

# FDA tells vaccine makers to update boosters to target omicron subvariants

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The U.S. Food and Drug Administration announced Thursday that it has asked vaccine makers to update their COVID-19 booster shots to target the omicron subvariants known as BA.4 and BA.5.

The two highly contagious subvariants now account for more than half of all new COVID cases in the United States.

"As we move into the fall and winter, it is critical that we have safe and effective vaccine boosters that can provide protection against circulating and emerging variants to prevent the most severe consequences of COVID-19," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in an agency news release.

"Vaccine manufacturers have already reported data from clinical trials with modified vaccines containing an [omicron](#) BA.1 component and we have advised them that they should submit these data to the FDA for our evaluation prior to any potential authorization of a modified vaccine containing an omicron BA.4/5 component," Marks added.

"Manufacturers will also 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 agency's decision mirrors the recommendation made Tuesday by its vaccine advisory panel that updated COVID-19 [booster](#) shots used this fall should protect against omicron and its highly contagious subvariants.

Pfizer and Moderna are expected to start producing reformulated doses this summer, *The New York Times* reported. During the expert panel meeting, Pfizer said a shot aimed at the subvariants could be ready for use in early October, while Moderna said it would be able to offer a similar shot in late October or early November.

The vaccines produced by Pfizer and Moderna typically take about three

months to produce doses of any reformulated shots, the *Times* said.

Given how fast the virus changes, lengthy human trials may have to be abandoned in favor of more laboratory tests and animal tests, the *Times* added. That's because [human trials](#) can take up to five months, which can make the vaccine obsolete before it's ever released to the public.

Both Pfizer and Moderna have been testing updated booster shots that target the omicron variant, with early trial results showing the tweaked shots boost protection against omicron. But since then, BA.4 and BA.5 have surfaced and are spreading.

"Omicron is clearly in the rearview mirror," Dr. Peter Hotez, a vaccine expert with Baylor College of Medicine in Houston, told the *Times*. An omicron booster isn't necessary unless it works against the newest omicron subvariants, but "I haven't seen evidence of that," he said.

Even the FDA said in a briefing document prepared for the advisory committee meeting that the bivalent booster targeting the original virus and omicron is "already somewhat outdated."

But Dr. Kelly Moore, president of Immunize.org, a nonprofit that works to increase vaccine rates, told the *Times* that an accelerated process is already used to update the flu vaccine each year.

Although this is the first time the process would be used with COVID vaccines, they have been safely given to hundreds of millions of people, she noted.

Updating them might call for "very well-educated guesswork," she said, that is "appropriate for the circumstances."

Still, the chance exists that the virus will change again and make the

updated vaccines ineffective.

Dr. John Beigel, a clinical research director at the U.S. National Institutes of Health, told the *Times*, "They [the new vaccines] may be old news by the time the fall comes."

In any event, a broad swath of the population will be offered booster shots, said Dr. Arnold Monto. He's a public health professor at the University of Michigan who chairs the FDA advisory panel.

"We know there's waning. We have to boost, and it's better to boost with something more relevant" than the existing vaccines, Monto told the *Times*.

But Dr. Paul Offit, a vaccine expert at Children's Hospital of Philadelphia and a member of the FDA [vaccine](#) advisory panel, countered that idea.

"Hospitalizations are down. Deaths are way down because we are protected against serious illness. That's what matters," Offit told the *Times*. Only those over 70, and those over 50 with serious underlying conditions will likely need a fall booster shot, because COVID can have serious consequences for these people, Offit added.

**More information:** Visit the U.S. Centers for Disease Control and Prevention for more on [COVID vaccines](#).

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