

June 14, 2021

### Summary

The United States has 33,462,286 confirmed COVID-19 cases and 599,769 reported related deaths. President Biden vowed Sunday that the United States would continue to provide vaccines to the world's poorest countries to curb the coronavirus pandemic, hinting that it may make another substantial donation of vaccine doses next year. The president said he did not want to make commitments before they were finalized, but added that the United States may "be in a position to provide another billion" doses over the next two years.

The FDA has concluded an investigation into cross-contamination between the Johnson & Johnson and AstraZeneca vaccines at a Baltimore facility that produces both drugs. As a result, Johnson & Johnson was ordered to dispose of 60 million doses of the vaccine. Moderna has applied for regulatory approval to allow use of its vaccine on adolescents between the ages of 12 and 17, amid a successful study on this age group and calls by experts to increase adolescent vaccinations. Following a successful Phase 3 trial of nearly 30,000 participants that yielded a 90.4% efficacy rate, Novavax is set to apply for authorization of its vaccine—the only to introduce protein spikes directly into the body—in third quarter 2021.

Recent CDC data indicates that the majority of US COVID-19 infections as of mid-April stemmed from the "Alpha" (66%) and "Gamma" (5%) variants. The share of each variant was less than 1% earlier in the year. This drastic increase reflects the higher contagiousness of the new variants. Yet, owing to the low risk of transmission outdoors, the CDC announced on June 10 that travelers are no longer required to wear masks in outdoor travel hubs or the outdoor spaces of ferries, buses, and trollies.

In the United States, case numbers have fallen to their lowest point since testing became widely available. In the last two weeks, several states, such as West Virginia, Maine, Pennsylvania, and Illinois, have reported a fifty percent decline in COVID-19 cases.

As of June 13, New York reported 7 deaths, 617 hospitalizations, and 163 COVID-19 patients in intensive care. Approximately 320, or .52%, of the 61,634 tests administered in New York were positive for COVID-19. New York has administered 20,099,155 doses of the vaccines to patients; 55.7% of New York residents have received at least one dose of the vaccines; and 49.2% are fully vaccinated. Governor Cuomo announced that applications are now open for the \$800 million COVID-19 Pandemic Small Business Recovery Grant Program. The New York State Fair will reopen this summer at 100% capacity with all buildings open.

## **U.S. Government**

- [\*Biden vows to continue to provide vaccines to world's poorest nations, hints U.S. may make another donation\*](#), June 13
  - President Biden vowed Sunday that the United States would continue to provide vaccines to the world's poorest countries to curb the coronavirus pandemic, hinting that it may make another substantial donation of vaccine doses next year.
  - The president said he did not want to make commitments before they were finalized, but added that the United States may "be in a position to provide another billion" doses over the next two years.
- [\*A judge dismisses Houston hospital workers' lawsuit about vaccine mandates\*](#), June 13
  - On Saturday, a federal judge in Texas [dismissed](#) a lawsuit brought by employees of Houston Methodist Hospital who had challenged the hospital's coronavirus vaccination requirement.
  - U.S. District Judge Lynn N. Hughes, of the Southern District of Texas, said that the hospital's decision to mandate inoculations for its employees was consistent with public policy.

## **Vaccines and Therapeutics**

- [\*Novavax says Covid-19 vaccine shows 90.4% overall efficacy in US/Mexico Phase 3 trial\*](#), June 14
  - In a Phase 3 trial of 29,960 individuals in the United States and Mexico, the Novavax vaccine, which unlike other vaccines introduces the body directly to COVID-19's protein spike, yielded a 90.4% efficacy rate against COVID-19. It was also found to have prevented 100% of severe and moderate cases.
  - The vaccine was "generally well-tolerated" and participants experienced a normal range of side effects.
  - These results bolster the vaccine's Phase 3 trial in the UK, which also yielded a high efficacy rate: 96.4% against the original strain, and 86.3% against the B.1.1.7 variant.
  - Novavax plans to apply for emergency use authorization by third quarter 2021, and is "on track" to manufacture 100 million doses by the end of that quarter.
- [\*Moderna's Covid-19 Vaccine Seeks FDA Authorization for Use in Adolescents\*](#), June 10
  - On June 10, Moderna applied for FDA authorization to allow use of its vaccine on adolescents aged 12 to 17. Moderna will present the results of a May study showing that its vaccine was both safe and effective for this age group.
  - If approved, Moderna's would be the second vaccine permitted for adolescent use, following approval of the Pfizer vaccine in May. Seven million Americans under the age of 18 have received a vaccination to date. Studies are now underway to test the efficacy of various vaccines on children below the age of 12. This comes amid a push by experts to vaccinate adolescents and build herd immunity.
- [\*F.D.A. details failures at a Baltimore plant that led to unusable vaccine doses\*](#), June 12
  - On June 11, the FDA ordered Johnson & Johnson (J&J) to throw out the equivalent of 60 million doses of its vaccine due to concerns about contamination in the Baltimore facility where it was produced. 15 million doses worth of the J&J vaccine had already been disposed due to concerns about contamination at this facility.
  - The Baltimore facility has been closed for two months while the FDA investigates. The FDA ultimately found that Emergent BioSolutions, which operates the facility, failed to

segregate zones where staff worked on the J&J vaccine from zones where staff worked on the AstraZeneca vaccine, which is also manufactured at the facility. Lacking evidence that cross-contamination would not impact effectiveness or safety, the FDA concluded there were grounds for disposing of the doses at issue.

- The FDA also cited other lapses in safety practices at the facility, including crowded manufacturing areas and inadequate quality assurance.

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

- [\*COVID Data Tracker Weekly Review\*](#), April 30
  - CDC summarized key COVID-19 disease indicators for last week.
  - As of June 11, the seven-day average number of daily new cases reported was 13,997. This is a 6.0% decrease compared to the previous week's average, and an overall 94.4% decrease compared to the national peak on January 10, 2021.
  - As of June 10, 305.7 million vaccine doses have been administered in the United States. Overall, approximately 172.4 million people in the United States have received at least one dose of vaccine, which is 51.9% of the population. Approximately 141.6 million people are fully vaccinated, which is 42.6% of the population. The seven-day average number of reported vaccine dose administrations was 1.1 million, a 13.87% increase compared to the previous week.
  - As of June 8, the seven-day average of new daily hospital admissions was 2,239, a 12.8% decrease compared to the previous week's average.
  - As of June 9, the seven-day average of reported deaths was 347 per day, a 1.9% increase compared to the previous week's average.
- [\*CDC estimates Alpha variant made up 66 percent of COVID-19 cases in April\*](#), June 10
  - According to CDC [data](#), the "Alpha" COVID-19 variant (B.1.1.7) comprised 66% of US COVID-19 infections in mid-April. For comparison, in December 2020, the Alpha variant only constituted 0.2% of such infections.
  - The "Gamma" variant has also proliferated in the US, increasing from 0.1% of all US COVID-19 infections in early January to 5% of infections by mid April.
- [\*CDC says U.S. travelers can avoid wearing masks in outdoor transit hubs, ferries\*](#), June 10
  - On June 10, the CDC announced it will no longer require travelers to wear masks in outdoor transit hubs and in outdoor spaces on ferries, buses and trolleys, due to the lower risk of coronavirus transmission outdoors.
  - Leading up to the announcement, the Biden administration had conducted extensive discussions with transit unions and related groups. The White House is also considering relaxing indoor mask policies for airline workers.

## **New York State**

- [\*New York State COVID-19 Updates\*](#), June 14
  - New York reported 7 deaths, 617 hospitalizations, and 163 COVID-19 patients in intensive care on June 13, 2021.
  - Approximately 320, or .52%, of the 61,634 tests administered in New York on June 13 were positive for COVID-19.
  - As of June 13, New York has administered 20,099,155 doses of the vaccines to patients; 55.7% of New York residents have received at least one dose of the vaccines; and 49.2% are fully vaccinated.

- Governor Cuomo [announced](#) that applications are now open for the \$800 million COVID-19 Pandemic Small Business Recovery Grant Program. The program reimburses New York Small businesses with grants of up to \$50,000 for COVID-19 related expenses from March 1, 2020 to April 1, 2021.
- The New York State Fair will [reopen](#) this summer at 100% capacity with all buildings open.

### **New York City**

- [New York City COVID-19 Updates](#), June 14
  - Beginning Monday, June 14, New York City’s senior centers will [reopen](#) for indoor and congregate activities.
  - Mayor Bill de Blasio [announced](#) that the first phase of recreation center reopenings will begin on June 14. To prevent overcrowding, centers will open to existing members who were active as of March 2020.

### **International**

- Media in [Britain](#) reported Monday that Prime Minister Boris Johnson was set to delay the widely anticipated lifting of all COVID-19-related restrictions under pressure from rising infections linked to a more virulent variant of the coronavirus (delta). The British cabinet late on Sunday agreed to postpone the final relaxing of all restrictions from June 21 — also nicknamed by many in Britain as “freedom day” — for at least another four weeks until July 19.
- In [Germany](#), where infection rates have been steadily falling for weeks, masks are still obligatory nearly everywhere. However, the country’s health minister, Jens Spahn, said on Monday that states could start setting their own policies governing masks — at least for outdoor areas — as the average number of recorded infections drops under 1,000 per day.
- In the first statistics of their kind released in the [United Arab Emirates](#), the Dubai Health Authority said over the weekend that 20 percent of those testing positive for the coronavirus had already been vaccinated.

Other recent events covered in detail elsewhere:

- [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
- [CMS Publishes 2022 Hospital IPPS/LTCH PPS Proposed Rule](#), May 5
- [Annual Meetings, Compensation and COVID-19: Where Things Stand](#), April 13
- [Managing Volatility in a Pandemic? Document your Derivatives Transactions Appropriately](#), April 13

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