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Inside C2

# Southern DAILY

Make Today Different

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## U.S. could authorize Pfizer COVID-19 shot for kids age 5-11 in October

Sept 10 (Reuters) - Top U.S. health officials believe that Pfizer Inc's (PFE.N) COVID-19 vaccine could be authorized for children aged 5-11 years old by the end of October, two sources familiar with the situation said on Friday.

The timeline is based on the expectation that Pfizer, which developed the shot with Germany's BioNTech (22UAY.DE), will have enough data from clinical trials to seek emergency use authorization (EUA) for that age group from the U.S. Food and Drug Administration (FDA) towards the end of this month, the sources said.

They anticipate the FDA could make a decision on whether the shot is safe and effective in younger children within three weeks of the EUA submission.

The decision on whether to authorize a vaccine for younger children is eagerly anticipated by millions of Americans, particularly parents whose children started school in recent weeks amid a wave of infections driven by the Delta variant.

Top U.S. infectious disease expert Dr. Anthony Fauci outlined the timetable during an online town hall meeting attended by thousands of staff at the National Institutes of Health (NIH) on Friday, according to one of the sources. A second source familiar with the situation said that the FDA anticipated a similar timeline for Pfizer.

If Pfizer submits its EUA by the end of September, and the data support its use, "by the time we get to October, the first couple of weeks of October... the Pfizer product will likely be ready," Fauci said, according to the source.

Fauci said that Moderna Inc (MRNA.O) will likely take about three weeks longer than Pfizer to collect and analyze its data on children age 5-11, according to the source. He estimated that a decision on the Moderna shot could come around November, according to the source. The second source said Fauci's timeline for Moderna appeared "optimistic." A nurse fills a syringe with Pfizer vaccine as mobile vaccination teams begin visiting every Los Angeles Unified middle and high school campus to deliver first and second doses of the coronavirus disease (COVID-19) vaccines in Los Angeles, California, U.S., August 30, 2021. REUTERS/Mike Blake

Officials at Pfizer, Moderna and NIH did not immediately comment.

Pfizer has previously said that it would have data on children age 5-11 ready in September and planned to submit for an EUA shortly after. Previously, federal health regulators, including Fauci, have suggested that an FDA decision might come in November or later. Moderna on Thursday told investors it expected data from its children's study by the end of the year.

Earlier on Friday, the FDA said it would work to approve the COVID-19 vaccines for children quickly once the companies submitted their data. It said it would consider applications based on a faster path to authorize the shot for emergency use.

Such emergency authorization requires companies to submit two months of safety data on trial participants, versus six months required for full licensure.

Pfizer partner BioNTech told Der Spiegel that it also expects to request authorization globally for the COVID-19 vaccine in children as young as five over the next few weeks and that preparations for a launch were on track.



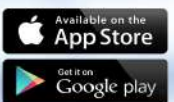
A nurse fills a syringe with Pfizer vaccine as mobile vaccination teams begin visiting every Los Angeles Unified middle and high school campus to deliver first and second doses of the coronavirus disease (COVID-19) vaccines in Los Angeles, California, U.S., August 30, 2021. REUTERS/Mike Blake



A parent walks their children on the first day of school, amid the coronavirus (COVID-19) pandemic, at West Tampa Elementary School in Tampa, Florida, U.S., August 10, 2021. REUTERS/Octavio Jones



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# WEA LEE'S GLOBAL NOTES

## CORONAVIRUS DIARY

09/11/2021

### Scars of History - 911

Twenty years ago terrorists crashed hijacked planes into New York's World Trade Center, the Pentagon and into a field in Pennsylvania killing nearly 3,000 people as smoke poured from the Twin Towers over Manhattan on the morning of September 11, 2001.

President Biden will be accompanied by First Lady Jill Biden when he visits lower Manhattan today. His visit will come less than two weeks after the last U.S. troops



departed from Afghanistan on August 31 ending the twenty years of war that was launched as a response to the 2001 attacks. On Friday President Biden also signed an executive order that would require the review, declassification and release of classified government documents related to the terrorists' attacks.

Up until today, the world still

is in chaos and the COVID-19 virus is still attacking our community and the entire world. So many people are still suffering even twenty years after the 911 attacks.

When we look back on history, the world leaders really need to have a plan for peace. War cannot solve the problem.

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**Southern DAILY** Make Today Different

## Editor's Choice



Firefly Aerospace's first Alpha rocket suffers a catastrophic anomaly during its first launch leading to the loss of the vehicle 2 minutes, 30 seconds after liftoff from Vandenberg Space Force Base, California, September 2. REUTERS/ Gene Blevins



People look at the damage caused by heavy rainfall in the municipality of Ecatepec, that left two persons missing and damaged cars and infrastructure, in the outskirts of Mexico City, September 7. REUTERS/ Edgard Garrido



Jennifer Lopez and Ben Affleck arrive in Venice the day before the screening of "The Last Duel", in Venice, Italy, September 9. REUTERS/Yara Nardi



The statue of Confederate General Robert E. Lee, the largest Confederate statue remaining in the United States, is removed by a construction team in Richmond, Virginia, September 8. REUTERS/Evelyn Hockstein



Workers paint over a graffiti depicting jailed Belarusian opposition politician Maria Kolesnikova in Saint Petersburg, Russia, September 8. The sign reads: "For our and your freedom". REUTERS/David Frenkel



A reveler wearing a protective mask calls a steer during the first running of the bulls fiesta since the coronavirus pandemic began in Villaseca de la Sagra, central Spain, September 5, 2021. REUTERS/Sergio Perez



## CDC Director: Studies Show COVID-19 Vaccine Effectiveness ‘Declining’ Against Delta Variant



Dr. Rochelle Walensky, the director of the Centers for Disease Control and Prevention, testifies during a congressional hearing in Washington on March 18, 2021. (Susan Walsh/Pool/AFP via Getty Images)

Compiled And Edited By John T. Robbins, Southern Daily Editor

Dr. Rochelle Walensky, the head of the Centers for Disease Control and Prevention (CDC), said that data sourced from Israel on COVID-19 vaccines show that the efficacy of the shots has dropped among individuals who received their vaccines early on. Citing three studies that were released by the CDC's Morbidity and Mortality Weekly Report, Walensky said on Aug. 18 that the vaccines' efficacy decreases over time in preventing infection. Although protection against death and hospitalization is "holding up well," the COVID-19 vaccines' effectiveness is "waning" in even preventing severe illness or death, she said.

"Even though our vaccines are currently working well to prevent hospitalizations, we are seeing concerning evidence of waning vaccine effectiveness over time and against the Delta variant," Walensky said during a news conference in explaining why federal officials are now recommending that booster shots be given to Americans eight months after they've been vaccinated with the Pfizer or Moderna shots.

The two vaccines, the most widely used

in the United States, were pegged at 95 percent and 94.1 percent effective, respectively, when granted emergency use authorization in December 2020. But the efficacy against infection has plummeted to 53.1 percent for both vaccines, one of the new studies found.



**A UK study suggests that COVID-19 vaccines are effective against the Delta variant after two doses, although the protection they offer begins to fall after 30 days.**Credit: Ian Forsyth/Getty Researchers with the CDC's COVID-19 Response Team and the Vermont-based Lantana Consulting Group discovered that the two doses of mRNA-based vaccines were about 75 percent effective in

preventing infection in nursing home residents from March through May. During June and July, though, the number dropped by 22 percent.

"Because nursing home residents might remain at some risk for SARS-CoV-2 infection despite vaccination, multiple COVID-19 prevention strategies, including infection control, testing, and vaccination of nursing home staff members, residents, and visitors, are critical. An additional dose of COVID-19 vaccine might be considered for nursing home and long-term care facility residents to optimize a protective immune response," the researchers, who analyzed weekly data from the Centers for Medicaid and Medicare, wrote.



**People who have had Covid-19 gain even more antibodies when fully vaccinated.**

Another study analyzed age-adjusted vaccine effectiveness in New York City between May 3 and July 25. Researchers with the New York State Department of Health and the University at Albany School of Public Health found that effectiveness against infection for adults dropped to 79.8 percent from 91.7 percent. They also said that data from four databases, including the Citywide Immunization Registry, showed that vaccine effectiveness (VE) against hospitalization "was relatively stable," ranging from 91.9 percent to 95.3 percent.

"These findings support a multipronged approach to reducing new COVID-19 hospitalizations and cases, centered on vaccination, and including other approaches such as masking and physical distancing," the researchers said, including additional vaccine doses.

The third study evaluated 1,129 fully vaccinated patients at 21 hospitals across 18 states. Researchers, including scientists from the University of Iowa, the University of Michigan, and Washington University, said the effectiveness of the Pfizer and Moderna vaccines against hospitalization declined to 84 percent between 13 and 24 weeks after vaccination from 86 percent between two and 12 weeks after vaccination.



Without booster shots, Walensky suggested, there will be "worsening

infections over time" among those who have been vaccinated against COVID-19. In the backdrop of the CDC's findings, Walensky said that "we are planning for Americans to receive booster shots starting next month," saying that their initiative is designed to "stay ahead of this virus."

As a result, booster doses of the mRNA vaccines made by Pfizer and Moderna will likely be distributed starting the week of Sept. 20. White House COVID-19 response coordinator Jeff Zients and Surgeon General Dr. Vivek Murthy told reporters during the news conference, however, that their plan is contingent on whether the CDC and Food and Drug Administration authorizes the booster doses. The CDC's advisory panel last week recommended booster shots for immunocompromised individuals, a day after drug regulators issued emergency use authorization for third shots for the population. Some outside scientists expressed concern about the move, which could inhibit efforts to get vaccines to developing countries.

"I'm truly disappointed. This decision is not justifiable at all looking at this data. We are going to use up millions of doses to reduce the small risk of mild infections in fully protected people with a tiny risk of hospitalization, while most of the world waits for a first dose," Dr. Muge Cevik, an infectious disease expert at the University of St. Andrews's School of Medicine, wrote on Twitter.



"The message I got from reading all three [studies] was that there may be some reduction in infection protection with delta in nursing homes, but no data about waning protection from severe disease or hospitalization," Dr. Walid Gellad, professor of medicine at the University of Pittsburgh's School of Medicine, added. Weeks ago, the CDC and FDA said that individuals "do not need a booster shot at this time," contradicting a recommendation made by Pfizer. Last week, the CDC director told The Wall Street Journal that she's "really struggling" with how to communicate the CDC's findings and recommendations to the American public. (Courtesy <https://www.theepochtimes.com/>)

**Related COVID Vaccines Protect Against Delta,**

## COMMUNITY

## U.S. Adults To Be Offered COVID Booster Shots In Sept.



Compiled And Edited By John T. Robbins, Southern Daily Editor

The Biden administration announced a plan for U.S. adults who received either Pfizer or Moderna's COVID-19 vaccine to receive booster shots starting in late September.

"Having reviewed the most current data. It is now our clinical judgment that the time to lay out a plan for COVID-19 boosters is now," said Surgeon General Vivek Murthy, MD, MBA, during a briefing of the White House COVID-19 Response Team on Wednesday. "Recent data makes clear that protection against mild and moderate disease has decreased over time."

This decline in protection appears to be due both to waning immunity and to the strength and pervasiveness of the Delta variant, he said. "Even though this new data affirms that vaccine protection remains high against the worst outcomes of COVID, we are concerned that this pattern of decline we are seeing will continue in the months ahead, which could lead to reduced protection against severe disease, hospitalization, and death," Murthy said. According to a joint statement from the CDC, FDA, NIH, and National Institute of Allergy and Infectious Diseases that laid out the details of the administration's plan, the boosters will be offered starting the week of September 20 to U.S. adults who received their second mRNA dose at least 8 months earlier.

"We are not recommending that you go out and get a booster today," Murthy clarified. The first shots will be given to people vaccinated earliest in the rollout: healthcare providers, residents and staff at long-term care facilities, and other seniors.

The plan is contingent on both the FDA completing an independent review of the safety and

effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and on the CDC's Advisory Committee on Immunization Practices (ACIP) recommendations after review of the evidence, the joint statement explained.



**CDC Director Rochelle Walensky, MD.** "Our plan is to protect the American people and to stay ahead of this virus," said CDC Director Rochelle Walensky, MD.

In explaining the new decision, she offered three key points: vaccine-induced protection does decline over time, effectiveness against hospitalization and death "remains relatively high," and the vaccines are generally less effective against Delta. New CDC data released in the Morbidity and Mortality Weekly Report (MMWR) on Wednesday showed that in New York state, vaccine effectiveness against infection declined from 91.7% to 79.8% from the period of May 3 to July 25, as the Delta variant became dominant. Effectiveness against hospitalization, however, was stable (91.9% to 95.3%).

Another MMWR of long-term care facilities in CDC's National Healthcare Safety Network reported declining effectiveness of the mRNA vaccines during Delta, dropping from an adjusted effectiveness rate of 74.7%

pre-Delta (March to May) to 53.1% during the period of Delta (June-July).

"Taken together, these data confirm that while protection against infection may decrease over time, protection against severe disease and hospitalization is currently holding up pretty well," said Walensky.

"Preliminary data" from two vaccine cohort effectiveness studies involving more than 4,000 healthcare personnel, first responders, and other frontline workers at eight different sites indicated "waning effectiveness against symptomatic and asymptomatic infection ... from 92% prior to Delta to 64% with Delta," Walensky added.



The effectiveness decreased against Delta, regardless of when an individual was vaccinated, she noted. "These data suggests full vaccination in the context of the Delta variant may be correlated with less protection against SARS-CoV-2 infection than against prior variants."

NIAID Director Anthony Fauci, MD, presented the immunological argument for recommending a third vaccine dose. He said that "regardless of the variant," antibody levels decline over time in fully vaccinated people, highlighting a recent study in Science. Higher antibody levels, meanwhile, are associated with better protection, he said, citing a recent preprint. Importantly, boosters with the Moderna vaccine have been shown to increase antibody titers by "at least 10-fold, and likely much more," said Fauci, adding that Pfizer has shared "similar data."

"So you get a dramatic increase in antibody titers when you do a third immunization dose," he said. Altogether, the current studies "support the use of a third booster mRNA immunization to increase the overall level of protection." The new guidance on boosters is restricted to recipients of Pfizer or Moderna's COVID shots, and do not apply to individuals who received the Johnson & Johnson vaccine, the rollout of which began later than the mRNA vaccines.

"We expect more data on J&J in the coming weeks," said Murthy. "With those data in hand, we will keep the public informed with a timely plan for J&J booster shots."

Murthy and other members of the response

teams continued to underscore the urgency of getting shots to unvaccinated Americans and people around the world, given that virtually all cases that have led to severe disease, hospitalization and death occurred in unvaccinated people. (Courtesy <https://www.medpagetoday.com/>)

**Related U.S. Surgeon General Urges U.S. Fight Against COVID Misinformation**

U.S. Surgeon General Vivek Murthy on Thursday called for a national effort to fight misinformation about COVID-19 and vaccines, urging tech companies, health care workers, journalists and everyday Americans

**But Their Effectiveness Weakens Over Time**

A massive UK study of COVID-19 cases shows that people who are jabbed have good immunity at first, but quickly become more vulnerable to the fast-spreading Delta variant. While the Pfizer-BioNTech and Oxford-AstraZeneca COVID-19 vaccines are effective against the highly infectious Delta variant of SARS-CoV-2, their protection drops away over time, a study of infections in the United Kingdom has concluded. Researchers at the University of Oxford, UK, and the country's Office for National Statistics analysed a vast data set comprising the results of 2,580,021 PCR tests to check for SARS-CoV-2 from 384,543 UK adults between 1 December 2020 and 16 May 2021 — when the Alpha variant was dominant — and 811,624 test results from 358,983 people between 17 May and 1 August 2021, when the Delta variant was more prevalent.



The results, published in a preprint on 19 August, suggest that both vaccines are effective against Delta after two doses, but that the protection they offer wanes with time. The vaccine made by Pfizer in New York City and BioNTech in Mainz, Germany, was 92% effective at keeping people from developing a high viral load — a high concentration of the virus in their test samples — 14 days after the second dose. But the vaccine's effectiveness fell to 90%, 85% and 78% after 30, 60 and 90 days, respectively.

The vaccine developed by Oxford and the pharmaceutical company AstraZeneca in Cambridge, UK, was 69% effective against a high viral load 14 days after the second dose, falling to 61% by 90 days. The drop in effectiveness shouldn't be cause for alarm, says Sarah Walker, a medical statistician at the University of Oxford who led the study. For "both of these vaccines, two doses are still doing really well against Delta", she says.

The data also suggest that the time between doses of vaccine doesn't affect vaccine effectiveness, and that people who have previously tested positive for COVID-19 as well as receiving two vaccine doses have the best protection against future infection. (Courtesy <https://www.nature.com/>)

the White House. "We must confront misinformation as a nation. Lives are depending on it." Given the role the internet plays in spreading health misinformation, Murthy said technology companies and social media platforms must make meaningful changes to their products and software to reduce the spread of misinformation while increasing access to authoritative, fact-based sources.

Too often, he said, the platforms are built to encourage, not counter, the spread of misinformation.

"We are asking them to step up," Murthy said. "We can't wait longer for them to take aggressive action."

**U.S. Surgeon General Murthy said, "Social media platforms are built to encourage, not counter, the spread of misinformation...." But the social media platforms have defended their work to stem the tide of misinformation.**

The criticism is not new, and Facebook, YouTube, Twitter and other platforms have defended their work to stem the tide of misinformation.

"We agree with the surgeon general," Twitter said in a statement. "Tackling health misinformation takes a whole-of-society approach." Murthy's recommendations went beyond tech firms. Teachers, he said, should expand lessons on media literacy and critical thinking. Journalists, he suggested, should work to responsibly debunk health misinformation without inadvertently spreading it further. And public health professionals, he added, should do a better job answering questions and explaining why public health guidelines sometimes change based on new information. As for everyday Americans, Murthy urged them to verify questionable health information with trusted sources like the U.S. Centers for Disease Control and Prevention and to exercise critical thinking when exposed to unverified claims.



"If people have loved ones or friends who believe or spread misinformation, he said, it's best to engage by listening and asking questions rather than by confronting them. Misinformation hasn't just harmed our physical health — it has also divided our families, friends, and communities," Murthy wrote in the advisory. "The only way to address health misinformation is to recognize that all of us, in every sector of society, have a responsibility to act."

(Courtesy <https://apnews.com/>)