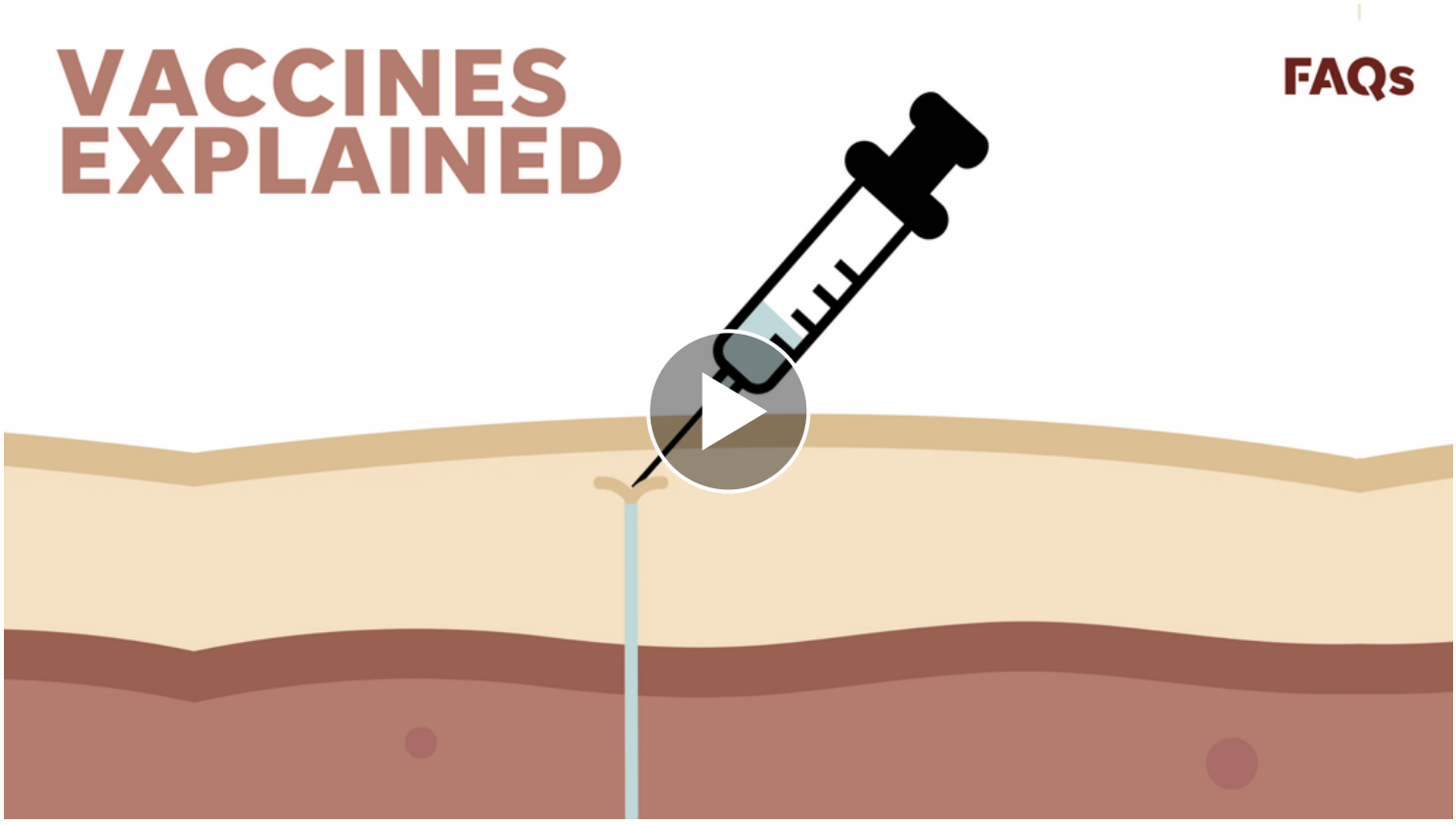
FDA says a coronavirus vaccine would have to be at least 50% effective to be approved

ELIZABETH WEISE | USA TODAY



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in preventing or at least decreasing the severity of COVID-19 in order for the Food and Drug Administration to approve it, the agency said Tuesday.

That threshold "would have been what I would have chosen since that is around what flu vaccines do that save lives," said Barry Bloom, an immunologist and professor of public health at the Harvard T.H. Chan School of Public Health in Boston. "Greater would, of course, be ideal."

Some have expressed concern the FDA might face pressure from the White House to approve a COVID-19 vaccine as quickly as possible, under an Emergency Use Authorization rather than the agency's typical process.

FDA guidance issued Tuesday indicates that at least the first vaccine to be approved must go through the full FDA licensure process, including Phase 3 clinical trials to show it protects people against disease or infection.

Phase 3 trials would need to show people have developed protection against the virus, not just that their blood indicates they may be protected, several vaccine experts said.

Bloom's interpretation is that the FDA will be more stringent in approving an initial vaccine.

"They will insist on disease/infection protection in initial trials and not make a guess about a biomarker for protection until the correlation with disease protection is established," he said. "That seems to suggest no shortcut in the front-running trials."

Subsequent vaccines likely would rely on the presence of biomarkers, Bloom said.

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"While the FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards," Hahn said.

Any potential emergency use authorization – which requires less testing than a full license – for a COVID-19 vaccine would be made on a case-by-case basis, the agency said.

The FDA said accelerated approval might be possible down the road when more is known about the immunology of SARS-CoV-2, the virus that causes COVID-19.

That's a reasonable approach, said Dr. William Schaffner, a professor of preventive medicine at Vanderbilt University in Nashville, Tennessee.

"The FDA preserves the option of moving rapidly in an urgent situation," he said.

Coronavirus vaccine vials
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The FDA has issued emergency approval for a vaccine only once, for an experimental anthrax vaccine in 2005. The FDA had originally declined to issue an emergency use authorization, but the Department of Defense pushed for one due to concerns over possible anthrax attacks against U.S. military forces.

Vaccine-associated enhanced respiratory disease

A clear concern in the FDA's guidance for the coronavirus vaccine is whether vaccine candidates might cause enhanced respiratory disease – not only failing to decrease the severity of COVID-19 but causing it to get worse.

While rare, data from animal studies in some vaccine candidates for other coronaviruses, such as SARS-CoV and MERS-CoV, has raised concerns regarding COVID-19, the FDA said.

Infecting healthy people to test a vaccine

The FDA also said challenge trials could be considered to test COVID-19 vaccines

them from getting COVID-19.

That might be necessary if there were so little SARS-CoV-2 virus circulating that it was no longer possible to study whether a vaccine was effective. If there's no chance people who've gotten test injections could get infected, it wouldn't be possible to test whether the vaccine works.

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The agency made clear in its document that challenge trials are not ideal. "Many issues, including logistical, human subject protection, ethical, and scientific issues, would need to be satisfactorily addressed," it said.

Side effects, public trust could undermine vaccine

There are several possible downsides to issuing a vaccine prematurely.

Side effects and bad outcomes may be rare enough that they appear only when many people receive the vaccine, or after enough time has passed for them to appear. That could give fuel to anti-vaccine groups that claim without evidence that vaccines are harmful.

Some people could be scared away from the vaccine if they don't believe it has been properly and thoroughly tested. If people won't take the vaccine, it doesn't matter how soon it's available.

Paul Offit, a vaccine expert at the University of Pennsylvania, has spoken of the possibility that a vaccine could be unveiled as an "October surprise" and the harm that could cause. The FDA's guidance made him less concerned, he said.

"I think this is all very reassuring," he said. "Now all they have to do is follow their own guidelines."

Contributing: Karen Weintraub