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Testimony Before the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) Concerning the EUA of the Pfizer-BioNTech COVID-19 Vaccine for the Prevention of COVID-19

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I am Dr. Sidney Wolfe, Founder and Senior Adviser of Public Citizen's Health Research Group. I have no conflicts of interest.

With the surging pandemic and interim efficacy and safety results made public two days ago, we agree with the need for an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine.

But an important unresolved conflict exists. If an EUA is granted for widespread use, should the 19,000 participants in the trial who received a placebo be notified of this and be offered a vaccine by Pfizer, clearly encouraging them to stay in the trial? Similarly, should blinded trial vaccine recipients to be told of their status, thereby encouraging continuation in the trial. What would you wish if you were subjects in the trial?

As status-uninformed trial participants, you might otherwise leave the trial to try getting vaccinated with the Pfizer or any other EUA-available vaccine.

The proposal for unblinding and providing vaccine to placebo participants has important advantages.

First, once an EUA is granted, the ethical obligation to both inform all placebo recipients of their status and offer them the vaccine within the context of the clinical trial is met.

Second, by retaining more trial participants than if the trial remains blinded after an EUA is granted, more recipients may be followed thereafter. The originally vaccinated group could be compared with the newly vaccinated placebo group to continually compare rates of new COVID-19 infection with increasing duration of vaccination as well as adverse reactions.

The Food and Drug Administration (FDA) states it "does not consider availability of a COVID-19 vaccine under EUA, in and of itself, as grounds for immediately stopping blinded follow-up

in an ongoing clinical trial or grounds for offering vaccine to all placebo recipients."[1] But in response to an October 22, 2020, VRBPAC meeting question about retaining placebo patients post EUA, the FDA's Dr. Doran Fink from the Center for Biologics Evaluation and Research replied: "[W]ith regards to mitigating the risk of dropout from ongoing clinical trials, we do share that concern. I don't have any specific remedies to offer at this time. We have asked the vaccine manufacturers and the other government agencies…to think carefully about how they would ensure clinical trial retention."[2]

Pfizer states "it intend[s] to continue the pivotal Phase 3 study with participants in both the vaccine and placebo groups as originally allocated for as long as possible… Nevertheless, we have an ethical responsibility to inform all ongoing study participants of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA."

Pfizer's current plan would be to accommodate trial participants wishing to leave the trial, informing them which group they are in and how they can receive the vaccine only when "practically eligible," depending on their government-specified priority group and the available supply where they live.

However, "it is Pfizer's preference that such [placebo] individuals are vaccinated within the study in order that both safety and efficacy data can continue to be collected. We believe this approach will minimize the number of current participants who choose to withdraw from the study once a vaccine is available and will maximize the collection of data that can inform the long-term efficacy and safety of BNT162b2."[3] [Emphasis added]

If you were in the trial, would you prefer being unblinded only if you wish to leave the trial to seek *possibly* available but needed vaccine or being automatically unblinded, given Pfizer's vaccine if in the placebo group or happy to find out you were vaccinated and more likely to stay in the trial?

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[1] Food and Drug Administration. FDA briefing document: Pfizer-BioNTech COVID-19 Vaccine; Vaccines and Related Biological Products Advisory Committee meeting. December 10, 2020. https://www.fda.gov/media/144245/download. Accessed December 10, 2020. PDF page 10.

[2] Food and Drug Administration. Transcript of 161st Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting. October 22, 2020. https://www.fda.gov/media/143982/download. Accessed December 10, 2020. PDF pages 205-206.

[3] Pfizer. Pfizer-BioNTech COVID-19 vaccine (BNT162, PF-07302048 Vaccines and Related Biological Products Advisory Committee briefing document. December 10, 2020. https://www.fda.gov/media/144246/download Accessed December 10, 2020. PDF page 17.