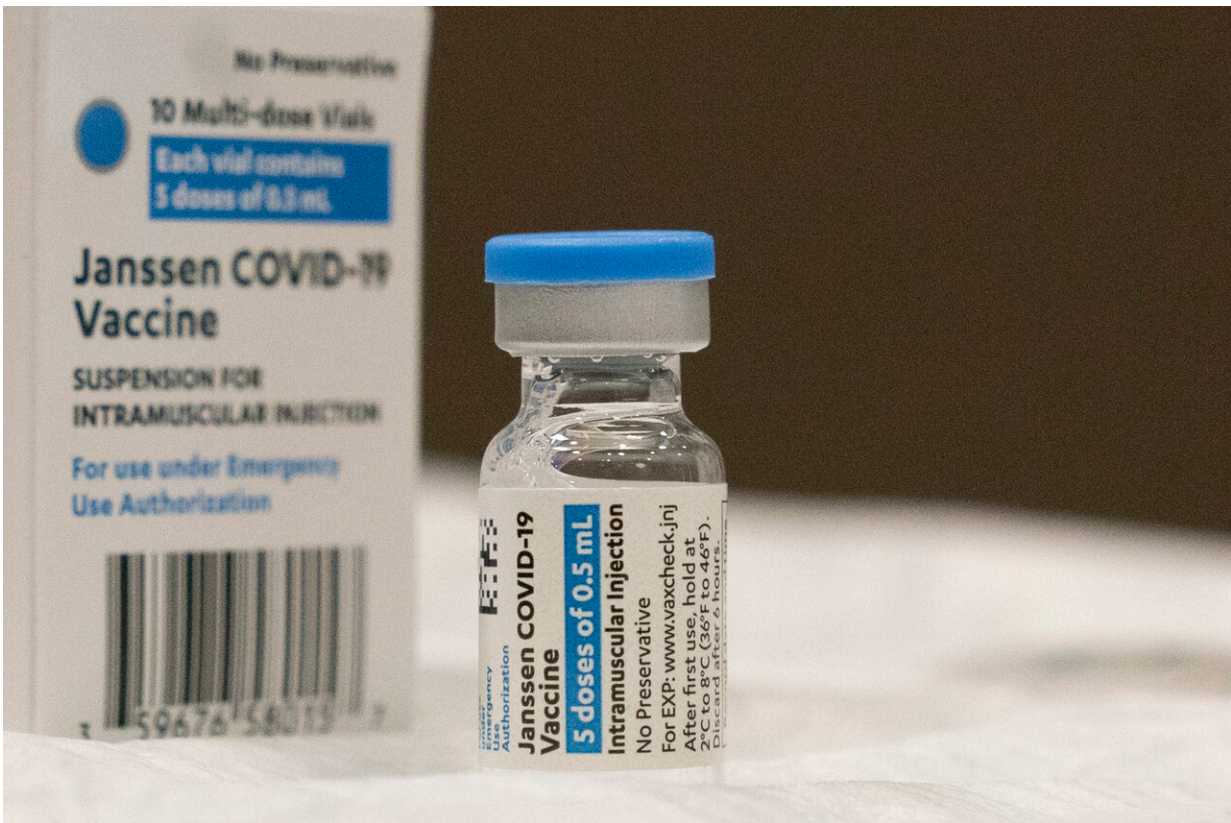


FDA panel takes up tough questions on J&J COVID-19 boosters

October 15 2021, by Matthew Perrone and Lauran Neergaard



In this March 3, 2021 file photo, a vial of the Johnson & Johnson COVID-19 vaccine is displayed at South Shore University Hospital in Bay Shore, N.Y. U.S. health advisers are meeting Friday, Oct. 15, to tackle who needs boosters of Johnson & Johnson's single-shot COVID-19 vaccine and when. Advisers to the Food and Drug Administration also will examine data suggesting that booster of a competing brand might provide better protection. Credit: AP Photo/Mark Lennihan, File

U.S. health advisers on Friday tackled who should get boosters of Johnson & Johnson's single-shot COVID-19 vaccine and when—and whether using a competing brand for the second dose might provide better protection.

The push for boosters kicked off last month after the Food and Drug Administration authorized third doses of the Pfizer [vaccine](#) for seniors and younger adults with [health problems](#), jobs or living conditions that place them at higher risk from the coronavirus. On Thursday, an FDA [advisory panel](#) unanimously recommended a half-dose booster of the similar Moderna vaccine for the same groups.

Friday, the same panel discussed a booster of J&J's vaccine—but the decision is more complex. Moderna and Pfizer asked the FDA to OK boosters at least six months after immunization, but J&J proposed a sliding schedule with an extra dose as early as two months later.

Adding another twist, the experts also will discuss preliminary data from a government "mix-and-match" study that suggested J&J recipients may have a far stronger immune response if they get either a Moderna or Pfizer booster rather than a second J&J dose.

The FDA will use its advisers' recommendations to decide whether to authorize boosters for both J&J and Moderna, likely next week, after which another government agency will rule on who should roll up their sleeves.

All three vaccines in the U.S. still offer strong protection against severe illness and death from COVID-19—and the nation's priority remains getting first doses to 66 million eligible but unvaccinated Americans who are most at risk as the extra-contagious delta variant continues to circulate.

But experts continue to debate whether there's value in using boosters to head off milder infections in most vaccinated adults, an approach proposed by the Biden administration.

FDA scientists recently flagged shortcomings in the data J&J submitted in applying for a booster dose, including little data on the strength of protection in people who got a six-month [booster](#). A review released earlier this week said a study of the two-month boost suggests "there may be a benefit."

J&J's single-shot vaccine has consistently shown lower effectiveness than the two-shot mRNA vaccines developed by Pfizer and Moderna, a point FDA reviewers noted in their review. That gap in protection is likely to play a key role as panelists weigh the need and scope of boosters.

The J&J vaccine was highly anticipated for its one-and-done formulation, and it is made with a different technology than its Pfizer and Moderna competitors. But its rollout was hurt by a series of troubles including manufacturing problems and some rare but [serious side effects](#) including a blood clot disorder and a neurological reaction called Guillain-Barre syndrome. In both cases, regulators decided the shot's benefits outweighed those risks.

The vast majority of the 188 million Americans who are fully vaccinated against COVID-19 have received the Pfizer or Moderna options, while J&J recipients account for only about 15 million.

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Citation: FDA panel takes up tough questions on J&J COVID-19 boosters (2021, October 15) retrieved 16 July 2023 from <https://medicalxpress.com/news/2021-10-fda-panel-tough-jj-covid-.html>

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