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FDA Ignores Safety Committee's Guidance, Authorizes Pfizer Booster for 65 and Older, Plus 'High Risk' Groups

Critics slammed the decision, calling it "unjustified and unethical" and a "consolation prize" for Pfizer, which wanted approval for everyone in the general population, over age 16.

By Megan Redshaw
Global Research, September 28, 2021
Children's Health Defense 23 September 2021

Region: USA
Theme: Science and Medicine

The U.S. Food and Drug Administration (FDA) on Wednesday amended the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID vaccine to allow for a single booster shot to be administered to people 65 and older.

In addition to older Americans, boosters will be made available to people 18 through 64 years of age at high risk of severe illness from COVID, and also those "whose frequent institutional or occupational exposure" to the virus puts them at high risk of serious complications from the disease caused by the virus, the agency said.

> "After considering the totality of the available scientific evidence and the deliberations of our advisory committee of independent, external experts, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for a booster dose in certain populations such as healthcare workers, teachers and daycare staff, grocery workers and those in homeless shelters or prisons, among others," **Dr. Janet Woodcock**, acting FDA commissioner said in a statement.

The FDA, in approving the emergency authorization, interpreted the advisory panel's recommendations issued Friday more broadly to cover a larger swath of people.

> During meeting of FDA advisory panel to recommend whether to approve 3rd dose of Pfizer's COVID vaccine, physicians pointed to data that confirms risks of Pfizer's COVID vaccine don't outweigh benefits.

> SIGN UP #TheDefender: https://t.co/zL66EdwTnDhttps://t.co/rV3ivOcHXn
>
> — Robert F. Kennedy Jr (@RobertKennedyJr) September 20, 2021

On Sept. 17, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) unanimously recommended EUA for a booster dose of Pfizer's vaccine for people 65 and older and those with compromised immune systems, to be administered six months after they get the first two doses.

However, the committee voted 16 to 2 against recommending boosters for the general population citing a lack of long-term data. The committee said the risks did not outweigh the benefits for those people.

> "The FDA considered the committee's input and conducted its own thorough review of the submitted data to reach today's decision," **Dr. Peter Marks**, director of the FDA's Center for Biologics Evaluation and Research, said in a statement.

Pfizer had asked for FDA approval to give its vaccine to everyone 16 and older six months after they are fully immunized with two shots, CNN reported. The company said it had enough evidence that immunity starts to wane after six months, and that giving a booster restores the immunity safely.

As The Defender reported Sept.16, Pfizer didn't test its booster at all in people who are actually at risk. The company conducted only a single phase 1 study that covered 12 people over age 65.

The company also combined its phase 2/3 booster trial and included no one over 55. According to data Pfizer submitted to the FDA, the drugmaker tested its booster in only 306 people — one of whom had a heart attack.

Pfizer compared people who received the vaccine with those who received the placebo but later also got the vaccine — because Pfizer unblinded the trial last year by giving placebo subjects the vaccine.

Critics weigh in: boosters 'unjustified and unethical'

In an email to The Defender, Dr. Meryl Nass, an internist and biological warfare epidemiologist, said Pfizer asked the FDA to fully license a third booster dose of its COVID mRNA vaccine for everyone 16 and up based on "unconvincing data."

Nass said:

> "Pfizer used a tiny subset of subjects — only 306 subjects — among whom more than a third dropped out over time. None were under 18, and only 12 were over 65. Furthermore, if you believe the incredibly good efficacy numbers claimed by the CDC, the first two doses continue to work very well and no booster is currently needed.
>
> "As a result, the FDA's vaccine advisory committee voted against approving the third booster dose for the general population. And that was the only question they had been asked to vote on. However, the FDA was unwilling to take that as its final answer.

> "So suddenly the FDA created a new question for the committee: Would it approve (i.e., license) boosters for those over 65 and /or immune compromised? In a transparent attempt to give Pfizer a consolation prize, the committee voted 'Yes.'"

Nass said authorizing the boosters for the groups designated by the FDA opens the doors to mandate the boosters for those people. "This is why issuing a license for COVID vaccines is such a fraught subject," Nass said.

Dr. Robert Malone, creator of mRNA vaccine technology, also responded to the FDA's decision. In an email to The Defender, Malone wrote:

> "In general, current data that I am aware of supports administration of booster doses to 'individuals 65 years of age and older and individuals 18 through 64 years of age at high risk of severe COVID-19.' However, I am not familiar with data that clearly demonstrate that 'individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.'
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> "This statement and risk group was not included in the VRBPAC recommendations, and appear to represent regulatory overreach on the part of the FDA and the commissioner.
>
> "The appearance is that the FDA is exceeding its mandate to focus on patient safety, efficacy and purity (adulteration) in order to advance, justify and enable additional vaccine booster mandate public policies for these groups based on public contact risks, rather than unsupported enhanced personal risks of COVID-19 complications.
>
> "What the data do show is that these vaccines do not provide robust protection from infection, high level viral replication and infection of others by vaccinated persons. In my opinion, vaccine booster mandates, coupled with coercive threat of punishment by termination of employment for these cohorts, are both unjustified and unethical."

Will boosters do more harm than good?

During the Sept. 17 VRBPAC meeting, **Steve Kirsch**, founder of the COVID-19 Early Treatment Fund, told FDA officials COVID vaccines kill more people than they save.

Kirsch said four experts did analyses using completely different non-U.S. data sources, and all of them came up with approximately the same number of excess vaccine-related deaths — about 411 deaths per million doses.

> "That translates into 150,000 people who have died [from COVID vaccines]," he explained.

Kirsch told committee members:

> "We were led to believe that vaccines are perfectly safe, but this is simply not true. For example, there were four times as many heart attacks in the treatment group in the Pfizer 6-month trial report. That wasn't bad luck, the VAERS shows heart attacks happen 71 times more often following these vaccines compared to any other vaccine. In all, 20 people died who got the drug — 14 died who got the placebo."

After FDA officials dismissed his comments, Kirsch sent a follow-up email, in which he cited a

study in Toxicology Reports to back up his assertion that the people in the age group for whom the FDA approved boosters — 65 and older — are at greater risk of dying from the vaccine than from the virus.

Kirsch pointed officials to this excerpt from the study:

> "Thus, our extremely conservative [author's emphasis] estimate for risk-benefit ratio is about 5/1. In plain English, people in the 65+ demographic are five times as likely to die from the inoculation as from COVID-19 under the most favorable assumptions! …
>
> "In summary, the value of these COVID-19 inoculations is not obvious from a cost-benefit perspective for the most vulnerable age demographic, and is not obvious from any perspective for the least vulnerable age demographic."

CDC expected to follow FDA guidance

The CDC's Advisory Committee on Immunization Practices (ACIP) met Wednesday to hear data about the safety and effectiveness of a Pfizer booster, and it is expected to make a recommendation when the committee meets today.

The CDC must give its stamp of approval for any booster doses to be officially given. The ACIP can further amend recommendations for how any vaccine booster doses should be given.

The recommendation from the ACIP will almost certainly receive a quick endorsement from CDC Director Dr. Rochelle Walensky. The shots are expected to be available as soon as this week at pharmacies and some doctor's offices.

In a letter sent Thursday and obtained by CNN, the CDC urged local and state health officials to wait to administer boosters until both agencies had signed off.

According to the CDC's latest data from its Vaccine Adverse Events Reporting System (VAERS), between Dec. 14, 2020, and Sept. 17, 2021, a total of 701,561 reports of adverse events from all age groups following COVID vaccines have been reported — including 14,925 deaths and 91,523 serious injuries.

Historically, VAERS has been shown to report only 1% of actual vaccine adverse events.

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