

September 20, 2021

### Summary

The United States has 42,111,835 confirmed COVID-19 cases and 673,985 reported related deaths. On Wednesday, while the United Nations General Assembly meeting is underway, President Biden will lead a virtual summit with world leaders to discussing expanding and enhancing efforts to address COVID-19. This summit is in the wake of White House announcing that in November it will revoke its travel ban on foreign visitors from 33 countries; under the new policy, travelers will be required to be fully vaccinated and have tested negative within three days in order to enter the U.S.

Today, Pfizer released early findings from its COVID-19 vaccine trial of adolescents 5 to 11, concluding the vaccine is safe and effective for this group. Once the company concludes its analysis, it will likely apply for authorization with the Food and Drug Administration (FDA). Meanwhile, on Friday, the FDA's outside advisory group overwhelmingly rejected a plan to authorize mass COVID-19 booster shots, citing inadequate data on both safety and utility. However, the group voted unanimously to recommend booster shots for high risk individuals and adults 65 and older.

A recent CDC study found that since the start of the pandemic, children and teens have experienced rising rates of obesity and weight gain.

West Virginia continues to see the highest number of cases per capita, with no sign of the outbreak lessening. Cases are rising in New Hampshire, Maine, Michigan and North Dakota. However, new case numbers are sharply declining in Florida, Mississippi, Georgia and Louisiana.

As of September 19, New York reported 32 deaths, 2,333 hospitalizations, and 557 COVID-19 patients in intensive care. Approximately 3,432, or 2.94%, of the 116,550 tests administered in New York were positive for COVID-19. New York has administered 24,706,127 doses of the vaccines to patients; 70.0% of New York residents have received at least one dose of the vaccines; and 62.6% are fully vaccinated. New York state is among the top five states for slowest transmission on a per-person basis, however, COVID-19 is still a major concern since new cases in New York State rose 19% overall in the past week. On September 17, Governor Kathy Hochul signed the Less is More Act, ordering the release of approximately 200 detainees at Rikers Island as COVID-19 cases are again rising inside the jail.

## **U.S. Government Updates**

- [\*Statement by White House Press Secretary Jen Psaki on COVID-19 Summit\*](#), Sept. 17
  - On Wednesday, while the United Nations General Assembly meeting is taking place, President Biden will lead a virtual COVID-19 Summit with world leaders to discuss expanding and enhancing efforts to address COVID-19.
  - Participants will be asked to further commit to enhancing access to vaccines; solving the oxygen crisis and making tests and other resources more available; establishing a sustainable health security financing mechanism and preparing for emerging threats; and aligning around targets, tracking programs and supporting one another in fulfilling commitments.
- [\*White House to revoke covid-19 travel ban on visitors from 33 countries\*](#), Sept. 20
  - On Monday, the White House announced that it would revoke its travel ban on visitors from 33 countries; the policy will take effect in early November.
  - Foreign nationals flying to the U.S. will be required to be fully vaccinated and will also have to test negative for the virus within three days of departure.
  - Unvaccinated Americans returning to the U.S. will be required to obtain a negative test within one day of leaving and again after arriving.
- [\*Biden will get a booster shot on camera, Psaki says\*](#), Sept. 20
  - On Monday, White House press secretary Jen Psaki announced that President Biden will get a COVID-19 booster shot on camera in the coming weeks; the date has not yet been announced.
  - Expert advisors to the Food and Drug Administration voted on Friday to recommend that the agency authorize Pfizer-BioNTech booster shots six months after vaccination for those 65 and older.
  - President Biden is also continuing to be tested for coronavirus weekly.

## **Vaccines and Therapeutics**

- [\*COVID Vaccine For Kids Ages 5 To 11 Is Safe And Effective, Pfizer Says\*](#), Sept. 20
  - Pfizer released initial findings from its COVID-19 vaccine trial of children 5 to 11. The findings demonstrate that the vaccine produces a strong immune response in children and that its side effects are safe—comparable to the side effects experienced by the 16 to 25 age group.
  - The participants were given a 10-microgram dose of the vaccine 21 days apart. In contrast, adults receive a 30-microgram dose.
  - Once Pfizer completes its analysis, it will submit the study to the FDA in support of an application for emergency use with respect to children. Still, experts have cautioned that the FDA will likely not make its decision until the end of 2021.
  - The US has seen a 240% rise in pediatric COVID-19 cases since July.
- [\*FDA advisory panel rejects widespread Pfizer vaccine booster shots\*](#), Sept. 17
  - On Friday, a group of outside experts advising the FDA on whether to authorize booster shots voted overwhelmingly against recommending such shots for the general population. The group pointed to inadequate data on the safety of booster shots. The group also questioned the utility of an extra dose, with some panelists noting that unvaccinated individuals are driving casualty rates.
  - Instead, the group voted unanimously in favor of authorizing booster shots for high-risk individuals, including adults 65 and older.

- The agency is not bound by the panel’s decision, but typically follows it. The recommendation is a blow to the White House, which has been busy devising plans for a mass booster rollout

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

- [COVID Data Tracker Weekly Review](#), Sept. 17
  - CDC summarized key COVID-19 disease indicators for last week.
  - As of September 15, the seven-day average number of daily new cases reported was 146,182. This is a 6.1% increase compared to the previous week’s average.
  - As of September 16, 383 million vaccine doses have been administered in the United States. Overall, approximately 210.7 million people in the United States have received at least one dose of vaccine, which is 63.5% of the population. Approximately 180.1 million people are fully vaccinated, which is 54.2% of the population. The seven-day average number of reported vaccine dose administrations was 773,763, a 1.6% decrease compared to the previous week.
  - As of September 14, the seven-day average of new daily hospital admissions was 11,165, a 5.7% decrease compared to the previous week’s average.
  - As of September 15, the seven-day average of reported deaths was 1,448 per day, a 17.4% increase compared to the previous week’s average.
- [Children And Teens Gained Weight At An Alarming Rate During The Pandemic, The CDC Says](#), Sept. 17
  - According to a recent CDC [study](#) of over 432,000 adolescents between 2 and 19, kids and teenagers have experienced a significant increase in weight gain since the start of the pandemic.
  - The percentage of obese adolescents increased from 19% to 22% during this time, while all weight groups saw an increase in the rate of weight gain.
  - Experts point to various factors, such as food insecurity, reduced access to health and nutritional services, and restrictions on school activities.

### **New York State**

- [New York State COVID-19 Updates](#), Sept. 20
  - New York reported 32 deaths, 2,333 hospitalizations, and 557 COVID-19 patients in intensive care on September 19, 2021.
  - Approximately 3,432, or 2.94%, of the 116,550 tests administered in New York on September 19 were positive for COVID-19.
  - As of September 19, New York has administered 24,706,127 doses of the vaccines to patients; 70.0% of New York residents have received at least one dose of the vaccines; and 62.6% are fully vaccinated.
  - New cases in New York State [rose](#) 19% overall in the past week, ranking the State in the top five states for slowest transmission on a per-person basis. New Yorkers constitute 5.8% of the country’s population, but only 3.7% of the country’s cases in the last week.
  - On September 17, Governor Kathy Hochul [signed](#) the Less is More Act, ordering the release of approximately 200 detainees at Rikers Island as COVID-19 cases are again rising inside the jail. Only 36% of individuals currently held at the jail are fully vaccinated against the virus.

## **New York City**

- [New York City COVID-19 Updates](#), Sept. 20
  - During New York City's first week of public school classes, more than 800 students and staff [tested](#) positive for COVID-19, causing the closure of 372 classrooms and partially closing a further 303. One East Harlem school was required to close altogether, offering only remote classes until September 28. The Department of Education indicated that 82.4% of students attended class on the first day of school, up from 80% in 2020 but still below the 90% present in 2019.
  - Following the first week of classes, Mayor Bill de Blasio [announced](#) changes to the City's school COVID policies on September 20. Schools will now conduct randomized weekly, rather than biweekly, testing. In addition, in the event that a positive case is found within a single classroom, unvaccinated students in that classroom will not have to quarantine if they had remained masked and kept three feet of distance. The measures are designed to minimize disruptions to classroom instruction.
  - New Yorkers are nervous as the United Nations [reconvenes](#) in the City, as several diplomats have indicated that they will not abide by local vaccination requirements. The City will be offering pop-up testing and Johnson & Johnson vaccinations for free on site to ward off the threat of a super-spreader event.

## **International**

- On Monday, the health minister of [India](#) announced that the country will restart coronavirus exports starting in October.
- [American Samoa](#), which was one of the last places without any COVID-19 cases, has just reported its first coronavirus case.
- [Italy](#) will make COVID-19 health passes mandatory for all workers, making it the first European country to do so.
- On Monday, the Prime Minister of [New Zealand](#), Jacinda Ardern, announced that the country will ease coronavirus restrictions in Auckland, which has spent the past five weeks under the strictest lockdown.

Other recent events covered in detail elsewhere:

- [Podcast: Non-binding Guidance: COVID-19 Vaccine Mandate Litigation](#), July 29
- [Three new General Licenses expand scope of COVID-19-related activity with Iran, Syria, and Venezuela under U.S. Sanctions](#), July 6
- [Regulatory Trends in Pharma Deal-making: Transitioning from the “Year of the Pandemic” to “Another Year of the Pandemic.”](#) June 3
- [Non-binding Guidance: The Defense Production Act and the COVID-19 Pandemic](#), May 27
- [Doug Brayley Discusses Employer Vaccination Policies on CNN](#), May 24

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