

## Trump, White House demand FDA justify tough standards for coronavirus vaccine, raising concerns of political interference

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*Some worry the move is an attempt to speed a vaccine before Election Day, which the president has tied to his reelection prospects.*

On the same day President Trump blasted the Food and Drug Administration's plan for tougher standards for a coronavirus vaccine as a "political move," a top White House aide demanded detailed justifications from the agency in what some fear is an attempt to thwart or block the standards designed to boost public trust in a vaccine.

The White House's involvement appears to go beyond the perfunctory review that agency officials had expected, and is likely to reinforce public concerns that a vaccine may be rushed to benefit the president's reelection campaign. Polls show that the number of people who say they're willing to take a coronavirus vaccine if it were available today has nosedived from 72 percent in May to 50 percent as of early this month, according to Pew Research Center, largely because of concerns that politics, rather than science, is driving the process.

Trump has repeatedly said a vaccine would be available by Election Day, or possibly sooner, worrying scientists that he might attempt to intervene in the review process. Companies will begin reporting safety and effectiveness data in coming weeks and months. And in conversations with some advisers, the president has directly tied the vaccine to his reelection chances, according to a senior administration official, who spoke on the condition of anonymity to discuss private deliberations.

The White House's decision to weigh in on the FDA plan was assailed by former FDA commissioners who had served both Republican and Democratic presidents.

"I don't know of any precedent where the White House asked to adjudicate scientific and clinical guidances, even in past public health emergencies," said Scott Gottlieb, Trump's first FDA commissioner. "To build trust among patients and providers, you wanted to leave these matters to the FDA process, which has a lot of rigor and integrity."

Robert Califf, commissioner under President Barack Obama, said White House officials lack the expertise to assess the FDA's safety protocols. "For the president to weigh in is not good," he said, "and it sets a precedent, which is worrisome in many regards, and makes you worry about what he'll do about the decision itself about individual vaccines."

The push from the White House comes during a week in which top health administration officials, including FDA Commissioner Stephen Hahn, vowed there would be no political interference in the vaccine approval process and sought to boost public trust in the process.

So far, the White House has not asked the FDA to withdraw or change the guidance for an emergency authorization of the vaccine — a far quicker process than a formal approval that gives the FDA the flexibility to set a lower bar for safety and effectiveness. The agency expects to use the process because of the urgency of the situation. In a Wednesday phone call, White House Chief of Staff Mark Meadows told Hahn the agency had to provide the detailed justification for the guidance, according to two people familiar with the call who spoke on the condition of anonymity to discuss internal deliberations.

The FDA, which had planned to release the guidance this week, instead has been working on detailed scientific justifications for the questions raised by White House officials, according to two people who spoke on the condition of anonymity to discuss internal deliberations. White House officials are especially interested in the agency's recommendation that manufacturers provide safety data for their clinical trial participants for a median of two months after they get their second vaccination shot. The FDA's data request would make it exceedingly difficult, though not entirely impossible, for a vaccine to be cleared by Election Day, experts say.

The recommendation is a way of ruling out some vaccine-related side effects, such as spinal cord inflammation called transverse myelitis or blood clotting issues, several experts said.

At a vaccine forum Thursday, Peter Marks, the top FDA career official who oversees vaccine reviews, said those types of side effects, though rare, tend to occur 42 to 60 days after the second dose of a vaccination, according to a research note from analyst Geoffrey Porges.

If the guidance is derailed, it may have little practical effect on how the FDA reviews prospective vaccines. The agency can still seek the information it wants from the companies, and the firms have known for weeks what the agency is looking for. But jettisoning the guidance would hurt the agency's effort to build trust among scientists and members of the general public who are worried an emergency authorization might pose major safety risks.

"Whatever happens with the guidance itself is not likely to change what FDA expects to see for any given product," said Patricia Zettler, an Ohio State University law professor and a former associate chief counsel at the FDA. "Nevertheless, this is yet another deeply, deeply troubling sign of political interference undermining FDA's critical public health work."

As the debate over vaccines has heated up, and polls show mounting concerns, Trump and White House aides blame Democrats for hurting the public trust in vaccines. Yet Trump himself has repeatedly bragged about the fact that the vaccine is on track to be developed in record time.

"It is a danger to the American public that the radical Left in coordination with their friends in the media has decided to become anti-vaxxers," said White House spokesman Judd Deere. "A

safe, effective, and proven vaccine will save lives and only win approval under the FDA's gold standard, not because of politics."

The politicization of the process is now coming from both parties. Citing Trump's denunciation of the FDA's proposed standard, New York's Democratic governor, Andrew M. Cuomo, said Thursday he would have state experts vet any FDA-cleared vaccine because he was "not going to trust the federal government's opinion."

Jason Schwartz, assistant professor at the Yale University School of Public Health, said Cuomo's announcement "may be well-intended, but setting up a state approval process would do more harm than good." State reviews of vaccines would "only add to confusion and uncertainty about these vaccines."

If the White House holds up or blocks the release of the FDA guidance, it will mark yet another instance of political interference in the delicate scientific and regulatory work of the nation's top health agencies. Trump has repeatedly clashed with the nation's top health agencies throughout the coronavirus response and undermined his health officials from the White House podium. Last week, for instance, he said Centers for Disease Control and Prevention Director Robert Redfield was "confused" when Redfield said a coronavirus vaccine would not be widely available until next summer or fall.

The president also undermined Hahn during a White House news conference Wednesday, after Hahn, in a Senate hearing, tried to reassure the public that any vaccine decision would be free of political interference.

When asked about the FDA's new guidance, Trump said he thought the new standards sounded "like a political move" and warned the White House might reject them. "I don't see why it should be delayed further," Trump said. "That is a lot of lives you're talking about."

The guidance initially seemed to move through the approval process as expected. On Tuesday, Health and Human Services Secretary Alex Azar and other top HHS officials were briefed and the FDA sent it to the White House later that day.

Inside the FDA, it was viewed as an elaboration upon guidance the FDA issued June 30, according to two senior administration officials who spoke on the condition of anonymity. That earlier guidance stated that to win regulatory approval, any coronavirus vaccine would have to prevent disease, or decrease its severity, in at least 50 percent of the people who receive it. It also said drug companies must monitor the vaccine's performance after approval for any emerging safety problems.

Later Tuesday, details of the guidance appeared in the press, including in The Washington Post, before it had received feedback or comments from the White House. Trump and White House aides were angered after they saw headlines — particularly one in the Drudge Report — that indicated the guidance could slow the vaccine timeline until after Election Day.

When Trump called Azar Wednesday afternoon to demand answers about the guidance, Azar said that Hahn was responsible for it and expressed frustration to the president — and later to other White House aides — that details had already appeared in the press, according to three people familiar with the call.

Also that afternoon, Meadows called Hahn and said the FDA had to provide “very detailed justification” on why the guidance required companies to do additional patient follow-up.

Joshua Sharfstein, a top FDA official in the Obama administration and now a Johns Hopkins University professor, said that by raising doubts about the integrity of the FDA, the president and his aides “are playing with matches. They could set fire to peoples’ trust in the vaccine process.”

He added that only the FDA, not the White House, has the expertise to determine what data is needed for approval or authorization. “This is a fight the president can’t possibly win,” he said. “There is no scenario where he says a vaccine is ready to go over the advice of the FDA, and anyone in their right mind wants to take it.”

But Meadows, appearing on CNN Thursday, raised questions about the timing of the guidance. “I found it very interesting that we would actually have new guidance that came out just a few weeks before we’re hopefully going to have some very good results on three clinical trials from some of these vaccines,” he said.

He called it “last-minute” advice from the FDA “that may perhaps change the parameters of ongoing trials.” Experts said the guidance would not change the design of trials; it simply explains the criteria by which the FDA would judge the data.

In a sign of concern about potential political interference, a group of prominent scientists and academics wrote to Pfizer’s chief executive, asking him to delay an application for FDA authorization until at least late November. “A premature application would prolong the pandemic, with disastrous consequences,” said the letter to Albert Bourla. Pfizer said in a statement that it shared the writers’ “commitment to rigorous safety standards,” but did not directly respond to their request.

— Carolyn Y. Johnson contributed to this report.

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