

FDA experts among group opposing US booster shot plan

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In this Aug. 26, 2021 file photo, Parsia Jahanbani prepares a syringe with the Pfizer COVID-19 vaccine in a mobile vaccine clinic operated by Families Together of Orange County in Santa Ana, Calif. An international group of scientists is arguing the average person doesn't need a COVID-19 booster yet—an opinion that highlights the intense scientific divide over the question. Credit: AP Photo/Jae C. Hong, File

The average person doesn't need a COVID-19 booster yet, an international group of scientists—including two top U.S. regulators—wrote Monday in a scientific journal.

The experts reviewed studies of the vaccines' performance and concluded the shots are working well despite the extra-contagious delta variant, especially against severe disease.

"Even in populations with fairly high vaccination rates, the unvaccinated are still the major drivers of transmission" at this stage of the pandemic, [they concluded](#).

The opinion piece, published in *The Lancet*, illustrates the intense scientific debate about who needs booster doses and when, a decision the U.S. and other countries are grappling with.

After revelations of political meddling in the Trump administration's coronavirus response, President Joe Biden has promised to "follow the science." But the review raises the question of whether his administration is moving faster than the experts.

The authors include two leading vaccine reviewers at the Food and Drug Administration, Drs. Phil Krause and Marion Gruber, who recently announced they will be stepping down this fall. Among the other 16 authors are leading vaccine researchers in the U.S., Britain, France, South Africa and India, plus scientists with the World Health Organization, which already has urged a moratorium on boosters until poor countries are better vaccinated.

In the U.S., the White House has begun planning for boosters later this month, if both the FDA and Centers for Disease Control and Prevention agree. Advisers to the FDA will weigh evidence about an extra Pfizer shot Friday at a key public meeting.

Georgetown University's Larry Gostin said the paper "throws gasoline on the fire" in the debate about whether most Americans truly need boosters and whether the White House got ahead of scientists.

"It's always a fundamental error of process to make a scientific announcement before the public health agencies have acted and that's exactly what happened here," said Gostin, a lawyer and public health specialist.

The FDA did not respond to requests for comment Monday morning.

The U.S. already offers an extra dose of the Pfizer or Moderna vaccines to people with severely weakened immune systems.

For the general population, the debate is boiling down to whether boosters should be given even though the vaccines are still offering high protection against severe disease—possibly in hopes of blocking milder "breakthrough" infections among the fully vaccinated.

Last week, CDC Director Dr. Rochelle Walensky said [new data](#) showed that as delta surged, the unvaccinated were 4.5 times more likely than the fully vaccinated to get infected, over 10 times more likely to be hospitalized and 11 times more likely to die. Still, government scientists are also weighing hints that protection is waning among older adults who were vaccinated early last winter.

The writers of Monday's commentary reported reviewing worldwide studies since delta began surging, mostly of U.S. and European vaccines. The team concluded "none of these studies has provided credible evidence of substantially declining protection against severe disease."

Because the body builds layers of immunity, gradual drops in antibody levels don't necessarily mean overall effectiveness is dropping "and

reductions in vaccine efficacy against mild disease do not necessarily predict reductions in the (typically higher) efficacy against severe disease," they wrote.

The more the virus spreads, the more opportunity it has to evolve into strains that could escape current vaccines. The Lancet reviewers suggest there could be bigger gains from creating [booster](#) doses that better match circulating variants, much like flu vaccine is regularly updated, than from just giving extra doses of the original [vaccine](#).

"There is an opportunity now to study variant-based boosters before there is widespread need for them," the scientists wrote.

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