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FDA vaccine panel OKs Moderna COVID boosters for high-risk adults

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Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Booster doses of Moderna's COVID-19 vaccine for certain groups of high-risk adults took a step closer to authorization on Thursday.

A Food and Drug Administration (FDA) vaccine advisory panel voted 19-0 to recommend emergency use authorization (EUA) for Moderna boosters for the same group as Pfizer-BioNTech boosters — people ages 65 years and older, people ages 18-64 years at high risk of severe COVID-19 and people ages 18-64 years whose institutional or occupational exposure puts them at high risk of serious COVID-19 complications.

The recommendations now go to the acting FDA commissioner who will review and can issue an EUA. The Centers for Disease Control and Prevention's (CDC's) vaccine committee will discuss boosters when it meets Oct. 20-21.

Moderna's booster is 50 micrograms, half the dose used in the primary series. It would be given at least six months after the primary series to address some evidence of waning immunity against severe disease, especially for people who are older.

An FDA staff analysis of Moderna's booster data determined it met its goal for geometric mean neutralizing antibody titer ratio but not for seroresponse rates. People with lower neutralizing antibody titers before the booster were more likely to achieve at least a four-fold increase after the booster than people whose titers were higher before the booster.

The analysis also found no evidence of increased reactogenicity after a booster compared to dose 2. The only exception was axillary swelling or tenderness in the vaccination arm in people ages 18-64 years.

The vaccine committee looked at data on Israel's successful booster program, although it primarily used the Pfizer-BioNTech vaccine.

Several FDA committee members spoke on the importance of protecting people who are exposed to COVID-19 due to their jobs.

“Oftentimes, individuals who have occupational exposure are Brown or Black people … and as we know they are more likely to have underlying conditions that predispose them to severe COVID-19,” said James Hildreth Sr., Ph.D., M.D., president and CEO of the Meharry Medical College.

Hayley Gans, M.D., professor of pediatrics at Stanford University Medical Center, also pointed to the need to protect health care workers and said protection would extend to children who are too young to get vaccinated.

“We’re starting to see once again our hospitals filling up with children who have been exposed through community transmission,” she said. “This is another way of protecting them.”

Some members noted they would have liked to see more data but still voted in favor.

“The data are not perfect, but these are extraordinary times and we have to work with imperfect data,” said Eric Rubin, M.D., Ph.D., editor-in-chief of the *New England Journal of Medicine*.

The FDA committee also had an informal discussion about making mRNA boosters available to all adults, but there was little interest.

Archana Chatterjee, M.D., Ph.D., dean of the Chicago Medical School, noted COVID cases have been declining in recent weeks, and there is a paucity of data showing a need for boosters in people under 65 who don’t have other risk factors.

“I am not convinced the epidemiology of the pandemic at the moment in the U.S. supports this request,” she said. “… In this population, the people who are vaccinated appear to be protected. The disease primarily seems to be occurring, especially in its more severe form, in those who are unvaccinated.”

The panel will meet again Friday to discuss Johnson & Johnson boosters.