# FDA Advisors Favor COVID Vaccine Booster for People 65 and Older

The committee voted against third shot for all adults, however, casting doubts on Biden's booster plan.

September 18, 2021 By Liz Highleyman

---

The Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee voted unanimously on September 17 to recommend a third dose of the Pfizer-BioNTech COVID-19 vaccine for people ages 65 and older, those prone to severe disease and those at high risk for occupational exposure to the coronavirus.

But at the close of a contentious all-day meeting, the committee declined to recommend boosters for all adults by a vote of 16 to 2, citing a lack of evidence that healthy younger people need an additional dose at this time. The decision only applies to people who received two doses of the Pfizer-BioNTech vaccine. The FDA will soon review data on boosters for people who received a double dose of the Moderna vaccine or the single-shot Johnson & Johnson vaccine.

The Pfizer-BioNTech vaccine, also known as BNT162b2 or Comirnaty, was granted emergency use authorization for people ages 16 and older on December 11, 2020, and full approval on August 23, 2021; it was authorized for teens ages 12 to 15 in May. Last month, the FDA authorized a third dose of the Pfizer-BioNTech or Moderna vaccine for moderately to severely immunocompromised people.

In mid-August, the Biden administration announced plans to offer boosters to all adults starting September 20. Under this plan, additional doses would be given several months after the second shot in the same order as the initial roll-out, starting with older individuals and health care workers.

Some experts say the plan was premature, arguing that there's little evidence that young healthy people need a booster now—or maybe ever. What's more, some stress that it would be more beneficial to focus on getting first and second shots to more people, both in the United States and worldwide. Administration officials say the two goals are not in conflict.

Those in favor of boosters say they could shore up waning immunity in the face of the highly transmissible delta variant of SARS-CoV-2, the coronavirus that causes COVID-19. The vaccines do

not provide as robust protection against infection with delta compared with earlier variants. A growing number of vaccinated individuals are testing positive for the virus, but usually with only mild or moderate symptoms.

Some experts feel that the first two Pfizer-BioNTech doses, spaced just three weeks apart, have been given too close together. Studies in the United Kingdom, where second doses were delayed to enable more people to get a first dose as soon as possible, have seen stronger responses. Several vaccines for other illness are given as three-dose regimens with the third shot four to six months after the second. The booster under consideration is a third dose of the same vaccine, not a new vaccine designed to target the latest variants, as annual flu vaccines do.

But others emphasize that vaccines remain highly effective at preventing hospitalization and death. A recent study from the Centers for Disease Control and Prevention (CDC) found that all three vaccines available in the U.S. continue to prevent severe illness, but suggests that the Moderna vaccine—which contains a higher dose of mRNA in each shot and is spaced four weeks apart—may provide better protection. Among non-immunocompromised adults, effectiveness against hospitalization from mid-March through mid-August was 93% with the Moderna vaccine, 88% with the Pfizer-BioNTech vaccine and 71% with the J&J vaccine.

> New @CDCMMWR shows all 3 #COVID19 vaccines used in the US provide strong protection against COVID-19 hospitalizations. The best vaccine is the one that's available to you now. #SleeveUp. More: https://t.co/cSIE2yXeCI pic.twitter.com/kKBFg1rVHx
>
> — CDC (@CDCgov) September 17, 2021

Antibody levels normally fall after natural infection or vaccination, but memory B cells can produce new ones, and T cells attack cells infected with viruses. B-cell and T-cell responses prevent the coronavirus from multiplying out of control, entering the lungs and causing severe illness. But this process takes a few days, which can give the virus time to replicate in the nose, cause mild illness and spread to other people.

Pfizer representatives, CDC officials, experts from Israel and the U.K. and others at the advisory committee meeting presented evidence that immunity is waning against delta infection, and a third Pfizer-BioNTech shot raises antibody levels, as expected. A recent study from Israel showed that a booster dose lowered the risk of severe illness for people ages 60 and older. But younger

age groups—and even older people, in some studies—remain well protected against hospitalization and death after the first two doses. What's more, given that younger people have a lower risk of severe COVID-19, there's concern that the benefits of a third dose might not outweigh the risk of rare vaccine side effects, including myocarditis (heart muscle inflammation).

The FDA is charged with authorizing vaccines and medications based on the risk-benefit balance for individuals—not their impact on public health, cost or global equity. The FDA is not required to follow advisory committee recommendations, but it usually does so.

The CDC then makes recommendations about how best to use FDA-authorized vaccines. The agency's Advisory Committee on Immunization Practices will meet September 22 and 23 to discuss third dose recommendations. The public can watch the virtual meeting online.

The CDC's purview does include consideration of public health benefits, such as reducing viral transmission. However, it remains unclear whether a third dose will substantially reduce transmission, which is driven mainly by unvaccinated people.

If the CDC recommends a third dose, it will raise questions about whether it will be required to be considered "fully vaccinated" under vaccine mandates. But a decision not to recommend boosters for all adults could set the stage for disappointment.

"Weeks ago, the administration decided that the public needs cake and deserves cake, and so shall have cake," John Moore, PhD, a virologist at Weill Cornell Medicine, told the New York Times. "Now, the public expects cake and would be very annoyed if its cake was taken away at this point."

Click here for briefing documents and slide presentations from the FDA advisory committee meeting.
Click here for more news about COVID-19 vaccines.

---