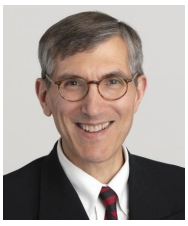
# Want to defeat COVID-19? Deliver a 70% effective vaccine—and get 70% of people to take it, FDA official says

*Several COVID-19 vaccine programs are gearing up for phase 3 trials this summer. (Getty Images)*



Peter Marks M.D., Ph.D. (FDA)

One of public health's greatest accomplishments was eradicating smallpox back in 1979. To eradicate SARS-CoV-2, the virus that causes COVID-19 illness, we'll need a vaccine that's 70% effective—and 70% of the population will need to receive it, an FDA vaccine official said Wednesday.

That's a higher bar than the FDA set last week. To pass muster at the agency, a COVID-19 vaccine will need to be at least 50% more effective than placebo, according to new FDA guidelines.

But the agency felt a 50% efficacy requirement was a “reasonable place” and about comparable to a flu vaccine on a good year, said Peter Marks, director of the Center for Biologics Evaluation and Research (CBER), during a webinar hosted by the Alliance for a Stronger FDA.

And despite R&D moving at record speeds, Marks cautioned that vaccines are still several months away. It’ll take “weeks to months” to get phase 3 trials enrolled, and some regimens will require two injections several weeks apart. Then, investigators will need to follow the trial participants “for a few months.”

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“We’re not going to have one in early fall,” he said. “It’s going to take months.”

For an emergency use authorization, the “most likely” timing would be after a late-stage trial's interim analysis shows safety and efficacy but before the developer can complete its full submission for approval, he added.

In the long run, there “may not be one winner” in the hunt for a COVID-19 vaccine. One vaccine might work in older adults, while another might perform better in younger people, Marks said.

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That's why the FDA is “strongly” encouraging companies to enroll a diverse group of trial participants, including racial and ethnic minorities, plus older adults and others, Marks said. The pandemic has disproportionately affected communities of color.

Citing the urgency, the agency is “poised to move review of any submissions" as quickly as possible, he added.

On the prospects of a “challenge trial,” where investigators would infect volunteers with COVID-19 to test a vaccine candidate's ability to protect, Marks didn’t completely rule it out. There are ethical concerns because there isn’t a ready treatment for the novel coronavirus, but the FDA would consider such trials “based on protocol” and “given the circumstances,” Marks said.

Still, in his experience, volunteers might say they want to participate, but once the “rubber hits the road” they might change their minds.

Even as vaccines are still in development, experts have started to warn about the public’s willingness—or lack of willingness—to embrace a vaccine. About half of Americans said they planned to get a vaccine, according to a poll from late May.

The FDA’s “job number 1” is to fairly evaluate any programs that are submitted, he said. Also, communicating benefits and risks clearly is critical, he added.

Marks was previously on the U.S. government's Operation Warp Speed program, which is seeking to deliver hundreds of millions of doses in early 2021. But last month he stepped back to protect his independent regulatory power at CBER, according to Politico.