FDA won’t approve a coronavirus vaccine unless there is ‘clearly demonstrated proof’ it’s effective

[A coronavirus vaccine must] be at least 50% more effective than a placebo in preventing the disease [to be FDA approved.]
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.

…

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.

Read the original post