FDA wars: Former FDA chief Scott Gottlieb challenges current head Stephen Hahn on fast-tracking COVID vaccine, predicts mid-2021 rollout

[Former FDA] Commissioner <u>Scott Gottlieb</u> is questioning FDA Commissioner <u>Stephen Hahn</u>'s comments about fast-tracking a coronavirus vaccine, stating that a full approval of a vaccine for the general population likely won't happen until 2021.

Hahn <u>said in an interview</u> published by The Financial Times on [August 30] that he is willing to fast-track a coronavirus vaccine before clinical trials are complete if it is determined to be "appropriate."

"I don't know what is meant by saying before the phase three trials are completed," Gottlieb said <u>later on</u> <u>CBS's "Face the Nation,"</u> in response to Hahn's interview.

"These phase three trials are event-based trials, meaning that they're going to start to read out data after a certain amount of events accrue in the clinical trials. And those events are people getting COVID infection. And so as the trials progress, if we start to see lower rates of COVID infection in the active group, the group that receives the vaccine versus the placebo group, the group that hasn't received the vaccine," Gottlieb added.

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"I think, again, of full approval for the general population, where people can go to CVS and get a shot, that's really a 2021 event, maybe the first quarter of 2021, probably more likely the first half," he added.

Hahn told the Financial Times that politics would play no part in any decision to fast-track a coronavirus vaccine.

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