FDA will require 50% efficacy for COVID-19 vaccines. How high is that bar?

FDA commissioner Stephen Hahn plans to present guidance on the efficacy threshold needed for COVID-19 vaccine approvals, WSJ reports. (FDA)

Coronavirus vaccine developers now have some advice from the FDA: To win approval, any vaccine must be at least 50% effective in preventing the disease.

FDA Commissioner Stephen Hahn plans to roll out that guidance at a Senate hearing today, the Wall Street Journal reports. It sets a bar about on par with a flu shot's performance in a good year—but it falls short of some expert recommendations for arresting the virus' spread.

The agency also won't approve a shot based on its ability to create antibodies in patients' blood, the WSJ reports. Experts don't yet know how those antibodies translate to protection against COVID-19.

Despite the urgency of this particular vaccine hunt, the FDA "will not reduce its standards or cut corners in its review to approve a vaccine," according to a summary of the guidance cited by the WSJ. On Tuesday, the agency published its guidance.

That pledge comes as some industry watchers worry the Trump administration could pressure the agency to approve a vaccine before the election for a political win. Hahn has said politics will not go into COVID-19 vaccine reviews.

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An efficacy figure of 50% would compare somewhat favorably to flu vaccine efficacy in the last decade, which has ranged from 19% to 60% since 2010, according to the CDC. Many childhood vaccines are effective for 85% to 95% of recipients, the World Health Organization says.

Merck's Everbo, an Ebola vaccine developed in response to a 2014 outbreak, was 100% effective in a "ring" vaccination study. The drugmaker is using the same platform for one of its COVID-19 vaccine programs.

But 50% efficacy falls short of what some researchers have concluded would have been needed to quash the COVID-19 outbreak. In a computer model, a team found that a vaccine would've needed to be at least 70% effective to halt the spread of the virus, if it were given to 60% of the population within 90 days of the outbreak starting.

For its part, the WHO has set its own success benchmarks for COVID-19 vaccines, according to GlobalData. The higher benchmark calls for 70% efficacy and a duration of protection for one year, while the lower threshold calls for 50% efficacy for 6 months.

In approving a COVID-19 vaccine, there are two approaches the FDA could take—a full approval or an emergency authorization. The full approval would require about 30,000 participants to enroll in a phase 3 trial, which experts have worried might be difficult to conduct if the outbreak quieted over the summer.

But with cases spiking in numerous states, researchers may be in a better position to recruit patients for massive efficacy studies. The U.S. government's Operation Warp Speed plans to kick off phase 3 trials of several leading candidates this summer, the WSJ previously reported.

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An emergency authorization, meanwhile, would be a quicker process than a full approval, but it'd still require the developer to show proof of efficacy. In any case, after potential approvals, the FDA will require a year-long post-marketing study to track potential risks, WSJ reports.

As of Monday, 17 COVID-19 vaccines are in human testing, and more than 130 are in preclinical research stages, according to the World Health Organization.