

FDA panel to weigh improved booster shots from Moderna, Pfizer

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A U.S. Food and Drug Administration advisory panel will vote on



Tuesday whether to recommend that updated COVID-19 booster shots be used this fall to protect against Omicron and its highly contagious subvariants.

Because the <u>virus</u> mutates so quickly, the FDA may approve the new vaccine formulations as COVID-19 cases are expected to surge again this winter. Given how fast the virus changes, lengthy <u>human trials</u> may have to be abandoned in favor of more laboratory tests and animal tests, the *New York Times* reported.

Human trials can take up to five months, which can make the vaccine obsolete before it's even released to the public, according to the *Times*.

Both <u>Pfizer</u> and <u>Moderna</u> have been testing updated <u>booster</u> shots that target the Omicron variant, with early trial results showing the tweaked shots boost protection against Omicron. Since then, subvariants of Omicron have surfaced and are spreading. As of June 18, the BA.4 and BA.5 subvariants accounted for <u>35% of all U.S. infections</u>.

"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 <u>briefing document prepared for the advisory</u> <u>committee meeting</u> that the bivalent booster targeting both the original virus and Omicron is "already somewhat outdated."

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

Beigel said one option is to stick with the existing vaccines, which continue to provide robust protection against <u>severe disease</u>, while offering very little protection against infection.

The advisory panel will likely split between those who believe a fall booster will be broadly necessary and those who would limit additional shots to high-risk individuals, the *Times* reported.

Dr. Arnold Monto, a public health professor at the University of Michigan who chairs the FDA <u>advisory panel</u>, predicted that a broad swath of the population will be offered <u>booster shots</u>.

"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 <u>vaccine</u> expert at Children's Hospital of Philadelphia and a member of the 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 who have 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 <u>COVID vaccines</u>.

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