

October 14, 2020

### Summary

The United States has 7,870,653 confirmed COVID-19 cases and 216,169 reported related deaths. Late-stage trials of Johnson & Johnson's vaccine candidate and Eli Lilly's experimental monoclonal antibody treatment were paused after study volunteers suffered unexplained illnesses. The medical journal *Lancet Infectious Diseases* published an article documenting a case of COVID-19 re-infection, suggesting that prior infection with COVID-19 does not necessarily render patients immune. White House officials met with scientists backing the controversial "Great Barrington Declaration" which advocates allowing the virus to spread freely among young, healthy individuals to reach herd immunity while implementing measures to protect the vulnerable. Dr. Fauci told the media that he reviewed President Trump's recent COVID-19 test results and "can say with a high degree of confidence that [the President] is no longer transmissible." Senators Shumer and Klobuchar filed a resolution calling for increased social distancing, mask wearing, and COVID-19 testing on Capitol Hill. Senate Majority Leader McConnell announced that the Senate will vote on a narrow stimulus bill providing funding for small businesses, schools, and federal unemployment insurance.

COVID-19 infections continue to rise throughout the country, as more than 20 states have recently set records for their highest new case counts in their seven-day average since the beginning of the pandemic. Governor Michelle Lujan Grisham of Nevada announced new public health regulations effective October 16, including closing time for restaurants and bars, hotel occupancy limit reductions, and limits on gathering of five or more people. The Michigan Supreme Court denied Governor Gretchen Whitmer's request to delay the effect of an opinion that ruled her executive orders on the coronavirus pandemic are unconstitutional. The ruling overturns Governor Whitmer's executive orders related to public health since April 30, when the Republican-controlled legislature advanced a bill that would not have renewed the state of emergency. Mississippi State Health Officer Dr. Thomas Dobbs announced state ICU beds are 80% full as community transmission of the virus spikes.

New York reported 7 deaths, 938 hospitalizations, and 201 COVID-19 patients in intensive care on Tuesday, October 13, 2020. Approximately 1,232, or 1.1% of the 111,744 tests administered in New York on October 13 were positive for COVID-19. Governor Cuomo sent a letter to New York localities threatening to withhold state funding if localities failed to enforce coronavirus restrictions. Governor Cuomo also announced that the NYDOH charged a concert promoter for hosting a concert in Southampton. The State seeks a \$20,000 fine. The Metropolitan Transit Authority announced that it will be forced to cut services and lay off thousands of workers if it does not receive \$12 billion in federal relief.

## Presidential updates

- [\*White House Officials Meet with Scientists Regarding Herd Immunity Strategy\*](#), October 13
  - Last week, HHS Secretary Azar and White House aid Atlas met with several scientists who have endorsed the Great Barrington Declaration.
  - The Great Barrington [Declaration](#) (“the Declaration”) is a document drafted by three infectious disease experts and reportedly signed by thousands of scientists and health care providers calling for a new pandemic strategy termed “Focused Protection.”
  - Under “Focused Protection,” countries would re-open their economies and allow the virus to spread freely among young, healthy individuals to reach herd immunity while implementing measures to protect the vulnerable.
  - During a call with reporters, White House officials [said](#) that the White House is not endorsing the Declaration; rather, “the [Declaration] is endorsing what the president’s policy has been for months,” noting that it’s been the President’s policy to “protect the vulnerable, prevent hospital overcrowding, and open schools and businesses.”
  - The infectious disease experts that drafted the Declaration have distinguished academic credentials. Martin Kulldorff is an epidemiologist at Harvard University. Sunetra Gupta is an epidemiologist at the University of Oxford. Jay Bhattacharya is a physician and health economist at Stanford Medical School.
  - Other experts have criticized the Declaration. Notably, WHO Director Tedros [called](#) the Declaration’s proposed approach to addressing the pandemic “simply unethical.” NIH Director Collins [warned](#) that the Declaration represents “a fringe component of epidemiology... it’s dangerous.” He also [opined](#) that the Declaration “fits into the political views of certain parts of our confused political establishment.”

## World Health Organization (WHO)

- [\*WHO COVID-19 Updates\*](#), October 14
  - WHO spokesman Tarik Jasarevic [explained](#) the WHO position on using lockdowns to control the pandemic after comments by Dr. David Nabarro, special envoy to WHO on COVID-19, were widely cited to show WHO shifted its stance on lockdowns.
  - Jasarevic explained, “[w]e have been very consistent from the beginning . . . [n]ational lockdowns shouldn’t be the default control measure, but movement restrictions may be among a range of measures governments can consider in certain geographical areas.”
  - WHO [updated](#) its Emergency Global Supply Chain System (COVID-19) catalogue, which lists medical devices needed to treat COVID-19 along with an indicative price to provide supply chain guidance to health care providers.

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

- [\*CDC Publishes Data Regarding Transmission Dynamics by Age Group\*](#), October 9
  - CDC researchers analyzed COVID-19 transmission dynamics by age group in 767 hotspot counties in June and July 2020.
  - At the start of the study, researchers identified counties as “hotspots” if they had more than 100 cases in the preceding 7 days and experienced increases in cases in the preceding 3-7 days. The 767 hotspots represented 24% of all United States counties and 63 % of the United States population.
  - Researchers examined positivity rates in the hotspots, aggregated the results across all hotspots and stratified by age group.

- The percent positivity among persons aged 0-17 and 18-24 years began increasing 31 days before hotspot identification. Increases in positivity among older age groups began after the increases in younger age groups.
- Positivity among persons aged 18-24 years was near its peak of 15% by the date of hotspot detection; among other age groups, percent positivity continued to increase for 21-33 days after hotspot detection and the decline for other age groups was slower than that for persons aged 18-24 years.
- Based on these findings, researchers concluded that there is an urgent need to address transmission among young adult populations, especially given recent increases in COVID-19 infections among young adults.

### **New York State**

- [\*New York State COVID-19 Updates\*](#), October 14
  - New York reported 7 deaths, 938 hospitalizations, and 201 COVID-19 patients in intensive care on Tuesday, October 13, 2020.
  - Approximately 1,232, or 1.1% of the 111,744 tests administered in New York on October 13 were positive for COVID-19
  - Governor Cuomo [sent](#) a letter to localities throughout New York saying the State will withhold funds for localities and schools in COVID-19 cluster zones that fail to enforce public health laws.
  - Governor Cuomo also [announced](#) that the NYDOH has charged “In the Know Experiences” for promoting a July concert in Southampton in violation of public health laws prohibiting mass gatherings. The State is seeking \$20,000 in fines. More than two thousand people attended the concert, where the Chainsmokers performed.
  - On October 13, Governor Cuomo [announced](#) that Ohio, Michigan, and Virginia would be added to the New York State COVID-19 travel advisory, which requires travelers from those states to quarantine for 14-days upon arrival. No states were removed.

### **New York City**

- [\*New York City COVID-19 Updates\*](#), October 14
  - During a Tuesday press conference, Mayor de Blasio [noted](#) that the targeted lockdowns have already helped to level off positivity rates in “red zones” where schools and non-essential businesses have been closed since last week. A [press release](#) from the Governor’s office indicated that red-zone positivity rates rose from 4.13% on Monday to 6.29% on Tuesday.  
The Grand Central Oyster Bar [closed](#) its doors after attempting to reopen because sales reached only 3% of pre-pandemic levels. The famed restaurant faced additional challenges compared to other New York City restaurants struggling to increase revenues because weekday commuter rail ridership has declined nearly 80% compared to before the pandemic.
- [\*New York’s MTA Faces Dire Outlook Without Federal Aid, State Comptroller Warns\*](#), October 13
  - New York Comptroller Thomas DiNapoli warned that Metropolitan Transportation Authority will be forced to cut service, lay off thousands of workers, and delay

improvements to buses, commuter rails, and subways if the MTA does not receive \$12 billion in federal aid.

- The MTA's budget shortfalls are driven by lower ridership during the pandemic. Fares and tolls are \$10.3 billion short of the MTA's early-year projections. Weekday ridership on New York City subways is down 70% compared to pre-pandemic levels, and there is an even steeper decline in commuter rail ridership.
- Although the MTA has already received \$4 billion in federal relief this year, the MTA projects a budget deficit of \$16 billion through 2023.

### **Other Related Updates**

- [\*DOL COVID-19 Updates\*](#), October 13
  - Department of Labor (DOL) [announced](#) that Labor Secretary Scalia's wife, Trish Scalia, tested positive for COVID-19. Secretary Scalia continues to test negative.
  - DOL noted that Secretary Scalia will follow the advice of health professionals and will work from home for the time being.
- [\*Trump Administration Expands Manufacturing Capacity with Cytiva for Components of COVID-19 Vaccine\*](#), October 13
  - DHHS, in conjunction with DOD, announced its agreement with Cytiva, a company headquartered in Massachusetts, to provide \$31 million in funding to increase the company's manufacturing capacity for products essential to the COVID-19 vaccine.
  - Cytiva manufactures vaccine-related products such as liquid and dry power cell culture media, cell culture buffers, mixer bags, and XDR bioreactors.
  - The funds will be used to expand Cytiva's manufacturing capacity and create duplicate capabilities at the company's Utah facilities within the next 12 months.
  - The federal government's commitment adds to a total of approximate \$1.1 billion in funding granted to purchase needles, syringes, vials, and supply kits, as well as expand manufacturing capacity ahead of the release of a COVID-19 vaccine.
- [\*Lancet Publishes Article Documenting Case of COVID-19 Re-infection\*](#), October 12
  - The medical journal Lancet Infectious Diseases, published an article documenting the case of a 25-year-old man in Nevada who contracted COVID-19 twice.
  - The man tested positive for COVID-19 first in April 2020 and again in June 2020. In between his two positive tests, the man tested negative twice. The man's second COVID-19 infection was more severe than his first infection.
  - Researchers analyzed the SARS-Cov-2 variants associated with each infection; they concluded that genetic discordance between the two variants was greater than could be accounted for by short-term in vivo evolution. This finding suggests that the man was infected with COVID-19 on two separate occasions by a genetically distinct virus.
  - Researchers concluded that prior exposure to SARS-CoV-2 may not guarantee total immunity. Researchers advised that all individuals, whether previously diagnosed with COVID-19 or not, should take identical precautions to avoid infection.
  - After Lancet published its article, experts [told](#) reporters at the *New York Times* that, though COVID-19 reinfection is possible, it is exceedingly rare. There have been few confirmed cases of COVID-19 reinfection. Yale immunologist Dr. Akiko Iwasaki [told](#) the *Times*, "if this was a very common event, we would have seen thousands of cases."

- [\*Congresspeople Call for Additional COVID-19 Precautions on Capitol Hill\*](#), October 13
  - Senators Shumer and Klobuchar filed a resolution calling for more testing, mask wearing, and contact tracing on Capitol Hill. Representative Davis has been calling for more robust testing on Capitol Hill for several months.
  - Since the start of the pandemic, approximately 20 lawmakers and over 100 Capitol Hill workers have [tested](#) positive for the virus.
  - Recently, Senators Lee and Tillis tested positive after attending an event at the White House for Supreme Court nominee Judge Amy Coney Barrett on September 26; so far, at least [ten](#) people that attended the event have tested positive, including President Trump. Senator Johnson and Representatives Carbajal and Bost also recently tested positive; they did not attend the event at the White House for Judge Barrett.
  - In May, Congressional attending physician Dr. Brian Monahan issued social distancing [guidance](#) instructing lawmakers to stay six feet apart and avoid large gatherings, among other things. In July, House Speaker Pelosi also [implemented](#) a mask mandate. However, Capitol Hill does conduct routine widespread testing of lawmakers and staff.
  - Both House Speaker Pelosi and Senate Majority Leader McConnell have resisted calls to increase testing. During an [interview](#), Pelosi said Dr. Monahan should determine if and when Capitol Hill needs to implement a more comprehensive testing program; Pelosi also noted that devising a comprehensive testing program that met the needs of all lawmakers and staff would be a large undertaking for Monahan’s small office.
  
- [\*NIH Study Aims to Identify Promising COVID-19 Treatments for Clinical Trials\*](#), October 13
  - National Institute of Allergy and Infectious Disease (NIAID), part of National Institute of Health (NIH), [launched](#) a study to determine whether certain approved therapies or investigational drugs in late-stage clinical development show promise against COVID-19 and merit advancement into larger clinical trials.
  - Named ACTIV-5 Big Effect Trial, the study will enroll adult volunteers hospitalized with COVID-19 at up to 40 U.S. sites. Approximately 100 volunteers will be assigned to each treatment, including the control group.
  - The Phase 2 trial is adaptive, randomized, double-blind, and placebo-controlled, and will compare different investigational therapies to a control arm to determine which experimental treatments have large effects.
  - The study will include risankizumab, a monoclonal antibody developed by Boehringer Ingelheim and AbbVie in conjunction with remdesivir, and will also test lenzilumab, a monoclonal antibody developed by Humanigen, with remdesivir.
  
- [\*NIH Updates COVID-19 Treatment Guidelines\*](#), October 12
  - NIH [updated](#) its [guidelines](#) on treating COVID-19.
  - The recommendations are now outlined according to severity of disease, acknowledge persistent symptoms after recovery, and include sections on managing COVID-19 in HIV-infected patients, sedation management, and post-intensive care syndrome.
  - For COVID-19 patients who are not hospitalized or who are hospitalized without supplemental oxygen, no particular antiviral treatment is recommended, and the panel recommends against using dexamethasone, a steroid effective for treating COVID-19.

- For hospitalized patients on oxygen but without mechanical ventilation, remdesivir alone or with dexamethasone is recommended.
- The guidelines acknowledge increasing evidence that some patients suffer symptoms after recovering from COVID-19, including headache, vision and hearing changes, loss of taste or smell, memory loss, and cognitive impairment for up to three months. No effective management strategies have been identified.
- [\*COVID-19 Vaccine and Treatment Trials Paused\*](#), October 13
  - Johnson & Johnson temporarily [paused](#) its COVID-19 vaccine candidate clinical trials, and National Institute of Allergy and Infectious Diseases (NIAID) [paused](#) a government-sponsored study of Eli Lilly's experimental antibody treatment.
  - Johnson & Johnson announced on October 12 it had paused the clinical trial of an experimental COVID-19 vaccine because of an unexplained illness in one of its volunteers. The company did not provide details about the unexplained illness.
  - The trial includes 60,000 people, the largest trial of any COVID-19 vaccine candidate.
  - Eli Lilly's trial was paused on October 13. The trial was designed to test the benefits of a monoclonal antibody therapy similar to the Regeneron therapy provided to President Trump during his treatment, in combination with the antiviral remdesivir.
  - An NIH spokeswoman said the trial was paused when an independent safety board found that after five days of treatment, the group of patients that received antibodies showed a different clinical status than the group who had received a saline placebo - a difference that crossed a predetermined threshold for safety.
  - The safety board will meet on October 26 and advise NIH whether to resume the trial.
- [\*FDA COVID-19 Updates\*](#), October 14
  - Food and Drug Administration issued and immediately implemented new [guidance](#) outlining a policy to help expand access to certain FDA-cleared molecular tests intended for detection and identification of flu viruses, which require the same critical components as many COVID-19 molecular assays.

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

Send questions to:

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