Placebo group: What happens after a COVID vaccine is authorized?

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Pfizer and Moderna are hoping to request emergency use authorization for a coronavirus vaccine by the end of November

If a coronavirus vaccine is authorized in the United States before the end of the year, will trial participants who received a placebo rush out to get vaccinated?

While the question hasn't received much attention among the general public, it's one that worries health experts and pharmaceutical manufacturers.

Currently tens of thousands of people in the United States and other countries are participating as volunteers in what are known as phase three clinical trials.

Typically half receive the experimental vaccine, while the remainder are given a placebo, though they do not know which one was administered to them.

The aim is to observe over the course of months how many people in each group naturally contract the virus and fall ill from COVID-19.

If the number of vaccinated participants contracting COVID-19 is at least 50 percent lower than in the placebo group, US drug authority FDA can grant it emergency use authorization.

But for a permanent authorization, the FDA requires a longer period of study—generally six months.

The aim is to confirm the safety of the vaccine since certain rare side-effects may not be detected during the two-month period currently scheduled for emergency use approval.

The problem is that, generally, for ethical reasons, once a medicine or vaccine is authorized, participants who received a placebo in a clinical trial are informed of it.

They could then understandably ask for the real vaccine or seek it out themselves, but that would decrease the placebo group.

Doing so would prevent a long-term comparison between the placebo group and those who were initially vaccinated.

The risk is even greater for dozens of trials not yet at the large-scale stage: Who would take the risk of receiving a placebo if a vaccine is available publicly?

The issue was discussed Thursday at an FDA advisory committee meeting on vaccines, but no real solution was reached.

'Ethical responsibility'

Doran Fink of the FDA's vaccines division noted that trials could continue among populations for which no vaccine has yet been authorized or for those without available doses.

But the dilemma is real for the majority.

"We do acknowledge that situations will likely arise where it is no longer ethically permissible and therefore no longer feasible to continue placebo controlled follow-up in an ongoing trial or to initiate a placebo controlled trial," Fink said Thursday.

"I don't have any specific remedies to offer. At this time, we have asked the vaccine manufacturers and the other government agencies who are involved in conducting these trials to think carefully about how they would ensure clinical trial retention."

One of the two companies hoping to request emergency use authorization by the end of November in the United States, Moderna (the other is Pfizer), has asked for instructions from authorities.

"Those participants are beginning to ask when they will know if they receive study vaccine, or placebo," said Moderna's Jacqueline Miller, who spoke at the same meeting.

Pfizer and its German partner BioNTech have written a letter to the FDA saying that they have "an ethical responsibility" to inform members of the placebo group and called on the agency to be open to other methods to evaluate the vaccines.

For now, the FDA has only one instruction: Continue the trials for as long as it remains feasible.

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