



Montreal, Canada

Cite this as: *BMJ* 2020;370:m3741

<http://dx.doi.org/10.1136/bmj.m3741>

Published: 24 September 2020

## Covid-19: FDA plans strict vaccine approval criteria, angering Trump

Owen Dyer

The US Food and Drug Administration (FDA) “will not delay, but will not cut corners” in approving a covid-19 vaccine, its commissioner Stephen Hahn promised a Senate hearing on 23 September, setting up a potential confrontation with President Trump.

Any decision will be made by the agency’s career scientists, said Hahn, following “the science and data and our rigorous standards. FDA will not permit any pressure from anyone to change that.”

As Hahn spoke, FDA scientists were informally briefing journalists around Washington to expect tough new standards in the coming days, setting almost as high a bar for vaccine emergency authorisation as demanded by the normal approval process. By requiring phase III trials to run for at least two months after a booster dose, the process rules out a vaccine before election day, which many public health experts fear has become a presidential priority.

Trump reacted sharply to the FDA’s plan. “It sounds like a political move,” he said, adding that the plan “has to be approved by the White House. We may or may not approve it.”

Trump said he has “tremendous trust” in the “massive companies” developing prospective vaccines. “When you have great companies coming up with these vaccines, why would the FDA have to be, you know, adding great length to the process?”

The FDA’s show of independence comes after the secretary of Health and Human Services, Alex Azar, sought to limit the agency’s role as the final arbiter of new regulations governing drugs and vaccines. Regulations approved by the FDA and other US health agencies have usually been signed off by the heads of those agencies. But, henceforth, Azar wrote in a 15 September memorandum to agency heads later obtained by the *New York Times*, such power “is reserved to the secretary.”<sup>1</sup>

The move is a “power grab,” former associate FDA commissioner Peter Lurie told the *New York Times*. Last month, Azar also revoked the FDA’s power to check the quality of coronavirus tests developed by laboratories for their own use.<sup>2</sup>

But the past month has also seen pushback from public health agencies alarmed by plunging public confidence in a prospective vaccine.<sup>3</sup> Their growing resolve to fight off political interference was on display in a Senate hearing on 23 September, where Centers for Disease Control and Prevention (CDC) director Robert Redfield rejected the possibility of a pre-election vaccine, and Anthony Fauci took on a newly stern tone with one of his most persistent critics, Senator Rand Paul.

A bipartisan group of four former FDA commissioners, including Scott Gottlieb, who served under Trump, has formed to publicly defend the agency. “The four

of us feel this is the time for us to step forward,” former commissioner Robert Califf told the *Washington Post*.

### Officials removed from office

The past month has led to the removal from office of several Trump loyalists, most of them public affairs officials. The health department’s public affairs office—which this week accused the media of undermining public health by covering the attempted sidelining of the FDA—lost its chief Michael Caputo and its science advisor Paul Alexander, after leaked emails showed their efforts to edit and block articles in the CDC’s principal publication, the *Morbidity and Mortality Weekly Report*.<sup>4</sup> Alexander was dismissed, while Caputo, who advised Trump supporters to “buy ammunition” for the election and questioned his own mental health in a Facebook video, took medical leave.

Two Trump appointees were also removed from the health department’s White House liaison office on 21 September after questioning the political leanings of veteran CDC scientist Anne Schuchat, who had publicly acknowledged failings in the US response.

Both the FDA and CDC have recently retracted statements and guidance that appeared to favour the Trump narrative and contradict the scientific consensus on covid-19.

On 25 August, FDA commissioner Stephen Hahn apologised and retracted a claim he made the previous day that convalescent plasma improved survival rates by 35%. The treatment had received emergency authorisation two days earlier on the eve of the Republican convention, where President Trump made inflated claims of its proven benefits.

The *New York Times* later reported that a week earlier Trump had called the director of National Institutes of Health, Francis Collins, whose agency was holding up the authorisation over doubts on its efficacy, telling him to “get it done by Friday.”<sup>5</sup>

The FDA removed its top spokesperson, Trump appointee Emily Miller, who aggressively defended Hahn’s 35% claim in overtly political press releases, after just two weeks on the job. Hahn’s apology frustrated health department leadership, and the outside communications consultant who had advised Hahn to make it, Wayne Pines, lost his contract.

The CDC, on 18 September, reversed guidance from the previous month which drew almost universal condemnation for claiming that those closely exposed to infected people did not need testing if they showed no symptoms.

Although presented as CDC guidance, that recommendation was written by health department staff and “dropped” into the agency website,

bypassing the scientific review process.<sup>6</sup> The CDC has not acknowledged the about-turn, calling its policy change a “clarification.”

A public affairs specialist for the National Institute of Allergy and Infectious Diseases (NIAID)—the agency run by Fauci—was unmasked on 21 September as a prolific anonymous conservative blogger who has branded the “media whoring Anthony Fauci” a “mask Nazi.”<sup>7</sup>

“The entire Wuhan virus scare was nothing more or less than a massive fraud perpetrated upon the American people by ‘experts’ who were determined to fundamentally change the way the country lives,” William Crews wrote under a pseudonym on the popular conservative website *Red State*.

“If there were justice,” he wrote, “we’d send a few dozen of these fascists to the gallows and gibbet their tarred bodies in chains until they fall apart.”

Crews apparently posted most of his articles during working hours at NIAID’s public affairs office. “NIAID first learned of this matter this morning, and Mr Crews has informed us of his intention to retire,” a spokeswoman for the agency said.

- 1 Kaplan S. In “Power Grab,” Health Secretary Azar asserts authority over FDA. *New York Times*. 19 September 2020. [www.nytimes.com/2020/09/19/health/azar-hhs-fda.html](https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html).
- 2 Cancryn A, Oweremohle S. HHS chief overrode FDA officials to ease testing rules. *Politico* 2020. [www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400](https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400).
- 3 Tyson A, Johnson C, Funk C. US public now divided over whether to get covid-19 vaccine. *Pew Research Center*. 17 September 2020. [www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine](https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine).
- 4 Dyer O. Trump appointees tamper with renowned CDC publication, claiming that scientists are trying to “hurt the president”. *BMJ* 2020;370:m3589. doi: 10.1136/bmj.m3589 pmid: 32933896
- 5 LaFraniere S, Weiland N, Shear MD. Trump pressed for plasma therapy, officials worry, is an unvetted vaccine next? *New York Times*. 12 September 2020. [www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html](https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html).
- 6 Mandavilli A. CDC testing guidance was published against scientists’ objections. *New York Times*. 17 September 2020. <https://www.nytimes.com/2020/09/17/health/coronavirus-testing-cdc.html>
- 7 Markay L. A notorious covid troll actually works for Dr Fauci’s agency. *Daily Beast*. 21 September 2020. [www.thedailybeast.com/redstate-covid-troll-streiff-is-actually-bill-crews-and-he-actually-works-for-dr-anthony-fauci](https://www.thedailybeast.com/redstate-covid-troll-streiff-is-actually-bill-crews-and-he-actually-works-for-dr-anthony-fauci).