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[Docket \(/docket/CDC-2021-0075\)](/docket/CDC-2021-0075/) / [Document \(CDC-2021-0075-0001\)](/document/CDC-2021-0075-0001/) (/document/CDC-2021-0075-0001)  
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## Comment from Health Watch USA

Posted by the **Centers for Disease Control and Prevention** on Sep 21, 2021

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Comment

Centers for Disease Control and Prevention

Sept. 22, 2021

[Docket No. CDC-2021-0075]

Advisory Committee on Immunization Practices (ACIP)

RE: Written Comment Regarding

The Sept 17, 2021 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee regarding boosters for the Pfizer/BioNTech vaccine resulted in recommending authorization of boosters for those 65 years of age and older along with those individuals who are high risk for COVID-19. After the formal vote, a poll was taken, and the committee unanimously agreed this recommendation should be extended to healthcare workers and those who are high-risk of occupational exposure to SARS-CoV-2. Thus, initially the committee focused on vaccinated individuals who are biologically high-risk of developing severe COVID-19, but finally, also recommended boosters for those at high-risk of SARS-CoV-2 exposure.

During a raging pandemic action is needed NOW, we do not have the luxury of waiting for the results of randomized controlled trials.

I would like to encourage the committee to broaden the FDA's recommendations. The following should be considered:

1. At least one committee member indicated the main goal was to prevent severe disease, which is defined as hospitalizations and death. However, this ignores the lasting and debilitating effects of Long-COVID, which can afflict 10 to 30% of those with even mild to moderate infections and poses a significant risk to our population.

2. Dr. Alroy-Preis, Israel's Director of Public Health Services, testified that the Pfizer booster created a 10-fold increase in protection in 40- to 60-year-olds. With the disease profile of Delta markedly shifting to younger age groups, providing boosters to a wider range of individuals would be good public health policy.

3. In the United States, over 386 million doses have been administered, with an extraordinary good safety record. The FDA Committee had concerns regarding myocarditis in the young. However, this is a rare event occurring in approximately 1 in 5000 young individuals and as stated by Dr. Alroy-Preis, 95% of these cases are mild. There is a much higher incidence of myocarditis in those who contract COVID-19.

4. The concern over vaccine availability in third-world countries is largely a zero-sum game and distribution of mRNA vaccines which require ultra-cold storage along with three doses is problematic. The United States has already discarded over 15 million vaccine doses which could have been placed into arms.

In view of the above, I would recommend reconsideration of offering Pfizer boosters to all who are 16 years of age or older, or at least offering boosters to those who are 30 years of age or older, plus all individuals who are at high risk of acquiring COVID-19. It will take time to roll out boosters and the cohort below age 30 were the last to receive vaccinations. This should provide time for further consideration and for additional data to emerge regarding boosters in this cohort.

Thank you for this consideration,

Kevin T. Kavanagh, MD, MS  
Somerset, Kentucky  
Health Watch USA

Attachments 1



20210922-The\_CDC\_ACIP\_Meeting



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#### Comment ID

CDC-2021-0075-0006



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ktt-gcwt-sol7

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