status of infected and potentially infected individuals.

- National Cancer Institute (NCI) Director Norman Sharpless explained the new tools “could allow us to use containment efforts, like COVID-19 testing, social distancing, and quarantine, precisely when and where they’re needed. That might let more people return to less restricted living.”
- The contracts are awarded in two phases. Phase one will be used to demonstrate feasibility of the project. After assessment, the contractually optional phase two would provide additional funding for development and demonstration of utility in response to the pandemic.
- [*National Institute of Health Funds Community Engagement Research*](#), September 16
 - NIH [announced](#) a \$12 million award for outreach and engagement efforts in ethnic and racial minority communities disproportionately affected by the COVID-19 pandemic.
 - The award to RTI international, a non-profit research institution, will support teams in 11 states established as part of the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities.
 - CEAL research teams will focus on COVID-19 awareness and education research, especially among African Americans, Hispanics/Latinos, and American Indians, and especially in Alabama, Arizona, California, Florida, Georgia, Louisiana, Michigan, Mississippi, North Carolina, Tennessee, and Texas.
 - NIH spokesman Dr. Gary Gibbons explained that “communities of color have been particularly affected, and also historically underrepresented in clinical research . . . That’s why NIH is partnering with messengers who live, work, and worship in the same communities where the disease has caused the highest rates of sickness and death.”
- [*FDA COVID-19 Updates*](#), September 18
 - The Food and Drug Administration (FDA) [published](#) comparative performance data for some authorized COVID-19 diagnostic tests. The data gives laboratories, healthcare providers, and patients a resource on the relative performance of available tests to better inform which tests they choose.
 - FDA [approved](#) an abbreviated new drug application for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, indicated for sedation of intubated and mechanically ventilated patients, and sedation of non-intubated patients prior to surgery.
 - FDA [warned](#) that some commercially available hand sanitizer products are defective. Some products are labeled as containing ethanol but tested positive for methanol or 1-propanol contamination—both of which can be life-threatening when ingested. Other defective products identified by FDA are subpotent, meaning they contain less than the required amount of ethanol.

Other recent events covered in detail elsewhere:

- [*International Reference Pricing for Medicare Drugs: New Lease on Life or Least Likely to Succeed?*](#), September 16
- [*Turning Over a New Lease? Are Turnover-Based Leases the Answer for Tenants Facing COVID-19 Related Business Disruption?*](#), August 27

- [HHS Prohibits FDA from Requiring Premarket Review of LDTs, Including During the COVID-19 Emergency, August 25](#)

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