Biden Admin Signed $3.2 Billion Pfizer Deal Before FDA Decided How Boosters Should be Reformulated

The U.S. Food and Drug Administration (FDA) advised COVID-19 vaccine manufacturers on June 30 that any modifications to booster shots for fall will need to target Omicron subvariants BA.4 and BA.5, which account for more than half of new virus cases in the U.S.

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 a $3.2 billion deal with Pfizer to purchase 105 million doses of its COVID-19 vaccine for a fall vaccination campaign. The announcement said these vaccines will include supplies of new unauthorized bivalent boosters containing the original Wuhan variant and

BA.4 and BA.5 Omicron subvariants.

In a press release, Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said manufacturers seeking to update current COVID-19 vaccines were advised they should "develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a two-component (bivalent) booster vaccine so that the modified vaccines can potentially be used starting in early to mid-fall 2022."

Vaccine manufacturers have reported some data from clinical trials using Omicron BA.1 but will have to submit their data to the FDA prior to its evaluation of any potential authorization of a modified vaccine containing the omicron BA.4 and BA.5 components.

There have been no clinical trials to date testing modified vaccines with Omicron subvariants in humans, although Marks claims 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."

Marks said Pfizer-BioNTech and Moderna were not asked to change the formulation for initial doses of their COVID-19 vaccines, since the current formula "provides a base of protection against serious outcome." Instead, the agency expects this coming year to be a "transitional period when a modified booster vaccine may be introduced," he added.

The New York Times reported Pfizer and Moderna are expected to accept the FDA's recommendation to modify their booster vaccines and will start producing the reformulated doses this summer for a fall rollout if federal regulators authorize the new booster campaign.

However, as stated above, Pfizer already signed a deal to produce reformulated boosters for the Biden administration before the FDA issued recommendations.

Dr. Ofer Levy, director of the precision vaccines program at Boston Children's Hospital and an adviser to the FDA, said he supported the FDA's recommendation.

"FDA is in a tough spot," Levy said. "While regulators could benefit from more data, we also have to make a damn decision here because the fall is coming."

FDA officials said that in order to have a modified booster ready by fall, the design of the vaccine would have to be selected by early summer, as manufacturers need a three-month lead time.

Pfizer said its modified booster targeting Omicron subvariants could be ready for use in early October, while Moderna has projected availability by late October or early November.

Is three months enough time to gather solid data that would deem a reformulated booster safe and effective for the masses? No. But Pfizer likely feels that's a risk its willing to take since the government has already invested billions on a contract for new boosters and political pressure has worked numerous times in the past.

Biden admin announces multi-billion-dollar deal with Pfizer before FDA decision

The U.S. Department of Health and Human Services (HHS) on June 29 announced it had made an advance purchase of 105 million doses of Pfizer-BioNTech's vaccine for $3.2 billion, with options to buy up to 300 million doses.

The Biden administration used repurposed money to buy the additional vaccines, "betting on a next generation of boosters without knowing who might need one or how they will perform."

The contract includes a combination of adult and pediatric doses, and supplies of re-formulated booster doses that will contain the original Wuhan variant and BA.4 and BA.5 Omicron subvariants.

The announcement was made one day after the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 19 to 2 to recommend future COVID-19 booster doses be modified to include an Omicron component, and before the FDA's announced it had made recommendations to vaccine makers that their boosters should target Omicron subvariants.

"Nobody is taking the booster shots and the White House just keeps ordering them and ordering them from Pfizer – and Pfizer is on track to make $50 billion off vaccines in 2022 alone and the government keeps on ordering, said Dr. David Gortler, a pharmacologist, pharmacist, FDA and healthcare policy oversight fellow, and FDA reform advocate at the Ethics and Public Policy Center in Washington, D.C.

He added:

> *"The White House has already paid $5.3 billion and has committed to an additional $5.3 billion to Pfizer for Paxlovid. Pfizer is additionally making billions every month producing a vaccine/booster that nobody wants to take because they have seen data over the past 18 months that it is not only ineffective but unsafe according to VAERS.*
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> *"Our former FDA commissioner [Dr. Scott Gottleib] is on the board of Pfizer and had until very recently been unrelentingly promoting vaccination and boosters nonstop along with Fauci, Biden, CDC [Centers for Disease Control and Prevention] and the FDA. Pfizer itself has determined that Paxlovid doesn't work and has already ceased enrollment in its EPIC-SR Paxlovid clinical trial.*

> *"Everybody knows that viruses mutate, and promoting 2019 vaccine 'boosters' for a 2022 mutated, less virulent and non-deadly virus is asinine," Gortler added. "I'm concerned that there might be some unseemly or unholy relationship going on between the FDA, Pfizer and the White House because continuing to purchase more boosters and primary series on infants and kids certainly doesn't make any sense biologically, immunologically or pharmacologically to anyone paying attention."*

During VRBPAC's June 28 meeting, advisors did not vote on whether additional data would be needed to recommend an updated composition of the primary-series vaccines authorized for emergency use in the U.S., or whether it would be appropriate to continue to use a primary-series vaccine as a booster.

The panel also did not decide whether shots should target the Omicron BA.1 variant or BA.4 and BA.5 subvariants, leaving the decision up to the FDA, who, as stated above, didn't announce its decision until after the Biden administration announced the existence of their contract.

VRBPAC said at the close of the meeting it would provide guidance the FDA could consider when making recommendations on future COVID-19 boosters doses.

It is unknown whether any guidance was provided by VRBPAC or reviewed by the FDA before it advised vaccine makers to update boosters to target Omicron subvariants – boosters Pfizer had already contracted to produce for the Biden administration.