White House Pushes Second Booster Shot One Week After $3.2 Billion Deal With Pfizer

The Biden administration on Tuesday announced a new strategy to manage Omicron subvariant BA.5, now responsible for the majority of COVID-19 cases in the U.S.

As part of its strategy, the White House is developing a plan to allow all adults, including those under 50, to receive a second booster shot amid worries of waning immunity among those who were vaccinated and boosted six months ago.

The announcement comes one week after the Biden administration revealed it had signed a $3.2 billion deal with Pfizer for 105 million additional vaccine doses – with an option for 300 million more – to include reformulated bivalent boosters targeting Omicron BA.4 and BA.5 subvariants.

Currently, people age 5 and older are eligible to receive a first COVID-19 vaccine booster dose. A second booster shot is available only to those 50 and older and immunocompromised

individuals 12 and older.

The Biden administration hopes swiftly expanding access to booster shots will enable people who already received their first booster dose to receive reformulated shots – not yet authorized – this fall.

In addition, officials want to use up vaccine doses that are reaching their expiration dates and would otherwise be discarded, despite peer-reviewed research showing second and third doses of Pfizer's COVID-19 vaccine provide protection against the Omicron variant for only a few weeks

Expanding eligibility for booster doses within the next two weeks would allow the Biden administration to use up extra vaccine doses without "getting tangled up with the administration's planned vaccination campaign" with reformulated boosters this fall, according to The Washington Post.

Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) officials privately signaled their openness to the strategy.

"This is a really complex decision, and there are pros and cons that need to be carefully weighed," one official told The Post.

Dr. Paul Offit, director of the Vaccine Education Center at the Children's Hospital of Philadelphia and vaccine adviser to the FDA, repeatedly criticized federal officials for what he characterized as "booster mania."

"I do think [a second booster shot] does make sense for certain groups, but a universal boosting strategy doesn't make sense," Offit said.

Ruth Link-Gelles, an epidemiologist who leads the CDC's task

force on vaccine effectiveness, believes a fourth dose provides "substantial additional protection" among those with frail immune systems and healthy adults over 50. But it is "too early to draw conclusions" about a fourth dose in the broader population, she said.

According to CDC officials, there is no U.S. data showing whether a fourth booster would provide protection for people under 50.

While the booster plan still needs approval from regulators and health officials, it is backed by White House coronavirus coordinator Ashish Jha and quadruple-vaccinated Dr. Anthony Fauci, medical advisor to President Biden.

In an interview on Monday, Fauci, who recently had COVID-19 and developed rebound symptoms after taking Pfizer's Paxlovid, said he's "leaning" toward allowing second booster shots for younger adults, pending authorization from the FDA and CDC.

Fauci admitted there was not enough clinical data to strongly recommend those under 50 receive a second booster shot, but said many in that age group received their last shot in November or December and protection against the virus is waning.

Persuading those who haven't been vaccinated or fully vaccinated to "get the full regime" is "critical," Fauci said. "We also need to allow people who are under 50 to get their second booster shot, since it may have been months since many of them got their first booster."

"The threat to you is now," Fauci warned during Tuesday's White House briefing. "Immunity wanes, whether that's immunity following infection or immunity following the vaccine."

"If you were infected with BA.1, you really don't have a lot of good protection against BA.4/5," – the two Omicron strains that now make up more than 80% of circulating variants as of

last week, he added.

Contrary to Fauci's statements, studies suggest natural immunity to COVID-19 yields better protection and stronger immunity than that provided by COVID-19 vaccines.

There is currently no data on the safety or efficacy of COVID-19 boosters targeting BA.4 and BA.5 variants, as they haven't been developed yet.

White House bypasses regulatory agencies to push COVID vaccines

Although White House officials said the decision on whether to expand eligibility for a second booster dose lies with the FDA and CDC, the Biden administration has a history of circumventing the process and applying pressure to regulatory agencies to endorse its plans.

"I know that the [FDA] is considering this, looking at it," Jha said during Tuesday's White House briefing. "And I know [CDC] scientists are thinking about this and looking at the data as well. The decision is purely up to them."

Fauci said conversations about booster eligibility have been going on for a while but said the final decision lies with the FDA and CDC.

"We always talked about it, it's not something new, but we all recognize what the lines of authority are and that's what we'll be depending on," he said.

Yet, Offit said in a recent interview with ZDoggMD that he believed the "fix was in" for modified COVID-19 boosters and felt the FDA's advisory panel was led during a recent meeting to "vote yes" to reformulate boosters without critical data.

Offit said he believed modified boosters were desired by the Biden administration, which he suggested is politicizing the process.

In September 2021, two senior FDA officials stepped down after the Biden administration sidelined the agency when it announced a plan to begin offering a third booster dose to people who already received two doses of an mRNA vaccine beginning the week of Sept. 20.

At the time, booster doses for the general population had not been authorized by U.S. regulatory agencies and FDA advisors had not met to discuss data and provide recommendations to the agency on whether they should be authorized.

Dr. Marion Gruber, former director of the FDA's vaccines office and her deputy, Dr. Philip Krause, stepped down because they were upset about the Biden administration's announcement that adults should get a booster eight months after they received a second shot, said people familiar with the decision.

Neither believed there was enough data to justify offering booster shots yet, the sources said, and both viewed the announcement, amplified by President Biden, as pressure on the FDA to quickly authorize them.

U.S. health regulators said there wasn't enough data to recommend booster doses for the general population.

Yet, the White House moved forward with its plan to make Americans eligible for a third dose, even though the plan first required authorization from the FDA and CDC.

Following the controversy, both the FDA and CDC have bypassed their vaccine advisory panels to expand COVID-19 vaccines or authorize additional doses to broader age groups.

Push for second boosters motivated by fall booster campaign

The FDA on June 30 told COVID-19 vaccine manufacturers that any modifications to booster shots for fall would need to target Omicron subvariants BA.4 and BA.5.

Original vaccines based on the Wuhan strain that is no longer circulating will be used for anyone getting their primary series of shots.

The FDA's announcement came a day after the Biden administration said it had already entered into its $3.2 billion deal with Pfizer to secure additional vaccines and reformulated boosters for a fall booster campaign.

The Biden administration's deal with Pfizer was announced on June 29, only one day after the FDA's advisory panel met to discuss whether future COVID-19 booster doses should even be modified.

During the June 28 meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), the committee voted to add an Omicron component to future booster shots but did not decide whether the new booster vaccines should target BA.1 or BA.4/BA.5 before the White House signed its deal with Pfizer.

VRBPAC said it would provide guidance to the FDA in making its decision, which was rendered after the White House made its announcement it had contracted with Pfizer to produce a specific type of modified vaccine targeting the subvariants.

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said during the meeting he hoped changing the booster would "convince people to go get that booster," adding the FDA already had plans in the works to begin a booster campaign in October.

Although there have been no clinical trials to date testing modified vaccines with Omicron subvariants in humans, Marks said manufacturers will be “asked to begin clinical trials with modified vaccines containing an omicron BA.4/5 component, as these data will be of use as the pandemic further evolves.”

The FDA did not publicly disclose what data it will need to see to authorize reformulated booster shots – which is a new product – but previous decisions on whether to authorize COVID-19 vaccines for the nation’s youngest age groups involved following a small number of clinical trial participants for only one month, which is not long enough to detect how quickly vaccine efficacy wanes or to discern any long-term adverse events.