FDA to Authorize Seventh COVID Vaccine Dose for People Over 65

The U.S. Food and Drug Administration (FDA) will authorize yet another COVID-19 vaccine dose for people who are at least 65 and have weak immune systems since the first six doses didn't work.

The FDA is expected to announce the decision in the next two weeks, and the Centers for Disease Control and Prevention is expected to "quickly endorse it," according to officials who spoke to The Washington Post under the condition of anonymity because they weren't allowed to share internal discussions.

The FDA's recommendation will be permissive – people will be allowed to get it but not required to, officials said.

The FDA has only authorized one booster dose of the new omicron bivalent COVID vaccine. Its focus as of late has been on an annual booster campaign beginning in the fall of 2023 with an updated vaccine to target whatever variant is expected

to circulate next winter. But it can't possibly miss out on the opportunity to sign off on yet another dose of an experimental vaccine that hasn't been proven safe – and for the most vulnerable of populations – before the "national emergency" ends and these doses expire.

"Those doses are going to be expiring and will be thrown out. So it makes sense to have those shots in arms instead of being tossed in the waste basket," Dr. Peter Hotez, co-director of the Texas Children's Hospital Center for Vaccine Development, told NPR.

Hotez, who is fully vaccinated and still got COVID-19, said protection from the last shot is fading, and people as young as 50 should be able to get a second bivalent booster if they want one. He provided no supporting evidence that a seventh shot is safe.

"It's better than nothing," Hotez wrote in an email about the FDA's decision to NPR. "I think 65 could be lowered to 50 or 55 unless they have specific data supporting that age cutoff."

The FDA should have data that supports giving anyone of any age an additional booster.

Officials acknowledge there is no extensive data on the bivalent vaccine, first authorized in August 2022. But they said real-world data and smaller studies show protection fades after several months. Although the CDC claims bivalent vaccines provide protection against serious illness, they support this claim with unpublished data presented at an advisory panel meeting that has not been made available to the public.

In addition, unpublished data presented at the CDC's vaccine advisory panel meeting in February confirmed earlier real-world reports that bivalent vaccines protect against serious illness – emergency room visits and hospitalizations – in adults, compared with people who received previous doses of

the original vaccine and no omicron-targeting dose.

Between the rollout of bivalent boosters in September 2022 and March 31, there have been 27,173 adverse events reported to the CDC's Vaccine Adverse Event Reporting System, with 40% attributed to Moderna's booster and 60% attributed to Pfizer/BioNTech. The data included 234 deaths, 2,093 serious injuries, and 80 reports of myocarditis and pericarditis (heart inflammation).