

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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August 24, 2020

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

Dear Dr. Hahn:

We write regarding the coronavirus disease of 2019 (COVID-19) vaccine development efforts, seeking assurance and reiterating our expectations that science and the protection of public health—not political expediency—will drive the U.S. Food and Drug Administration’s (FDA) decisions to authorize or approve a COVID-19 vaccine for use by the American people. The trust of the American people and the health of the nation depend on FDA and the Trump Administration abiding by this standard.

We all want a safe and effective COVID-19 vaccine as soon as possible. Since the beginning of the pandemic alone, Congress has already provided over \$8 billion for the pursuit of COVID-19 vaccines, therapeutics, and diagnostics.¹ This investment has enabled the unprecedented timeline of COVID-19 vaccine research, development, and manufacturing activities currently underway. Further, on May 15, 2020, the U.S. House of Representatives passed an additional \$4.75 billion for COVID-19 countermeasure efforts, including additional support to expedite vaccine efforts as part of the Heroes Act.² These resources are crucial not just for the speed of the endeavor, but also to ensure their safety and efficacy. As U.S. Department of Health and Human Services (HHS) Secretary Alex Azar said earlier this month, “The point is not to be first with a vaccine, the point is to have a vaccine that is safe and effective for the American people and the people of the world.”³ We could not agree more.

¹ Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, PL 116–123.

² H.R. 6800.

³ *Azar on Russia vaccine claim: Point is to be ‘safe and effective,’* The Hill (Aug. 11, 2020).

We appreciate the actions FDA has taken to provide leadership and expertise on the required evidence and safety considerations for the future authorization or approval of a COVID-19 vaccine. FDA's June guidance and recently published information confirming these safeguards provided valuable insight into how FDA will uphold its responsibilities.⁴ Further, FDA convening the Vaccines and Related Biological Products Advisory Committee (VRBPAC) may allow for public transparency into the safety and efficacy discussions and the decision-making process.⁵

You recently testified before the Committee that, when determining whether to approve a potential COVID-19 vaccine, FDA "will use the science and data that come to us, and we will use our high standards to assess the safety and efficacy of a vaccine."⁶ Industry experts agreed in a subsequent hearing that the guidance published by FDA outlining the agency's expectations for clinical development and licensure was sufficient to protect the health and safety of patients.⁷

According to FDA's guidance and your own statements, any authorized or approved COVID-19 vaccine would need to show in a placebo-controlled randomized trial that it prevents the disease, or decreases its severity, for at least 50 percent of people who are vaccinated.⁸ In understanding this efficacy threshold was informed by our seasonal flu vaccine efforts, we appreciate your explanation that a COVID-19 vaccine that could prevent "the majority of people from becoming infected would be a tremendous step forward towards herd immunity and a return to normal life."⁹

Given the time necessary to enroll and conduct phase III clinical trials as well as the duration of minimum safety monitoring requirements laid out in FDA's guidance, licensure of a

⁴ U.S. Food and Drug Administration, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 30, 2020) (FDA-2020-D-1137); Anand Shah, Peter Marks, Stephen Hahn, *Unwavering Regulatory Safeguards for COVID-19 Vaccines*, *Journal of the American Medical Association* (Aug. 7, 2020); Anand Shah, Peter Marks, Stephen Hahn, *Ensuring the Safety and Effectiveness of a COVID-19 Vaccine*, *Health Affairs* (Aug. 18, 2020).

⁵ Anand Shah, Peter Marks, Stephen Hahn, *Ensuring the Safety and Effectiveness of a COVID-19 Vaccine*, *Health Affairs* (Aug. 18, 2020); *Morning Pulse*, Politico (Aug. 10, 2020).

⁶ House Committee on Energy and Commerce, Testimony of the Honorable Stephen M. Hahn, M.D. Commissioner, U.S. Food and Drug Administration, *Hearing on Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (June 23, 2020).

⁷ House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations Subcommittee, *Hearing on Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine*, 116th Cong. (July 21, 2020).

⁸ Stephen Hahn, *FDA commissioner: No matter what, only a safe, effective vaccine will get our approval*, *Washington Post* (Aug. 5, 2020).

⁹ Anand Shah, Peter Marks, Stephen Hahn, *Ensuring the Safety and Effectiveness of a COVID-19 Vaccine*, *Health Affairs* (Aug. 18, 2020).

COVID-19 vaccine will be unlikely before spring 2021.¹⁰ As a result, any COVID-19 vaccine made available for public use before then would only be possible through FDA issuance of an emergency use authorization (EUA). Recently, you stated that, prior to issuing an EUA, FDA “would have to be very secure about the safety and some level of clinical efficacy,” and furthermore you committed not to “‘back away from the floor’ of 50 percent efficacy.”¹¹ You also acknowledged that most Americans are not familiar with the distinction between an authorization and approval by FDA, and that FDA’s “actions and communications can provide clarity about product safety and insight into regulatory decision-making.”¹²

While we were encouraged by your past statements, we are gravely concerned about the actions and the communications by the President, the White House, and HHS. Just this past weekend, the President falsely accused FDA of making COVID-19 vaccine clinical trial enrollment difficult as part of a “deep state” plot to delay a vaccine until after Election Day.¹³ Not only did White House Chief of Staff Mark Meadows defend the President’s accusations against FDA, he applauded them, stating, “sometimes you have to make them feel the heat if they don’t see the light.”¹⁴ As FDA Commissioner, it is your responsibility to lead and defend the agency, yet when the President and his Chief of Staff accused the FDA of being part of the “deep state” you remained silent.

Unfortunately, this is merely the latest example of science being politicized throughout the Trump Administration’s COVID-19 response. Whether sidelining the Centers for Disease Control and Prevention,¹⁵ undermining its public health guidance,¹⁶ or denigrating the Administration’s own experts such as Dr. Anthony Fauci, the Director of the National Institutes of Health’s National Institute of Allergy and Infectious Diseases,¹⁷ it is clear that there are many reasons for us to remain vigilant about the increasingly pervasive role politics is playing in our

¹⁰ U.S. Department of Defense, *Operation Warp Speed Accelerated Vaccine Process* (accessed Aug. 24, 2020) (www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/); U.S. Food and Drug Administration, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 30, 2020) (FDA-2020-D-1137).

¹¹ *Vaccines may win emergency uses for some specific populations, FDA commissioner says*, Politico (Aug. 10, 2020).

¹² Anand Shah, Peter Marks, Stephen Hahn, *Ensuring the Safety and Effectiveness of a COVID-19 Vaccine*, Health Affairs (Aug. 18, 2020).

¹³ *Trump calls out FDA chief, suggests agency is slow-walking Covid clinical trials*, Politico (Aug. 22, 2020).

¹⁴ *Mark Meadows defends Trump’s “deep state” attacks on FDA*, Axios (Aug. 23, 2020).

¹⁵ *‘We’ve been muzzled’: CDC sources say White House putting politics above science*, CNN (May 20, 2020).

¹⁶ Tom Frieden, Jeffrey Koplan, David Satcher and Richard Besser, *We ran the CDC. No president ever politicized its science the way Trump has*, Washington Post (July 14, 2020).

¹⁷ *White House goes public with attacks on Fauci*, The Hill (July 13, 2020).

scientific institutions.

We are increasingly concerned by the political pressure that is being exerted by this Administration on FDA. FDA issuing and then rescinding an EUA for hydroxychloroquine,¹⁸ followed this weekend by the issuing of an EUA for blood plasma as a treatment for COVID-19,¹⁹ raise serious questions of scientific independence. In both of these instances, the President exerted pressure on FDA to take action despite reports of conflicting evidence of the effectiveness of the treatments.²⁰ As has been reported, the President's behavior feeds the public's fear that "FDA will succumb to political pressure and approve a vaccine or drug that is not yet ready for prime time."²¹ This makes it all the more imperative that FDA take the threat to the public's vaccine confidence into account when conducting the benefit-risk assessment of a potential COVID-19 vaccine. As you put it, FDA's decisions should be grounded on the "scientific evidence and rooted in a benefit-risk calculation that always puts the safety of patients first."²²

We expect nothing less from FDA moving forward. It is essential that FDA maintain its scientific independence, adhere to required standards and protocols, and as you have repeatedly and recently promised, make decisions "based solely on good science and data."²³ Should political pressure arise, we believe it is your duty to the American people to notify Congress and the American people. Any political involvement in a future vaccine or treatment threatens to undermine the credibility of the agency, and public confidence in vaccines and treatments approved for use by FDA.

Given the ongoing threats COVID-19 poses to Americans' public health, and with hopes that an effective vaccine can be developed safely in record time, we request responses to the following by September 4, 2020.

¹⁸ *FDA's hydroxychloroquine reversal raises even bigger questions about Trump's role in pushing for the drug*, Washington Post (June 15, 2020).

¹⁹ *FDA, under pressure from Trump, authorizes blood plasma as Covid-19 treatment*, Stat News (Aug. 23, 2020).

²⁰ *Id*; *FDA's hydroxychloroquine reversal raises even bigger questions about Trump's role in pushing for the drug*, Washington Post (June 15, 2020).

²¹ *Trump calls out FDA chief, suggests agency is slow-walking Covid clinical trials*, Politico (Aug. 22, 2020).

²² Anand Shah and Stephen Hahn, *The FDA Response To COVID-19 At Six Months: Regulatory Innovation In The Face Of A Pandemic*, Health Affairs (Aug. 18, 2020).

²³ Stephen Hahn, *FDA commissioner: No matter what, only a safe, effective vaccine will get our approval*, Washington Post (Aug. 5, 2020).

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1. What safeguards and practices are in place, to mitigate against any political pressure from the President, the White House, and HHS, and also to prevent even the appearance of any political interference or expediency?
2. What further actions will FDA take to ensure that the evidence of safety and efficacy of a future vaccine will guide any and all decisions to issue an EUA prior to full licensure approval of a COVID-19 vaccine?
3. What, if any, remaining discussions, infrastructure assessments and modifications, and decisions must be made with regard to post market surveillance prior to vaccine authorization or licensure? What is your timeline for completing these steps?
4. Will all meetings, materials, and recommendations made by VRBPAC related to a COVID-19 vaccine or vaccine candidate be made public in real time? Please detail what components will be publicly available and how they will be released to the public (i.e., via public website).
5. What steps will you take to communicate to FDA staff their obligation to raise any and all concerns with regard to political interference undermining FDA's public health mission and science-based authority, as well as options available to them, including contacting Congress or the Committee?

Thank you for your timely attention to this matter. We look forward to the response and further updates as the nation the COVID-19 pandemic. For any questions about this request, please contact Jesseca Boyer and Stephen Holland of the Majority staff at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.
Chairman



Anna G. Eshoo
Chairwoman
Subcommittee on Health



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations