# Inside the FDA's reversals and walk-backs as it grapples with the coronavirus pandemic

Washington (CNN)Dr. Stephen Hahn repeatedly pledged in a CNN interview Tuesday that science and data would be his "north star" while leading the Food and Drug Administration through the coronavirus pandemic. Then, a few hours later, President Donald Trump went on national television and politicized medical research and brazenly flouted FDA warnings.

The FDA had already put out a stark 1,000-word warning about the risks of hydroxychloroquine, a malaria drug some hoped would be an effective treatment for Covid-19. But this week, Trump suddenly announced he was taking the drug and falsely claimed there was no FDA warning.

Such is the life of a Food and Drug Commissioner in the Trump Era, in the year of the worst pandemic since 1918, with 1.5 million sick Americans and more than 95,000 lives lost.

Whether due to political pressure -- a charge Hahn denies -- or the natural burden of dealing with a global pandemic, the FDA has had to issue a number of high-profile walk-backs and revisions to its efforts to tackle Covid-19.

The agency's initially strict regulations for diagnostic test developers were removed after complaints. Its emergency authorization for hydroxychloroquine was followed by a sharp warning about deadly side effects. It issued a pullback after letting faulty antibody tests flood the market. In April it changed its guidance to allow the use of Chinese-made KN95 masks in healthcare settings, only to reverse course in May and ban many of them. There were even issues with the FDA-authorized test the White House used to screen visitors.

"Some of the science and data aren't perfect in emergency situations," Hahn told CNN in an interview this week. "You make the best with the information you have at hand."

To be sure, the coronavirus pandemic poses an unprecedented challenge to the nation's foremost health regulator. The agency has to walk a tightrope between speed and safety, responding quickly to a fast-moving crisis yet maintaining its job of thoroughly vetting tests, drugs and devices that could save lives. The FDA, Hahn acknowledged, is adapting as more is learned about the virus.

But former FDA officials and drug safety experts worry that, in some cases, the FDA might be more devoted to placating Trump -- and giving him quick wins to tout on television -- than sticking to the science.

"The political engagement here is magnitudes above anything I experienced over my public health career," said Dr. Stephen Ostroff, the FDA's former chief scientist who twice served as acting commissioner. "You want to separate out those political dimensions so you can make data-driven decisions. It has been incredibly challenging. Some of the things that have ended up happening, like the enthusiasm for hydroxychloroquine, have been exceptionally unfortunate."

Hydroxychloroquine rollercoaster

The tug-of-war between Trump and his public health agencies -- including the FDA -- has played out most publicly in the still-ongoing battle over hydroxychloroquine.

The anti-malaria drug has been on the market for decades, and was seen early on as a potential coronavirus treatment.

In March, Trump and Hahn were publicly out of sync: Trump promoted the drug and cited anecdotal success stories, while Hahn stressed the need for a "large, pragmatic clinical trial."

According to a whistleblower complaint from Rick Bright, the former director of an office involved in vaccine development at the Department of Health and Human Services, federal health officials were pressured to greenlight the widespread, unsupervised use of hydroxychloroquine to score a "short-term political victory" for Trump, even though FDA scientists weren't satisfied by the data.

The White House, HHS and the FDA deny Bright's allegations.

Nevertheless, the FDA granted an emergency use authorization (EUA) for the drug on March 28. This allowed a large donation from drug manufacturers to be used in the US, but only in hospitals or clinical trials -- far short of what Trump wanted. While the EUA cited "anecdotal reports" that the drugs "may" work, that note of caution was often lost amid the President's public promotions of the drug.

"It's an impossible political situation," one former top FDA official told CNN on the condition of anonymity. "They were fairly artful with their wording to make it clear they thought this was BS."

Also of concern to health experts who spoke to CNN, the FDA quietly lifted bans on previously censured drugmakers in India, to hasten the flow of hydroxychloroquine and other drugs into the US. Some of these manufacturers had been flagged for repeatedly misleading the FDA about the quality of their products, with one inspection finding a "cascade of failure" last summer.

"So, does the FDA believe these companies, that were trying to fool them in the past, suddenly became good manufacturers?" said Dinesh Thakur, a former pharmaceutical executive who became a drug safety whistleblower, leading to a $500 million settlement by his ex-company.

With the EUA in hand, Trump praised Hahn for moving quickly on hydroxychloroquine and other approvals. But within weeks, more studies came out suggesting the drug had no meaningful impact and could even lead to cardiac arrest. Finally on April 30, the FDA issued a science-heavy warning on hydroxychloroquine, stating unequivocally that the drug hasn't been proven safe for Covid-19 patients and that it should only be used be used under direct supervision of doctors.

On Friday, The Lancet medical journal published the results of an observational study of 96,000 Covid-19 patients, which found that the drugs were linked to greater risk of often deadly heart problems. The study concluded that seriously ill patients who got Trump's much-touted treatment plan of hydroxychloroquine combined with an antibiotic were more likely to die than people who got neither drug.

In an interview this week, Hahn defended his agency's handling of hydroxychloroquine. He acknowledged the political climate surrounding the drug, but said, "I stand by our decisions because I think they are rooted in science and data, and we'll continue to reevaluate."

But some experts say it's time for the FDA to pull the authorization.

"I just didn't see it, and I still don't see it," said Ostroff, the FDA's former chief scientist, referring to the efficacy of the drugs. "At this point, I'm not sure there remains a very strong rationale for keeping that EUA in place."

Ostroff was one of a handful of former officials who shared this view in recent interviews, even though pulling the authorization won't prevent doctors from prescribing the drugs off-label.

The FDA warning was a brave stand in the eyes of some Republican health experts, like former HHS Secretary Tommy Thompson, who served for four years under President George W. Bush.

"Politically, they're getting pushed pretty hard on hydroxychloroquine, but they're standing up and saying that it's not a clear-cut decision," Thompson told CNN in an interview. "You've got to applaud them for that. The desperation is there, but they're saying it still needs to be discussed."

Even with new research highlighting the risks of hydroxychloroquine, Trump continued publicly pressing the FDA to take action. He tagged Hahn and the FDA in a Saturday night tweet where he said "many physicians" want the FDA to remove restrictions on hydroxychloroquine, citing a supportive tweet from a plastic surgeon in Kentucky.

Hahn didn't reply to Trump on Twitter. But Sunday morning, Hahn posted a reminder for Americans to follow social distancing and wear masks during the Memorial Day holiday.

Paging Dr. Hahn

When China reported a cluster of unknown respiratory illnesses in December -- soon to be identified as Covid-19 -- Hahn had been on the job just two weeks.

His nomination had sailed through the Senate in bipartisan fashion after a hearing focused heavily on the risks of flavored e-cigarettes, the most prominent public health challenge the administration faced at the time. The word "pandemic" was mentioned only twice at the hearing.

A radiation oncologist, Hahn worked as the chief medical executive at the University of Texas MD Anderson Cancer Center before joining the FDA. He acknowledged that he has been learning on the job, both about the novel coronavirus -- as all health officials are -- and about the ins and outs of the FDA.

That's included learning how to guide the agency from his home while self-quarantining for 14 days earlier this month after coming into contact with someone infected with coronavirus.

Hahn says he has continued his usual routine of waking up at 4 a.m. and doing P90X -- an at-home plyometrics and resistance workout -- and brushed up on his reading in Italian when he needed a few minutes to unwind.

"I'm not going to argue that I'm happy that it happened," Hahn said of his recent move to self-quarantine, but he said it served as a reminder that Americans still face great risk from the virus.

'Open and honest counsel'

Hahn has managed mostly to fly under the radar, even amid waves of speculation about whether Trump is on good terms with many of the medical experts around him. The President has clashed with infectious disease expert Dr. Anthony Fauci; reportedly been on the brink of firing HHS Secretary Alex Azar; or been at odds with Dr. Robert Redfield, director of the Centers for Disease Control and Prevention.

Personable and unassuming, Hahn's style couldn't be further from Trump's brash showboating. Still, the two men get along well, sources tell CNN.

"He's fantastic," Trump said of Hahn at a March briefing. "He has been working 24 hours a day. He's been — he's worked like, probably as hard or harder than anybody in this — in the group, other than maybe Mike Pence or me."

Hahn has repeatedly and publicly denied that the President has pressured him to make decisions, such as authorizing hydroxychloroquine.

"I enjoy a very good relationship with the President. He asks for and he receives my open and honest counsel," Hahn said.

Whether the President takes that counsel to heart is another question. Just this week, Trump publicly usurped FDA guidance with his own medical wisdom when he unexpectedly announced he was taking hydroxychloroquine to prevent coronavirus, even though there's no proof it works, and the FDA is urging Americans against this course of action.

"Doctors are free to write prescriptions for unapproved indications of approved drugs, and that includes hydroxychloroquine," Hahn said, declining to comment on Trump's medical decisions, citing the fact that Trump said he consulted with and is being watched by the White House physician.

The testing tightrope

The FDA's struggle to hit the right balance between speed and efficacy was perhaps clearest when it came to testing.

As the CDC struggled to get its coronavirus test up and running in February, the FDA was proactive in troubleshooting. The agency sent an official to visit the CDC labs in Atlanta and determined contamination at the lab was likely causing the tests to malfunction.

But in the meantime, clinical labs were sitting on the sidelines, frustrated that the FDA's regulations made it hard for them to get tests approved. More than a month after the first known US coronavirus case, the FDA finally loosened its rules and large commercial test-makers began bringing their diagnostic tests to market, allowing the US to -- belatedly -- scale up testing.

Since then, the FDA has issued a warning that one of the prominent tests it authorized -- the Abbott ID Now test used by the White House -- sometimes falsely indicates individuals are negative for the virus. The FDA is looking into the issue. Abbott has defended its test.

When it came to antibody tests -- designed to check for prior Covid-19 infection -- some former FDA officials said the agency went too fast in granting approvals.

In March, the FDA announced companies could sell antibody tests without providing evidence they actually worked. Since then, some tests on the market have proven to be inaccurate or fraudulent — a serious risk since people who get a false positive result may wrongly believe they have already had the virus, and potentially developed some immunity.

In May, the FDA pulled an about-face, updating its guidance to require companies to promptly submit antibody tests for approval. It arranged for the US government to independently validate the tests available.

If the FDA regrets the initial free-for-all of allowing unproven antibody tests on the market, Hahn isn't letting on. The agency needed to get some tests out quickly, FDA officials said, and once a dozen or so had emergency use authorizations, the FDA tightened the rules.

"One of the lessons learned here is that this real-world evidence becomes very important in urgent situations," Hahn said. "What we have to find is the right balance so that we can ensure that the right tests are on the market."

Scott Whitaker, president and chief executive of medical technology association AdvaMed and a former Health and Human Services official during the Bush administration, defended the FDA's leadership on testing.

"If they had not moved quickly to get more serology tests to market, they would have been criticized for being too slow," said Whitaker, who has worked closely with Hahn on testing and capacity issues for his group's members. "Before this crisis, they were dealing with a normal world and a normal FDA and their job of making sure products are safe and effective before they get to market. When the world changed then they changed, as they should have."

Politics versus science

The whiplash at the FDA is symptomatic of a larger issue. What happens when a notorious science skeptic is President during a once-in-a-century pandemic?

Long before he entered the White House, Trump made a name for himself denying climate change and linking vaccines to autism. As President, he has claimed that windmills cause cancer and even suggested that ingesting disinfectant may help treat coronavirus.

With this backdrop, it's no surprise that Trump has repeatedly clashed with the federal health officials and agencies that are charged with following science -- not polls or public pressure.

"He chooses convenience over science," said Michael Gerrard, a Columbia Law School professor who tracks what he says are anti-science actions by the Trump administration. "What we saw with hydroxychloroquine and the FDA is all quite consistent. It's tragically not surprising."

In some cases, Trump has even turned to celebrity doctors for advice.

Dr. Mehmet Oz, the highly controversial TV personality, has been informally advising Trump, according to The New York Times. And Trump even summoned Hahn to the White House to listen to a pro-hydroxychloroquine presentation in April from Fox News host Laura Ingraham and two physicians who regularly appear on her program, according to the Washington Post.

Exasperated by the idea of Fox News personalities lecturing the FDA chief, the former top FDA official who spoke to CNN on the condition of anonymity said, "I would have quit on the spot."

Hahn's colleagues, current and former, dismiss the notion that Hahn is carrying out Trump's bidding, describing him as honest and transparent.

"Every position comes with some political realities to it," said Dr. Ramesh Rengan, who has known Hahn for 15 years and is chair of the radiation oncology department at the University of Washington. But, he added, "He's never taken the easier road. He's taken the right road."

This is not the first White House to lean on the FDA. There were high-profile partisan fights over the approval of emergency contraception during the Bush and Obama years, and dealing with pressure, both political and from industry, comes with the job.

But some experts say Trump has gone farther than his predecessors, and that some of the recent reversals and missteps under Hahn have tarnished the agency's hard-won reputation.

"We took 100 years to build this reputation as a science-based, impartial regulator. That's why everyone around the world trusts the FDA," said Thakur, the pharmaceutical whistleblower who now focuses on global drug safety issues. "I get this is an emergency, and you need to respond to the public need, but we aren't using science."

CLARIFICATION: The story has been updated to clarify the description of Rick Bright's former role at the Department of Health and Human Services.

## Vocabulary

### Executive

##### Noun

* A person or group of persons having administrative or supervisory authority in an organization.
* The person or persons in whom the supreme executive power of a government is vested.
* The executive branch of a government.

##### Adjective

* Of, relating to, or suited for carrying out plans, duties, etc.
* Pertaining to or charged with the execution of laws and policies or the administration of public affairs
* Designed for, used by, or suitable for executives

### Research

##### Noun

* Diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc.
* A particular instance or piece of research.

##### Verb (used without object)

* To make researches; investigate carefully.

##### Verb (used with object)

* To make an extensive investigation into

### Needed

##### Adjective

* Necessary, required, or wanted (usually used in combination)

### Impact

##### Noun

* The striking of one thing against another; forceful contact; collision
* An impinging

##### Verb (used with object)

* To drive or press closely or firmly into something; pack in.
* To fill up; congest; throng

##### Verb (used without object)

* To have impact or make contact forcefully
* To have an impact or effect

### Respond

##### Verb (used without object)

* To reply or answer in words
* To make a return by some action as if in answer
* To react favorably.

##### Verb (used with object)

* To say in answer; reply.

##### Noun

* Architecture. a half pier, pilaster, or the like projecting from a wall as a support for a lintel or an arch, the other side of which is supported on a free-standing pier or column.
* Ecclesiastical. a short anthem chanted at intervals during the reading of a lection. responsory. response.

### Social

##### Adjective

* Relating to, devoted to, or characterized by friendly companionship or relations
* Seeking or enjoying the companionship of others; friendly; sociable; gregarious.
* Of, relating to, connected with, or suited to polite or fashionable society
* Living or disposed to live in companionship with others or in a community, rather than in isolation

##### Noun

* A social gathering or party, especially of or as given by an organized group
* Digital Technology. social media

### Cloze Questions

##### Fill in the blanks

1: Hahn \_\_\_\_\_\_\_\_ he has \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ of waking up at 4 a.m. and doing P90X -- an \_\_\_\_\_\_\_\_\_\_\_\_\_\_ plyometrics and resistance workout \_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_ up \_\_\_\_ \_\_\_\_\_\_ reading in Italian when he \_\_\_\_\_\_\_\_\_\_\_\_ a \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ to unwind.

2: The tug-of-war between Trump \_\_\_\_\_\_ his \_\_\_\_\_\_\_\_\_\_\_\_ health agencies \_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the FDA -- has \_\_\_\_\_\_\_\_\_\_\_\_ out most \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_ the still-ongoing \_\_\_\_\_\_\_\_\_\_\_\_ over hydroxychloroquine.

3: According to a whistleblower complaint from \_\_\_\_\_\_\_\_ Bright, the former \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ of an office involved in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_ Department of Health and Human \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ federal health officials \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_ widespread, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_ of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_ a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ political victory" \_\_\_\_\_\_ Trump, \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ FDA scientists weren't satisfied by \_\_\_\_\_\_ data.

### Discussion Questions

1: Summarise the article in your own words

2: Do you agree with the article's point? Why/why not?

3: Can you come up with an argument against this article's point?