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Centers for Disease Control and Prevention **Sept. 22, 2021**
[Docket No. CDC–2021–0075]
Advisory Committee on Immunization Practices (ACIP)

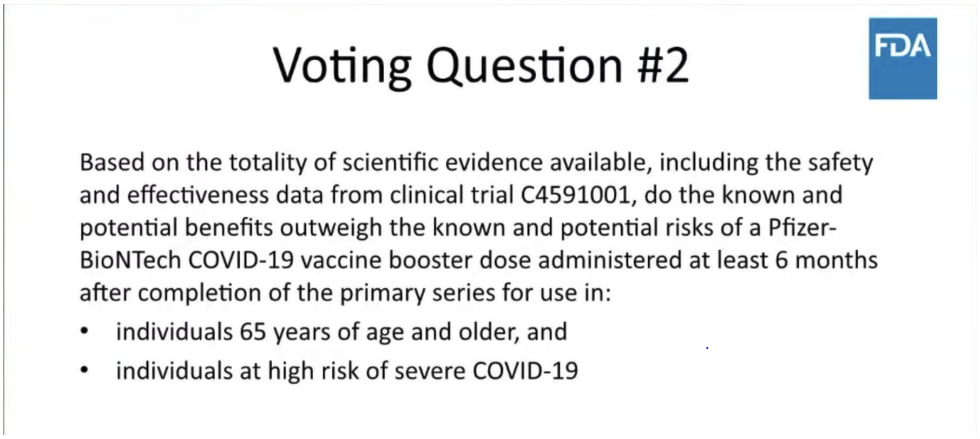
RE: Written Comment Regarding Authorization of Pfizer/BioNTech Boosters.

One might describe the Sept 17, 2021 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee(1) regarding boosters for the Pfizer/BioNTech vaccine as indecisive. After hearing a plethora of leading experts regarding waning immunity of the Pfizer vaccine, the FDA initially voted to turn down the proposal to offer a third dose to anyone 16 years of age and older.

This came as a surprise to me, since the Israeli presentation clearly indicated the need for proactive action in a wide range of age groups, and healthcare providers need maximum flexibility in their recommendation of boosters to patients. In addition, we should all be aware of the dangers of taking a reactive stance, especially during a raging pandemic where action is needed NOW and the immunity elicited by vaccines may take weeks to kick in. We do not have the luxury of waiting 6 months for the results of randomized controlled trials.

Dr. Alroy-Preis MD, MPH, MBA, Israel's Director of Public Health Services, pointed out that Pfizer vaccine boosters not only augmented immunity in the elderly, also 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, not providing boosters to a wide range of individuals would appear to not be good public health policy.

The committee then took a temporary recess and afterwards authorized the Pfizer booster for those individuals 65 years of age and old, and to individuals at high risk for severe COVID-19.



The emphasis appeared to be on the prevention of "severe" disease in those at high biological risk, including those individuals who are 65 years and older and at least 5 months post full vaccination. In this age group, Israeli data found breakthrough infections to be associated with an 8.6% chance of hospitalization and a 2% incidence of death.(2)

Many or our national authorities and at least one FDA committee member appeared to be mitigating the severity of COVID-19 infections which are not hospitalized, giving the impression that these are "mild" cases and intervention is not urgent. I have personal friends which have developed mild to moderate cases with resultant loss of smell, chronic fatigue, and brain fog. After many weeks they are still not yet able to return to normal activity. These cases represent the severest infections many will experience in their lifetime, and these infections need to be prevented.

There was also concern regarding myocarditis in the young, and if in this age group the risks versus benefits would warrant boosters. However, even in the young, cases of myocarditis are rare (1 in 5,000 to 1 in 6,000). As emphasized by Dr. Sharon Alroy-Preis, 95% of these cases are mild, and even young individuals can and do develop Long COVID.

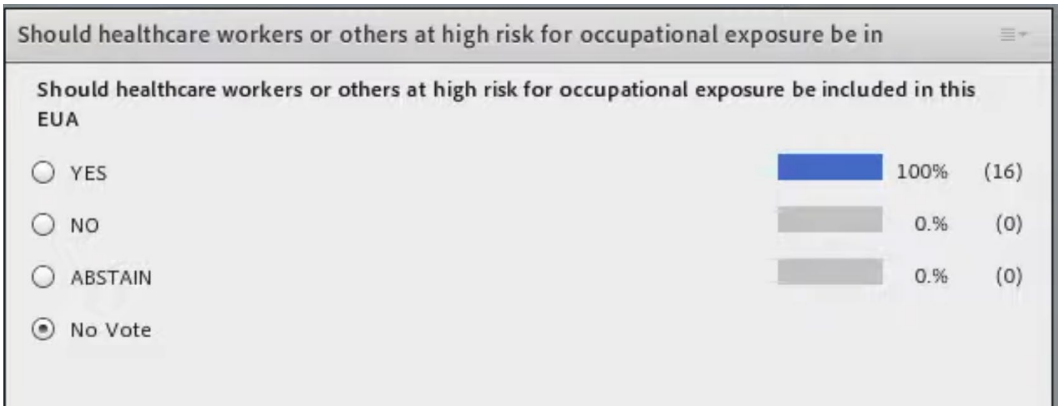
Finally, concern was expressed regarding availability of vaccines in third world countries. However, the ultra-cold storage and distribution in third-world nations is problematic at the very least, and as stated on Face the Nation by Dr. Francis Collins, this is largely a zero-sum game.(3) In addition, the United States has discarded millions of doses of mRNA vaccines which need to be placed into arms.(4)

After the second vote it was asked, what about healthcare workers? Suddenly, I could feel an urgency in the committee and the emphasis appeared to shift. Healthcare workers know all too well the lasting and debilitating effects of Long COVID-19. They were one of the first to become vaccinated and are some of the first experiencing breakthrough infections. They are tired, burned out, and many on the brink of collapse. They do not need to be told to tough it out, you are not going to be getting a booster.

It was proposed to take an informal poll regarding the need to extend the interpretation of the approved FDA recommendation to healthcare workers. It was then mentioned that other workers with high occupational exposure should also be included. Someone then asked what about those at high risk for COVID-19 who are not employed? But the committee did not include these individuals. One committee member mentioned this would be too difficult to interpret.

From my point of view this was unwise, since the proposal now may exclude caregivers of unvaccinated school age children, and places these caregivers at an unnecessary risk.

The final poll question which passed unanimously was "Should healthcare workers or others at high risk for occupational exposure be included in this EUA" It was clearly stated that this would include healthcare workers, other frontline workers (such as teachers) and potentially essential infrastructure workers.



I feel this was a 180-degree change in thinking. Initially, the concern appeared to be centered on having definitive data which showed severe breakthrough infections were developing, especially in those who are biologically at high risk for disease. Now the concern was focusing on having a high risk of exposure to COVID-19, regardless of the biological susceptibility of the individual.

However, not to include those with non-occupational exposure was not being consistent and would place many at unnecessary risk.

It should be remembered that vaccine complications are exceedingly rare. Even myocarditis does not occur frequently, and is usually seen in males under the age of 30. In addition, Dr. Sharon Alroy-Preis reported boosters provided a 10-fold in protection down to the age of 40.

In view of the above, I feel ACIP should provide further clarification and interpretation of the FDA recommendations. It would be more reasonable to either reconsider the initial proposal of offering 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 individuals who are at high risk for severe Long COVID.

Although the latter proposal will exclude many individuals who could benefit from a booster, one needs to remember, it will take some time to roll out boosters and the group below 30 was the last to receive vaccinations, thus, would be expected to be the last to have waning protection. This will give time for more consideration and additional data to emerge regarding optimization of boosters in this cohort.

Thank you for this consideration,

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References

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