

Pfizer to Seek Emergency Use Authorization for COVID Booster Shots — But CDC, FDA Say Science Is Lacking

U.S. federal health agencies and the maker of one of the most popular COVID vaccines are publicly at odds over whether fully vaccinated people will soon need a third booster shot.

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Pfizer [announced](#) Thursday it will seek [Emergency Use Authorization](#) (EUA) from the U.S. Food and Drug Administration (FDA) in August for a third dose of its COVID-19 vaccine. The drugmaker predicted those who have been fully vaccinated will need a booster shot within six to 12 months of receiving their second dose of the Pfizer vaccine.

But hours later, the U.S. Department of Health and Human Services (HHS) issued a [joint statement](#) by the FDA and Centers for Disease and Control and Prevention (CDC) saying, “Americans who have been fully vaccinated do not need a booster shot at this time.”

The statement did not explicitly [mention Pfizer](#), but said “a science-based, rigorous process” headed by the CDC, FDA and the National Institutes of Health would determine when or whether boosters were necessary.

According to the HHS statement:

“FDA, CDC and NIH are engaged in a science-based, rigorous process to consider whether or when a booster might be necessary. This process takes into account laboratory data, clinical trial data and cohort data — which can include data from specific pharmaceutical companies, but does not rely on those data exclusively.”

In a [statement to CNN](#) Friday, the World Health Organization said:

“We don’t know whether booster vaccines will be needed to maintain protection against [COVID-19](#) until additional data is collected,” adding, “limited data [is] available on how long the protection from current doses lasts, and whether an additional booster dose would be beneficial and for whom.”

Scientists “applauded the statement” from HHS, [The Washington Post reported](#), saying boosters were not imminent and the science isn’t clear on if or when they will be needed.

“My opinion right now ... is that current vaccination seems to be largely ‘holding,’” said [E. John Wherry](#), an immunologist at the University of Pennsylvania’s Perelman School of Medicine. “But the companies seem to suggest their continued follow-up of their trial patients shows concerning levels of waning of immunity. Not much of these data from the companies are publicly available yet. I agree we need as much independent data and assessment as possible on this topic.”

[John P. Moore](#), professor of microbiology and immunology at Weill Cornell Medicine, said:

“No one is saying we’ll never need a booster, but to say we need it now and give the public the impression the vaccines are failing and something needs to be done as a matter of urgency. ... The time isn’t now. The decisions that are going to be made will be made by federal agencies.”

The HHS statement followed [recommendations](#) made June 23 by the CDC’s Advisory Committee on Immunization and Practices (ACIP). Members of the ACIP COVID-19 working group said they would recommend booster shots only if there were a demonstrated decline in efficacy — not just a waning antibody response.

Boosters may be recommended if there’s a variant that’s able to evade the vaccines, according to [slides](#) presented by Dr. Sara Oliver, a medical epidemiologist with the CDC’s National Center for Immunization and Respiratory Diseases.

[Dr. Sharon Frey](#), ACIP member and clinical director of the Center for Vaccine Development at Saint Louis University Medical School, said:

“I would have to agree with the interpretation of the working group in the sense that there’s no data to support recommendations to support boosters at this time. There’s no evidence against declining protection at this time.”

Pfizer CEO insists boosters are needed

Pfizer has been working on [two different booster strategies](#) it anticipates could carry sales beyond the immediate pandemic need: a third 30 mg dose of its current vaccines and an updated vaccine that targets the South African variant.

All U.S. pharmaceutical companies involved in making COVID vaccines are working on formulating and testing booster shots to prepare for the possibility, [The Washington Post reported](#).

Pfizer [argued](#) that as antibody blood concentration wanes, boosters will be required to ensure the broad population can’t carry the virus. This would quench the epidemic faster, the company said.

Pfizer [said](#) its vaccine’s effectiveness had eroded, citing two lines of evidence outside scientists have not seen in detail. This included an [Israeli government analysis](#) that showed reduced efficacy with Pfizer’s vaccine and the [Delta variant](#), and data from Pfizer’s continued follow-up of people who were vaccinated last summer.

“While protection against severe disease remained high across the full six months, the observed decline in efficacy against symptomatic disease over time, and the continued emergence of variants, are key factors driving our belief that a booster dose will likely be necessary to maintain highest levels of protection,” [Pfizer said](#) in a statement.

Pfizer said it would submit data to regulators within weeks showing a third dose of its vaccine at six months caused antibody levels to shoot up five to 10 times higher than the original two-dose regimen. Moderna announced similar data in May.

Pfizer motivated by profit margins

Less than 24 hours after Pfizer announced plans to seek emergency use authorization of a third dose, the drugmaker’s stock [was up 1.6%](#).

Pfizer CEO Albert Bourla has [said for months](#) a booster would likely be needed within a year of the initial two-dose inoculation — followed by annual vaccinations, even as public health officials and [academic scientists](#) said it wasn’t clear yet when a booster would be needed.

Booster shots for COVID are expected to serve as a [key revenue driver](#) in the years to come for [Pfizer](#) and its primary rival in the U.S., [Moderna](#). Pfizer in May projected global sales of its COVID vaccine to reach [\\$26 billion](#) in 2021.

The company has also been frank that its [current pricing](#) — \$19.50 per dose in the U.S. — is temporary. On an earnings call in February, Frank A. D’Amelio, Pfizer’s executive vice president of global supply, [assured investors](#) the company sees the vaccine market evolving as the pandemic wanes, and will likely be able to charge more per dose than it was getting under pandemic supply deals.

D’Amelio [said](#) a more typical price for a vaccination was \$150 or \$175 per dose.

“Now, let’s go beyond a pandemic-pricing environment, the environment we’re currently in. Obviously, we’re going to get more on price,” D’Amelio said. “So clearly, there’s a significant opportunity for those margins to improve once we get beyond the pandemic environment that we’re in.”

Pfizer said it would begin testing a booster shot specifically programmed to combat the Delta variant in August, reaffirming concerns by scientists who predicted in April that pharmaceutical companies like Pfizer, would create a [vaccine treadmill](#) with continuous booster shots targeted at emerging variants.

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