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Testimony Before the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) Concerning the Emergency Use Authorization (EUA) of the Janssen Ad26.COV2.S 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 and support granting an EUA for Janssen's vaccine, despite decreased efficacy in older people with co-morbidities.

With the current EUA availability of two COVID-19 vaccines — the third probably next week — it will be neither practically nor ethically feasible to continue recruiting new participants to placebo-controlled trials unless they will ultimately get vaccinated, whether initially randomized to the vaccine or placebo group.

On December 10th, before your committee, I stated that:

> An important unresolved conflict exists. If an EUA is granted for widespread use, should the 19,000 participants in the [Pfizer] trial who received a placebo be notified of this and be offered a vaccine by Pfizer, clearly encouraging them to stay in the trial?
>
> Status-uninformed, trial participants might otherwise leave the trial to try getting vaccinated with the Pfizer or any other EUA-available vaccine.
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> The unblinding, vaccine-providing proposal has important advantages.
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> 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.
>
> The originally vaccinated group could be compared with the newly vaccinated placebo group to continually monitor rates of new COVID-19 infection with increasing duration of vaccination as well as adverse reactions.
>
> Pfizer's stated preference was "that such individuals be 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."

Now, 2½ months later, Janssen proposes that "Upon authorization by a regulatory authority, all placebo participants receive 1 dose of Ad26.COV2.S" (slide CO 62 today).

If granted by the FDA, for Janssen's and subsequent EUA-granted COVID-19 vaccines, all placebo participants will later get a vaccine. But what about the 19,000 Pfizer subjects and 15,000 Moderna subjects who were randomized to placebo groups? At the time of EUA authorization, both companies had similarly expressed their preference that subjects previously given placebos be notified of this and offered a vaccine.

As of now, how many of the original 34,000 Pfizer or Moderna placebo recipients have been notified of their status and offered a vaccine? When will this occur for the 20,000 Janssen placebo recipients?