

United States Senate

WASHINGTON, DC 20510

September 1, 2020

The Honorable Stephen Hahn, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn,

I am alarmed by your statement to the *Financial Times* that the Food and Drug Administration (FDA) is prepared to authorize a COVID-19 vaccine for emergency use before the completion of Phase III clinical trials.¹ It is essential that FDA engage in a transparent and rigorous process for review of all COVID-19 vaccine candidates. The agency must adhere to clear standards and guidelines for vaccine authorization and approval, not rely on *ad hoc* “podium policy.” I urge you to issue official FDA guidance clarifying your remarks on the criteria for emergency authorization of COVID-19 vaccines and making clear the agency will uphold its commitments to scientific integrity and regulatory independence. The nation cannot afford for FDA to jeopardize the fight against COVID-19 by cutting corners and undermining public confidence when it comes to the safety and efficacy of vaccines.

Last month, almost 400 leading public health experts wrote to you urging that FDA authorize or approve COVID-19 vaccines only after the agency has been able to evaluate safety and efficacy data from completed Phase III clinical trials.² Days later, you assured the public in an editorial that a “safe and effective COVID-19 vaccine that meets or exceeds the FDA regulatory standards will provide important momentum for pandemic recovery” and underscored the importance of a “clear public understanding of the evidence supporting vaccine safety and efficacy.” In addition, you emphasized that “[i]ssuance of an EUA for a COVID-19 vaccine may be appropriate once studies have demonstrated the safety and effectiveness of the vaccine.”³

Notwithstanding these assurances, in a *Financial Times* article published on August 30, you stated that FDA may find it “appropriate” to authorize a COVID-19 vaccine “before the end of Phase Three” clinical trials.⁴ In response, your predecessor, Dr. Scott Gottlieb, questioned the approach of “fast tracking” a vaccine before Phase III clinical trials are complete, saying FDA must wait for certain pre-specified benchmarks to occur before the agency “can make a decision around the efficacy of these vaccines.”⁵

¹ <https://www.ft.com/content/f8ecf7b5-f8d2-4726-ba3f-233b8497b91a>

² <https://www.nytimes.com/2020/08/05/health/covid-19-vaccine-fda.html>

³ <https://jamanetwork.com/journals/jama/fullarticle/2769421>

⁴ <https://www.ft.com/content/f8ecf7b5-f8d2-4726-ba3f-233b8497b91a>

⁵ <https://thehill.com/policy/healthcare/514336-gottlieb-questions-fda-chiefs-vaccine-fast-track-comments-full-approval-a>; <https://www.cbsnews.com/news/transcript-scott-gottlieb-discusses-coronavirus-on-face-the-nation-august-30-2020/>

Your assertion that FDA may authorize vaccines for emergency use prior to completion of Phase III trials risks creating uncertainty and distrust in FDA's process for the review of COVID-19 vaccines during a critical time in this public health emergency. I am especially concerned about these statements given reports of political interference in FDA decisions to authorize COVID-19 therapies, including hydroxychloroquine and convalescent plasma, and baseless allegations from President Trump that FDA's career public servants are trying to stop treatments and vaccines for COVID-19 from reaching the public. It is your responsibility to push back against any attempted political interference in FDA scientific decision-making and ensure the COVID-19 vaccine review process meets the highest standards and is beyond reproach.⁶

In June, FDA issued guidance that provided the agency's current thinking on standards for approval of a COVID-19 vaccine.⁷ I urge you to issue similar guidance on standards for emergency authorization of a COVID-19 vaccine to address uncertainty raised by your recent comments. In addition, I request you provide me a briefing within seven days to discuss this matter. To further discuss compliance with this request, please contact Katlin McKelvie Backfield with my Health, Education, Labor, and Pensions Committee Staff at (202) 224-7675.

Sincerely,

A handwritten signature in blue ink that reads "Patty Murray". The signature is written in a cursive style and is positioned above a horizontal line.

Patty Murray
United States Senator

⁶ <https://www.help.senate.gov/imo/media/doc/April%2030%20-%20BARDA%20letter%20FINAL.pdf>

⁷ <https://www.fda.gov/media/139638/download>