

FDA OKs another Pfizer, Moderna COVID booster for 50 and up

March 29 2022, by Lauran Neergaard and Matthew Perrone



Vials for the Moderna and Pfizer COVID-19 vaccines are seen at a temporary clinic in Exeter, N.H. on Thursday, Feb. 25, 2021. The Food and Drug Administration has authorized another booster dose of the Pfizer or Moderna COVID-19 vaccine for people age 50 and up, Tuesday, March 29, 2022. Credit: AP Photo/Charles Krupa, File

Americans 50 and older can get a second COVID-19 booster if it's been at least four months since their last vaccination, a chance at extra protection for the most vulnerable in case the coronavirus rebounds.

The Food and Drug Administration on Tuesday authorized an extra dose of the Pfizer or Moderna vaccine for that age group and for certain younger people with severely weakened immune systems.

Hours later, the Centers for Disease Control and Prevention recommended the extra shot as an option but stopped short of urging that those eligible rush out and get it right away. That decision expands the additional booster to millions more Americans.

Everyone eligible for a first booster who hasn't gotten one yet needs to, FDA vaccine chief Dr. Peter Marks said. But the second booster is only for these higher-risk groups because there's evidence protection can wane and FDA decided the option "will help save lives and prevent severe outcomes."

The move comes at a time of great uncertainty. COVID-19 cases have dropped to low levels after the winter surge of the [super-contagious omicron variant](#). Two vaccine doses plus a booster still provide strong protection against severe disease and death, CDC data show.

But [an omicron sibling](#) is causing a worrisome jump in infections in Europe—and [spreading in the U.S.](#)—even as vaccination has stalled. About two-thirds of Americans are fully vaccinated, and half of those eligible for a first booster haven't gotten one.

Pfizer had asked the FDA to clear a fourth shot for people 65 and older, while Moderna requested another dose for all adults "to provide flexibility" for the government to decide who really needs one.

FDA's Marks said regulators set the age at 50 because that's when chronic conditions such as heart disease and diabetes become more common, increasing the risks from COVID-19.

Until now, the FDA had allowed a fourth vaccine dose only for the immune-compromised as young as 12. Tuesday's decision allows them another booster, too—a fifth dose. Marks said those patients are more likely to see their immune protection wane sooner and therefore can benefit more from extra protection. Only the Pfizer vaccine can be used in those as young as 12; Moderna's is for adults.

There's limited evidence to tell how much benefit another booster could offer right now. FDA made the decision without input from its independent panel of experts that has wrestled with how much data is required to expand shots.

"There might be a reason to top off the tanks a little bit" for older people and those with other health conditions, said University of Pennsylvania immunologist E. John Wherry, who wasn't involved in the government's decision.

But while he encourages older friends and relatives to follow the advice, the 50-year-old Wherry—who is healthy, vaccinated and boosted—doesn't plan on getting a fourth shot right away. With protection against severe illness still strong, "I'm going to wait until it seems like there's a need."

None of the COVID-19 vaccines are as strong against the omicron mutant as they were against earlier versions of the virus. Also, protection against milder infections naturally wanes over time. But the immune system builds multiple layers of defense and the type that prevents severe illness and death is holding up.

During the U.S. omicron wave, two doses were nearly 80% effective against needing a ventilator or death—and a booster pushed that protection to 94%, the CDC recently reported. Vaccine effectiveness was lowest—74%—in immune-compromised people, the vast majority of whom hadn't gotten a third dose.

U.S. health officials also looked to Israel, which during the omicron surge opened a fourth dose to people 60 and older at least four months after their last shot. The FDA said no new safety concerns emerged in a review of 700,000 fourth doses administered.

Preliminary data posted online last week suggested some benefit: Israeli researchers counted 92 deaths among more than 328,000 people who got the extra shot, compared to 232 deaths among 234,000 people who skipped the fourth dose.

What's far from clear is how long any extra benefit from another booster would last, and thus when to get it.

"The 'when' is a really difficult part. Ideally we would time booster doses right before surges but we don't always know when that's going to be," said Dr. William Moss, a vaccine expert at the Johns Hopkins Bloomberg School of Public Health.

Plus, a longer interval between shots helps the immune system mount a stronger, more cross-reactive defense.

"If you get a booster too close together, it's not doing any harm—you're just not going to get much benefit from it," said Wherry.

The newest booster expansion may not be the last: Next week, the government will hold a public meeting to debate if everyone eventually needs a fourth dose, possibly in the fall, of the original vaccine or an

updated shot.

Even if higher-risk Americans get boosted now, Marks said they may need yet another dose in the fall if regulators decide to tweak the vaccine.

For that effort, studies in people—of omicron-targeted shots alone or in combination with the original vaccine—are underway. The National Institutes of Health recently tested monkeys and found "no significant advantage" to using a booster that targets just omicron.

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Citation: FDA OKs another Pfizer, Moderna COVID booster for 50 and up (2022, March 29)
retrieved 24 April 2024 from

<https://medicalxpress.com/news/2022-03-fda-oks-pfizer-moderna-covid.html>

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