Tweaked COVID boosters in US must target newer omicron types

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A Northwell Health registered nurse fills a syringe with a COVID-19 vaccine at a pop up vaccination site the Albanian Islamic Cultural Center, April 8, 2021, in the Staten Island borough of New York. The Food and Drug Administration on Thursday, June 30, 2022 recommended that COVID-19 booster shots be modified to better match more recent variants of the coronavirus. Credit: AP Photo/Mary Altaffer, file

U.S. regulators told COVID-19 vaccine makers Thursday that any booster shots tweaked for the fall will have to add protection against the newest omicron relatives.

The Food and Drug Administration said the original vaccines would be used for anyone still getting their first series of shots. But with immunity waning and the super-contagious omicron family of variants getting better at dodging protection, the FDA decided boosters intended for fall needed an update.

The recipe: Combination shots that add protection against the omicron relatives named BA.4 and BA.5 to the original vaccine. Those mutants together now account for just over half of new U.S. infections.

It's still a gamble as there's no way to know if an omicron relative still will be a threat as cold weather approaches or if a newer mutant will take its place. And the current Pfizer and Moderna vaccines still offer strong protection against COVID-19's worst outcomes as long as people have gotten already recommended boosters.

But the combination approach, what scientists call "bivalent" shots, would allow the boosters to retain the proven benefits of the original vaccine while adding to its breadth of protection. It's a common vaccine strategy: Flu shots, for instance, can protect against four influenza strains and are tweaked annually depending on what's circulating.

The FDA's decision comes after its scientific advisers earlier this week recommended that any boosters for a fall campaign should contain some version of omicron—but left undecided whether it should be the omicron mutant that caused last winter's surge or the genetically distinct relatives that have replaced it.

Pfizer and Moderna already were brewing and testing boosters updated

against the first omicron mutant in anticipation of an October rollout. They found adding the extra protection was safe—and spurred production of more omicron-fighting antibodies than just getting another dose of today's vaccine.

Pfizer had begun work on another experimental dose to target the newer strains the FDA ultimately settled on.

"We're continuing to collect more data from our study on BA.4/5 and will be in touch as soon as we are ready to submit," Pfizer spokeswoman Jerica Pitts said in an emailed message.

Moderna told FDA's advisers that switching to the even newer strains now circulating might delay its booster update another month. A company spokeswoman said Moderna plans to submit its vaccine data to regulators.

The FDA's order doesn't guarantee that those combo shots would be offered in the fall. Manufacturers still have to provide key data before the agency decides whether to authorize modified boosters—and the Centers for Disease Control and Prevention then would have to decide how they're used.

For now, an all-important first booster of current vaccine already is urged for all Americans age 5 and older. People 50 and older are eligible for a second booster. With omicron, authorities say the shots' protection against COVID-19 hospitalization, while still robust, has slipped some in older adults and a second booster can help restore it.

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