

FDA expected to OK additional COVID-19 booster shots for adults over 50 next week

By Brenda Goodman, CNN

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(CNN) — The Biden administration is expected to give older adults the option of getting a second Covid-19 vaccine booster as early as next week.

Two sources familiar with the government's plans said the US Food and Drug Administration is planning to authorize a fourth dose of the Pfizer and Moderna mRNA vaccines for adults over age 50 next week.

The US Centers for Disease Control and Prevention is expected to follow soon after with what's known as a permissive recommendation, which means that the shots will not be officially recommended but may be given to people who want them, said a source who spoke to CNN on the condition of anonymity since they had not been given permission to discuss the details with reporters.

Details of the plans were first reported by The New York Times.

The decision to make fourth doses available now will bypass independent groups of scientific advisers for both the FDA and CDC, which would normally meet and publicly review the available science and then make recommendations to the agencies.

Dr. Eric Topol, a cardiologist who is director of the Scripps Translational Research Institute in California, said the decision was expected next week, ahead of [an April 6 meeting](#) of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of independent experts who advise the FDA on its vaccine decisions. Boosters are on the agenda for discussion at that meeting, which will focus on future planning for boosters and variant-specific vaccines.

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Topol, who was apprised of the FDA's plans, said it was his understanding that the change would apply to both the Pfizer/BioNTech and Moderna vaccines.

Topol also said he was in favor of giving Americans the option of fourth doses.

"There are solid data from Israel for age 60+ (the only group reported on to date) for enhanced protection (vs severe illness) out to 3 months compared with 3 doses. It is reasonable to extend that and provide it as an option, since the 3rd dose has pronounced benefit in age 50+," Topol wrote in an email to CNN.

Topol noted that the FDA's move legitimizes what many Americans are doing anyway. Anyone who wants a fourth dose can go to a pharmacy and receive one just by saying that they need one because they are immunocompromised.

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Others felt there wasn't yet enough science available to support the decision.

seen enough data on fourth doses to make a determination about whether they are needed for anyone beyond those who are already recommended to get them -- adults who are severely immune deficient.

"The only data that I've seen has been for participants followed for just a few weeks. The most important information is going to be how well a fourth dose protects highly vulnerable people against serious disease and death, and I don't know when that will be available," Rubin said in an email to CNN. Rubin said the FDA might have access to that data, but he had not seen it yet.

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Dr. Paul Offit, director of the vaccine education center at the Children's Hospital of Philadelphia and a member of the FDA's VRBPAC, also said he felt the administration was acting ahead of the science.

"Where's the evidence that somebody over 50 benefits from a fourth dose? Because the evidence to date appears to support the possibility for those over 65, although I haven't, we haven't, seen all the data," Offit told CNN, speaking of the VRBPAC committee members. "But where's the evidence for a 50 to 64 year old? Where's that evidence? Because absent that evidence, then there shouldn't be this recommendation,"

he said.

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