FDA to Require Proof Virus Vaccine Is Effective Before Approving Its Use – Wall Street Journal, June 30, 2020

The Food and Drug Administration released guidance Tuesday outlining conditions for approving a Covid-19 vaccine, including that any vaccine be at least 50% more effective than a placebo in preventing the disease.

That 50% benchmark is used routinely for flu vaccines. The FDA said it wouldn't approve—or give emergency-use authorization—to any coronavirus vaccine unless the maker had clearly demonstrated proof of its safety and effectiveness in a clinical study.

FDA Commissioner Stephen Hahn described the agency's guidance at a Senate hearing Tuesday, after it was reported earlier by The Wall Street Journal. In response to senators' questioning, Dr. Hahn stressed that the FDA wouldn't approve any vaccines for the general public without clinical evidence that they are safe and effective.

"We have not lost sight of the need to protect our regulatory independence" during the coronavirus pandemic, Dr. Hahn said. He said he is optimistic that therapeutics like convalescent plasma and monoclonal antibodies would play a significant role this fall in helping people infected with Covid-19.

In its new guidance, the FDA said it wouldn't approve a vaccine simply if it leads to antibodies in patients' bloodstreams, because it isn't known what level of antibodies confers protection.

The agency also said it would require a vaccine maker to conduct further safety monitoring after any approval, and recommended that vaccine recipients be followed for a year after treatment. Such "post-market studies" might be necessary to "further assess known or potential serious risks," the summary document said.

Developing a vaccine is a priority for the Trump administration, which has dubbed the initiative Operation Warp Speed. The FDA has vowed to use all its available authority to expedite a safe and effective Covid-19 vaccine, fuelling hopes that a preventive treatment can be developed quickly.

The FDA has sometimes been faulted for moving too fast in the campaign to prevent and treat the virus. At least 160 antibody tests for Covid-19 entered the U.S. market without previous FDA scrutiny in March, as the agency rushed to get them to the public. Under fire, the FDA mandated stricter review. The agency also granted emergency-use authorization for two malaria drugs, chloroquine and hydroxychloroquine, for Covid-19 treatment, which it later revoked after determining both were ineffective.

Guidances are a method the FDA uses to state its policies to an industry, in this case vaccine makers. A virus vaccine could be granted approval two ways—either by full approval or emergency authorization. Full FDA approval would require a vaccine company to amass trial data and submit all the details to an advisory committee of outside experts, a process that typically takes months. An emergency authorization could happen more quickly but would

still require the vaccine maker to show through a clinical study that the vaccine produced lower levels of disease, according to the guidance.

Government and industry officials have said the FDA's standards for full approval would require at least 30,000 people in a clinical trial. But since coronavirus infections are surging in many parts of the U.S.—including in Arizona, Florida and Texas—it might be relatively easy for companies and doctors to sign up patients eager to participate in a vaccine study that could protect them.

Questions:

1. What did you think of the article?
2. How easy was it to understand?
3. What issues does it raise?
4. Why do you think the Trump administration are keen to develop a vaccine?
5. The administration have called the search for a vaccine "Operation Warp Speed", why have they called it this?
6. If you "fuel hopes," what are you doing?
7. Which country do you think might win the race to produce a vaccine?
8. Which country would you trust to produce a sound vaccine?
9. When a vaccine is available, will you have it? Why or why not?
10. If you won't have the injection, how will you try and keep yourself from getting the virus?
11. How do you think the vaccine will be distributed around the world?
12. How much would you pay for it?
13. Final thoughts.

Vocabulary: What do these words from the article mean?

placebo
benchmark
lost sight
play a significant role
confer
dubbed
vowed
expedite
faulted
Under fire
mandated
revoked
amass
to sign up