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## **6 Days After Letter From 65 Top Health Experts, Pfizer Backs Off October Vaccine Prediction**

Shifting Gears, Pharma Chief Decries Politicization of the Vaccine Process

Six days after receiving a letter from 65 top national health authorities, Pfizer Chairman and CEO Albert Bouria yesterday backed off earlier predictions that a vaccine would be ready for FDA emergency approval by October.

Bouria has previously announced that the pharmaceutical giant would have a vaccine sufficiently tested to submit to the FDA for an Emergency Use Authorization (EUA) by October. That date coincided with the Trump Administration's repeated claims that a vaccine would be developed and ready to use before the November election.

In a Sept. 25 letter to Bouria, 65 of the nation's top academic health authorities told the CEO that Pfizer's accelerated vaccine process and announcements were eroding public trust in ways that could ultimately cause enough people to refuse to take the drug, preventing the achievement of national herd immunity. Signing the letter were top leaders from U.S. medical schools including those at the Universities of Pennsylvania, Harvard, Yale, Johns Hopkins, NYU, Duke, Vanderbilt, George Washington, California, Tulane, Washington, and others.

Six health leaders from Penn were among the signatories: **Eve Higginbotham**, SM, MD, ML, Dean for Penn Medicine Office of Inclusion and Diversity; **Ezekiel Emanuel**, MD, PhD, Chair of the Department of Medical Ethics and Health Policy (MEHP); **Jonathan Epstein**, Executive Vice Dean and Chief Scientific Officer; **Steven Joffe**, MD, MPH, Interim Chair, MEHP; **Kevin Volpp**, MD, PhD, Division Chief, MEHP; **Rachel Werner**, MD, PhD, Executive Director, Leonard Davis Institute of Health Economics.

"If your vaccine is 75 percent effective," their letter told the Pfizer executive, "an estimated two thirds of the population would need to be vaccinated to achieve herd immunity. This vaccination rate would far exceed that of the annual influenza vaccine. To be successful, the public needs to have the utmost trust in the vaccine and the science behind it. This is why a rigorous safety standard based on science is so essential."

The letter cited the safety standard requiring current vaccine trial participants to be monitored for a minimum of two months following receipt of their second vaccine dose of the Pfizer drug. That would push FDA action beyond the election.

"Given that many trial participants have not yet received their second dose,

monitoring should occur through at least late November before an application for an Emergency Use Authorization should be considered by the FDA," the health authorities' letter said. "We respectfully urge you to abide by this rigorous safety standard. There is too much at stake. Submission of an application for an EUA before this standard is met would severely erode public trust and set back efforts to achieve widespread vaccination. In short, a premature application would prolong the pandemic, with disastrous consequences."

On Sept. 30, the *New York Times* echoed the same concerns as those in the letter from additional health authorities across the country. The newspaper also noted that Pfizer's ability to achieve the October delivery date had "an significant upside, to the tune of billions of dollars, in being first to the U.S. market with a vaccine. And staying in the president's good graces — particularly when he keeps talking about ways to lower drug prices — might not be a bad thing for a company that brought in nearly \$40 billion in 2019 from sales of high-priced, brand-name drugs."

The next day, Oct 1, Bouria sent a memo to Pfizer employees saying the company is no longer bound by its previous prediction that it would be ready to submit to the FDA in October. He also decried the politicization of the vaccine development process by the Trump administration.

"The amplified political rhetoric around vaccine development, timing and political credit is undercutting public confidence," Bouria wrote. "I can't predict exactly when, or even if our vaccine will be approved by the FDA for distribution to the public. But I do know that the world will be safer if we stop talking about the vaccines' delivery in political terms and focus instead on a rigorous independent scientific evaluation and a robust independent approval process."