

The Trump administration is undermining the credibility of the FDA

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With our country having passed the grim milestone of 200,000 covid-19 deaths, losing the equivalent of the entire population of Salt Lake City, the Food and Drug Administration might soon face one of its most important decisions in our lifetimes: the authorization of a coronavirus vaccine. A vaccine is urgently needed to reduce the health impacts of the virus and help Americans return to normalcy.

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.

These are matters of medicine over which political leaders have no expertise, which is why our nation has long recognized the importance of having sound science drive public health and safety decisions. In 1906, when President Theodore Roosevelt signed a bill to create what is now the FDA, one of his first actions was to delegate the oversight of food and drug safety to the agency's scientists. In the 114 years since, FDA professionals have created a consumer safety net that has been a worldwide model for evidence-based public health policy. Indeed, for decades, when we and our predecessors spoke as FDA commissioners about issues of regulation and people's health, the public knew we were speaking on behalf of experts whose judgments were grounded in science.

That is changing in deeply troubling ways. The White House has said it might try to influence the scientific standards for vaccine approval put forward by the FDA or block the agency from issuing further written guidance on its criteria for judging the safety and benefits of a potential covid-19 vaccine. This pronouncement came just after key leaders at the FDA, the Centers for Disease Control and Prevention and the National Institutes of Health all publicly supported that guidance.

The White House statements came on the heels of other concerning actions that could impact the FDA's scientific standards. On Sept. 15, Health and Human Services Secretary Alex Azar revoked the FDA's authority to establish rules for food and drug safety, instead claiming that sole authority for himself. This came in the wake of acknowledged acts of political influence on the FDA's coronavirus communications, significant misstatements by the secretary and other political leaders about the benefits of hydroxychloroquine and convalescent plasma, and the overruling of FDA scientists on the regulation of covid-19 laboratory tests. At risk is the FDA's ability to make the independent, science-based decisions that are key to combating the pandemic and so much more.

These actions are eroding the public's confidence. This month, an Axios-Ipsos poll found that 42 percent of Americans lacked trust in FDA decision-making. Although the FDA fared far better than pharmaceutical manufacturers, and the federal and state governments, it was a striking departure from previous levels of trust. Public confidence in the FDA was once much higher.

The implications of the recent shift are potentially dire. When the FDA warns about a risk from contaminated food, will people heed it? When a new drug for cancer or heart disease is approved, will clinicians and families trust it to work? And most urgent for today: When the FDA approves a covid-19 vaccine, will Americans accept it?

The number of Americans who would be willing to take a coronavirus vaccine has declined sharply. The Pew Research Center recently reported that 78 percent expressed concern that the approval process will be too hasty. Only 21 percent of respondents said they would definitely take the vaccine — half the percentage that said this only four months ago.

If the FDA makes available a safe and effective vaccine that people trust, we could expect to meaningfully reduce covid-19 risk as soon as next spring or summer. Without that trust, our health and economy could lag for years.

Despite recent political actions, we continue to have confidence in the integrity and high-quality scientific work of FDA staff. Following defined practice, each vaccine clinical trial will continue until independent oversight boards and the sponsoring manufacturers stop them. The FDA has already effectively communicated its strict standard for evidence from these trials to the manufacturers, despite comments from the White House. The health professionals whom people still trust won't recommend a vaccine that hasn't met the FDA's standards. Drug makers have also pledged to use the FDA's scientific standards.

But the perception of political influence matters. With more than 750 Americans on average dying a day from covid-19, the FDA must be supported to play its unique and essential role. Scientists should make decisions based on data, unfettered by political pressure or the intrusions of ideology or vested interests. Political intrusion only prolongs the pandemic and erodes our public health institutions.

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