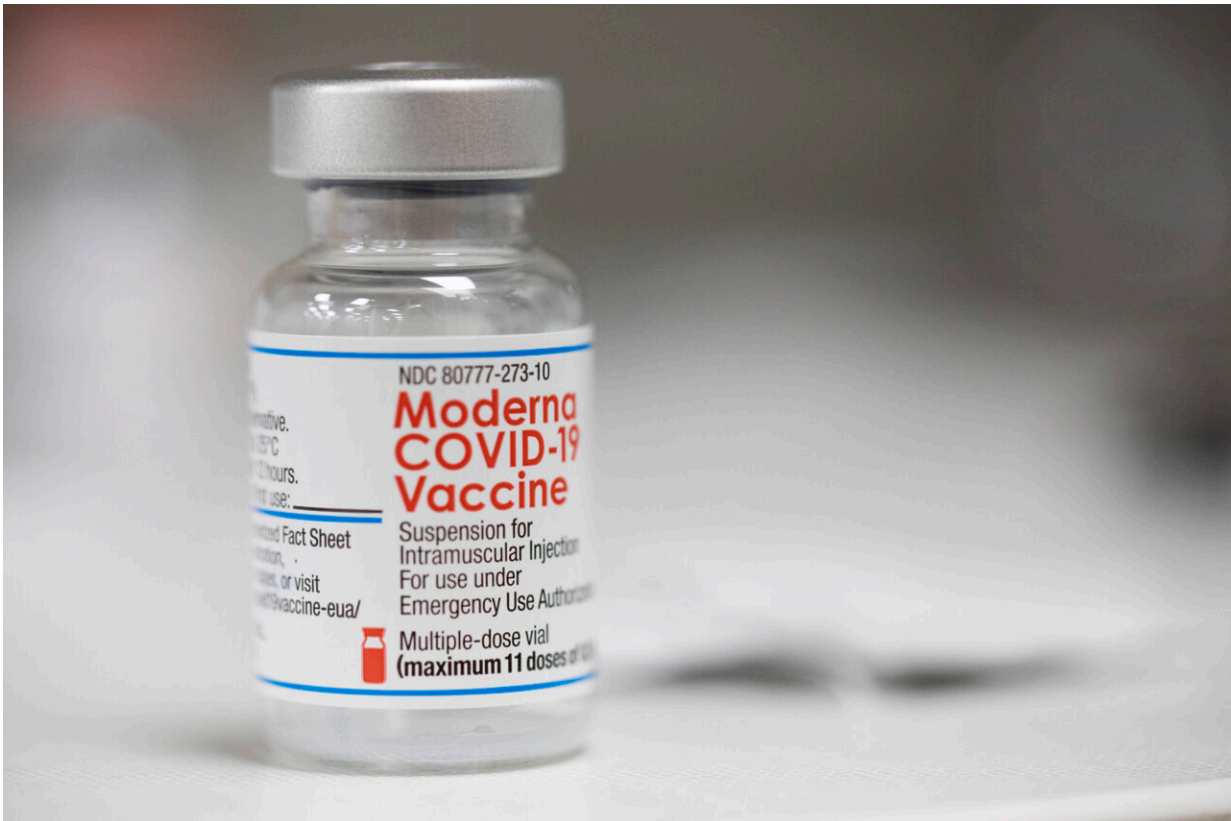


FDA advisers back Moderna's COVID-19 vaccine for older kids (Update)

June 14 2022, by Mike Stobbe



A vial of the Moderna COVID-19 vaccine is displayed on a counter at a pharmacy in Portland, Ore. on Dec. 27, 2021. A government advisory panel met Tuesday, June 14, 2022, to decide whether to recommend a second brand of COVID-19 vaccine for school-age children and teens. The Food and Drug Administration's outside experts will vote on whether Moderna's vaccine is safe and effective enough to give kids ages 6 to 17. If the panel endorses the shot and the FDA agrees, it would become the second option for those children, joining Pfizer's vaccine. Credit: AP Photo/Jenny Kane, File

A government advisory panel Tuesday endorsed a second brand of COVID-19 vaccine for school-age children and teens.

The Food and Drug Administration's outside experts voted unanimously that Moderna's vaccine is safe and effective enough to give kids ages 6 to 17. If the FDA agrees, it would become the second option for those children, joining Pfizer's vaccine.

The same FDA expert panel will meet Wednesday to consider [tot-sized shots from Moderna and Pfizer for the littlest kids](#), those under 5.

Moderna's COVID-19 vaccine has long been available for adults in the U.S. and elsewhere and more than three dozen countries offer it to older children, too. If the FDA authorizes Moderna's vaccine for teens and younger children, the Centers for Disease Control and Prevention will next decide whether to formally recommend the shots.

The Massachusetts company is seeking clearance for two doses, and plans to later offer a booster. Tuesday's vote was only for two doses—full-strength for 12-17 and half-sized doses for those 6-11.

"The data do support that the benefits outweigh the risks for both of these doses, in both of these age groups," said the CDC's Dr. Melinda Wharton, a member of the panel.

"I believe that this will provide families an important option" and may be particularly important for families who live in areas where coronavirus spread is increasing, said another panel member, Dr. Ofer Levy of Boston Children's Hospital.

The FDA held up Moderna's teen vaccine for months while it

investigated a rare side effect, heart inflammation. That's mostly a risk for teen boys and young men, and also can occur with the Pfizer vaccine. Moderna got extra scrutiny because its shots are a far higher dose.

In their review, FDA scientists said there were no confirmed cases of the heart inflammation in Moderna's kid studies. But experts say the studies may have had too few participants for a rare side effect like that to appear.

"That clearly needs to be watched closely going forward as we expand the use of the vaccine," said Dr. Mark Sawyer, a panel member from the University of California, San Diego's medical school.

As for other side effects, FDA officials said nothing worrisome was reported—mainly sore arms, headache and fatigue.

The FDA analysis concluded that two doses of Moderna are effective in preventing symptomatic COVID-19 illness in teens and younger kids, with the levels of virus-fighting antibodies comparable to those developed in young adults.

Vaccine effectiveness was estimated at 93% for the teens, and 77% for the younger children, according to the FDA analysis. However, the research was done when earlier versions of the coronavirus were causing most U.S. infections, before more contagious versions emerged. It's also based on a limited number of COVID-19 cases, making the estimates a bit rough.

A booster shot was added to the studies, and data is expected in about the next month, Moderna officials said. Booster shots are [now recommended for children vaccinated with Pfizer's shots](#), as well as for all adults.

One panel member, Dr. Paul Offit, noted that vaccine effectiveness has declined against newer variants of the coronavirus. Offit, of Children's Hospital of Philadelphia, said he supported Moderna's proposals only because he expects a third dose will be offered, which he says is needed before someone should be considered fully vaccinated.

How much demand there will be for even two Moderna shots isn't clear. Teens became eligible a year ago for Pfizer's vaccine, which uses the same technology, and only 60% have gotten two doses. Shots for younger kids started in November; about 29% have been fully vaccinated, according to the CDC.

If the FDA authorizes Moderna shots for teens and schoolchildren, a CDC spokesperson said the agency is not expected to review the vaccine until later this month.

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