

HEALTHCARE

FDA panel votes to greenlight updating COVID vaccines for omicron

BY JOSEPH CHOI - 06/28/22 5:10 PM ET

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An expert advisory vaccine panel for the Food and Drug Administration (FDA) on Tuesday voted in favor of recommending updated COVID-19 vaccines specifically designed to combat the omicron variant.

Among the voting members of the FDA's Vaccines and Related Biological Products Advisory Committee, 19 voted in favor of recommending an omicron-specific booster, while two voted against the endorsement.

Several members of the vaccine panel reasoned that the likely benefits of an omicron-specific vaccine — possibly a bivalent shot — outweighed the possible risks.

During the meeting, however, members brought up several possible points of contention regarding the recommendation.

Some members argued that approaching the COVID-19 pandemic like it was the flu with seasonal boosters was not the right path, pointing out that the SARS-CoV-2 virus has been shown to mutate faster than the influenza virus.

Other members noted during the meeting that an entirely different variant of the COVID-19 virus could emerge by the fall, when some health authorities are anticipating a possible new surge in cases.

Stanley Perlman, a member of the committee and a professor of immunology at the University of Iowa, expressed concerns about whether it would be appropriate globally for the U.S. to begin administering bivalent doses — believed to offer stronger protection — when much the world still lacks access to standard coronavirus vaccines.

Perlman noted that there was already a widespread feeling that the U.S. and other wealthy countries place themselves first and said it could be “ultimately a bad thing” for the U.S. to administer enhanced vaccines that the rest of the world cannot access.

However, several other members argued that time was of the essence and that it was better to have an updated booster dose available in time, rather than holding off. Both Moderna and Pfizer have shared data on candidates for possible booster doses effective against the omicron variant.

Earlier this month, Moderna announced it was submitting preliminary data on an omicron-containing bivalent COVID-19 booster. According to the company, its booster candidate was found to enhance neutralizing activity against the omicron variant by eight fold above baseline levels.

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Pfizer announced last week that its omicron-adapted candidates — one monovalent dose and one bivalent dose — had been observed to elicit multifold increases in neutralizing activity against omicron.

Pfizer said it shared its data with the FDA.

Updated at 5:52 p.m.

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