

FDA Updates COVID-19 Vaccine Safety Guidelines

The Food and Drug Administration (FDA) has released updated safety guidelines for coronavirus vaccine makers that would make it impossible for a vaccine to be ready by election day. The FDA now says that vaccine manufacturers need to follow vaccine trial participants for two months to monitor side effects before seeking emergency approval.

Data from Phase 3 studies should include a median follow-up duration of at least two months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile, including: adverse events; cases of severe COVID-19 disease among study subjects; and cases of COVID-19 occurring during the timeframe when adaptive (rather than innate) and memory immune responses to the vaccine would be responsible for a protective effect.

Emergency Use Authorization for Vaccines to Prevent COVID-19

President Trump has continued to insist that a vaccine will be ready before elections on November 3rd, and the administration had tried to block the FDA from formally publishing these safety guidelines. The FDA has been communicating these guidelines to the public and vaccine manufacturers informally.

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Seven former FDA commissioners released an op-ed in the Washington Post that criticized President Trump's handling of the COVID-19 vaccine process.

But a safe and effective vaccine will not be enough; people will also have to choose to take it. This depends on widespread confidence that the vaccine approval was based on

sound science and not politics. If the White House takes the unprecedented step of trying to tip the scales on how safety and benefits will be judged, the impact on public trust will render an effective vaccine much less so.”

7 former FDA commissioners: The Trump administration is undermining the credibility of the FDA

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Two of the commissioners responsible for this statement, Scott Gottlieb and Mark McClellan, are on the boards of two of the companies with a coronavirus vaccine in development, Pfizer and Johnson & Johnson respectively.