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Science Doesn't Support Third Shot, Say Officials Who Left FDA in Spat with Biden over Boosters

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In a paper published in the Lancet, experts warned there could be risks to boosters if they are widely introduced too soon, or too frequently, especially with vaccines that can have immune-mediated side-effects.

Current evidence on COVID vaccines does not appear to support a need for booster shots in the general public right now, according to an international team of vaccine scientists, including some from the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO).

> "Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high," Marion Gruber and Phil Krause, two senior FDA vaccine leaders, wrote in an opinion piece published Monday in the Lancet.

The scientists said the benefits of COVID vaccination outweigh the risks, but there could be risks to boosters if they are widely introduced too soon, or too frequently, "especially with vaccines that can have immune-mediated side-effects (such as myocarditis, which is more common after the second dose of some mRNA vaccines, or Guillain-Barre syndrome, which has been associated with adenovirus-vectored COVID-19 vaccines)."

> "If unnecessary boosting causes significant adverse reactions, there could be implications for vaccine acceptance that go beyond COVID-19 vaccines. Thus, widespread boosting should be undertaken only if there is clear evidence that it is appropriate," the scientists wrote.

The scientists said COVID vaccines continue to be effective against severe disease, including that caused by the Delta variant — but most of the observational studies on which that conclusion is based are preliminary and difficult to interpret due to potential confounding and selective reporting, they said.

As The Defender reported last month, studies by the Centers for Disease Control and Prevention (CDC) confirmed COVID vaccine effectiveness against infection has decreased over time, and is less effective in combating the Delta variant.

Gruber and Krause emphasized "careful and public scrutiny of evolving data will be needed to assure boosting is informed by reliable science more than politics."

The team wrote:

> "The message that boosting might soon be needed, if not justified by robust data and analysis, could adversely affect confidence in vaccines and undermine messaging about the value of primary vaccination. Public health authorities should also carefully consider the consequences for primary vaccination campaigns of endorsing boosters only for selected vaccines.
>
> "Booster programmes that affect some but not all vaccinees may be difficult to implement — so it will be important to base recommendations on complete data about all vaccines available in a country, to consider the logistics of vaccination, and to develop clear public health messaging before boosting is widely recommended."

The scientists noted boosting may be appropriate for some individuals where a one- or two-dose vaccine did not provide adequate protection — such as immunocompromised people — although they noted people who did not respond robustly to a primary vaccination, may also not respond well to a booster.

Both the FDA and CDC have already signed off on allowing third doses for immunocompromised people. But experts are divided on whether boosters are necessary for the general population.

The FDA's Vaccines and Related Biological Products Advisory Committee will meet Friday to discuss Pfizer and BioNTech's application to administer their COVID vaccine as a third dose, or "booster" shot, to people ages 16 and older.

The scientists also echoed the views of the WHO in arguing current vaccines could "save more lives" if they are used in people who are not yet vaccinated rather than for boosters.

The WHO last week called for a moratorium on boosters in wealthy nations until at least the end of the year.

In a statement to CNN on Monday, an FDA spokesperson said the new opinion paper does not reflect the views of the FDA:

> "As noted in the article, the views of the authors do not represent the views of the agency. We are in the middle of a deliberative process of reviewing Pfizer's booster shot supplemental approval submission, and FDA as a matter of practice does not comment on pending matters before the agency. We look forward to a robust and transparent discussion on Friday about that application."

As The Defender reported Sept. 1, Gruber and Krause announced they will leave the FDA this fall, raising questions about the Biden administration and the way it sidelined the agency.

> Two of FDA top vaccine regulators will leave the agency this fall, because they don't believe there is data to support the Biden administration's push to offer COVID booster shots later this month.https://t.co/eAynNSpeuJ
>
> — Robert F. Kennedy Jr (@RobertKennedyJr) September 2, 2021

Gruber and Krause were upset that the Biden administration announced adults should get a booster eight months after they received a second dose — prior to boosters undergoing review or receiving approval by the FDA.

Neither Gruber or Krause believed there was enough data to justify offering booster shots yet, sources said, and both viewed the announcement, amplified by President Biden, as pressure on the FDA to quickly authorize them.

As The Defender reported earlier this month, the Biden administration announced a plan to begin offering a third booster dose to people who already received two doses of an mRNA vaccine beginning the week of Sept. 20.

U.S. health regulators have said there isn't enough data to recommend booster doses for the general population.

Still, the White House has moved forward with its plan to make Americans eligible for a third dose of either Pfizer or Moderna's vaccines eight months after the date of their second injection, even though that plan requires authorization from the FDA and CDC first.

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