United States Senate
WASHINGTON, DC 20510

September 14, 2020

The Honorable Dr. Stephen Hahn
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to seek your commitment that the Food and Drug Administration's (FDA) review process for potential vaccinations against the coronavirus disease 2019 (COVID-19) will be fully transparent and accountable. We are encouraged by the development of a number of vaccine candidates,[1] and we share the FDA's goal of facilitating "the timely development of safe and effective vaccines to prevent COVID-19."[2] However, we are concerned that the accelerated timeline and intense political pressure around the vaccine development process could have the unintended consequence of undermining public confidence in the safety and quality of an eventual vaccine.

The rapid speed of COVID-19 vaccine development is unprecedented. Currently, more than 100 vaccines against COVID-19 are in development around the world,[3] with 37 currently in human clinical trials.[4] The previous record time for a vaccine to move from concept to approval was four years.[5] This progress reflects remarkable effort and collaboration by scientists around the world, as well as significant financial support from governments.[6] To address public concerns that the rapid speed of vaccine development could implicate the integrity of the review process,[7] the FDA issued guidelines in June 2020 to assist in the clinical development and

[1] New York Times, "Coronavirus Vaccine Tracker," Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer, September 8, 2020, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.
[2] Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines," press release, June 30, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid.
[3] New York Times, "Different Approaches to a Coronavirus Vaccine," Jonathan Corum, Knvul Sheikh, and Carl Zimmer, May 20, 2020, https://www.nytimes.com/interactive/2020/05/20/science/coronavirus-vaccine-development.html.
[4] New York Times, "Coronavirus Vaccine Tracker," Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer, September 8, 2020, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.
[5] Washington Post, "These are the top coronavirus vaccines to watch," Aaron Steckelberg, Carolyn Y. Johnson, Gabriel Florit and Chris Alcantara, September 8, 2020, https://www.washingtonpost.com/graphics/2020/health/covid-vaccine-update-coronavirus/.
[6] *Id.*
[7] JAMA, "Unwavering Regulatory Safeguards for COVID-19 Vaccines," Anand Shah, Peter W. Marks, and Stephen M. Hahn, August 7, 2020, https://jamanetwork.com/journals/jama/fullarticle/2769421.

licensure of vaccines for COVID-19.[8] Yet, the Trump Administration continues to apply political pressure on the agency—including President Trump's promise in his Republican National Convention speech that a vaccine will be approved by the end of 2020.[9] The Centers for Disease Control and Prevention's (CDC) recent announcement[10] that states should be prepared to distribute a vaccine by November 1 has further raised concerns that the approval process will be rushed.[11] That political pressure risks undermining public confidence in the FDA's review process unless the agency commits to expanding transparency even further.

President Trump has been exerting political pressure on the FDA for months, and at times, the agency has appeared to submit to this pressure. On August 22, President Trump tweeted, "The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd,"[12] referring to the presidential election. Just one day later, at a White House briefing, President Trump announced that the FDA was issuing an emergency use authorization (EUA) for convalescent plasma, claiming that the treatment is "safe and very effective" according to the FDA,[13] even as senior government scientists and former FDA officials say that plasma has not been "proven as an effective treatment."[14] The EUA announcement came only a few days after several of the federal government's top health officials, including Dr. Francis Collins and Dr. Anthony Fauci, argued to the FDA that the evidence on the effectiveness of convalescent plasma was too weak to justify its authorization, due to the lack of a control group in the primary study of its effectiveness.[15] Moreover, you overstated the benefits of convalescent plasma and, following criticism from medical experts, apologized for the overstatement.[16]

In March, President Trump promoted an unproven treatment for COVID-19 by declaring the malaria drug hydroxychloroquine a "game changer" against COVID-19 and called on the

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[8] Food and Drug Administration, "Development and Licensure of Vaccines to Prevent COVID-19," June 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19.

[9] Stat News, "Trump pledges a Covid-19 vaccine by end of 2020 – without acknowledging the scientific uncertainty," Lev Facher, August 27, 2020, https://www.statnews.com/2020/08/27/trump-pledge-vaccine-end-2020/.

[10] Letter to Governors from CDC Director Robert Redfield, August 27, 2020, https://drive.google.com/file/d/13qdjVpfU_2VvSQNadN6yubdVdKhlzmDU/view.

[11] New York Times, "C.D.C. Tells States How to Prepare for Covid-19 Vaccine by Early November," Sheila Kaplan, Katherine J. Wu, and Katie Thomas, September 2, 2020, https://www.nytimes.com/2020/09/02/health/covid-19-vaccine-cdc-plans.html.

[12] Tweet by Donald J. Trump, August 22, 2020, https://twitter.com/realDonaldTrump/status/1297138862108663808.

[13] Remarks by President Trump in Press Briefing, August 23, 2020, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/.

[14] Politico, "FDA authorizes plasma treatment despite scientists' objections," Zachary Brennan and Sara Owermohle, August 23, 2020, https://www.politico.com/news/2020/08/23/plasma-treatment-coronavirus-fda-trump-400390.

[15] New York Times, "F.D.A.'s Emergency Approval of Blood Plasma is Now on Hold," Noah Weiland, Sharon LaFraniere, and Sheri Fink, August 28, 2020, https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html.

[16] ABC News, "FDA chief apologizes for overstating plasma effect on virus," Matthew Perrone and Deb Riechmann, August 25, 2020, https://abcnews.go.com/Health/wireStory/fda-commissioner-overstated-effects-virus-therapy-72595122.

FDA to "put [it] in use IMMEDIATELY."[17] On March 28, the FDA issued an EUA for the drug's use with patients hospitalized with COVID-19,[18] but less than a month later, on April 24, it cautioned that hydroxychloroquine had "not been shown to be safe and effective" for treating COVID-19 and that it was aware of reports of "serious heart rhythm problems" in COVID-19 patients treated by hydroxycholoroquine.[19] The FDA revoked the EUA altogether on June 15.[20] Trump advisor Peter Navarro criticized the revocation of the EUA, calling it "a Deep State blindside by bureaucrats who hate the administration they work for more than they're concerned about saving American lives."[21] The former director of the Biomedical Advanced Research and Development Authority (BARDA), Dr. Rick Bright, has since filed a whistleblower complaint, alleging that he was demoted because he resisted pressure from the White House and Administration officials to direct resources toward this unproven and ineffective treatment, in violation of the terms of the EUA.[22]

More recently, *Axios* reported that "[t]o the alarm of some government health officials, President Trump has expressed enthusiasm for the Food and Drug Administration to permit an extract from the oleander plant to be marketed as a dietary supplement or, alternatively, approved as a drug to cure COVID-19, despite lack of proof that it works."[23] MyPillow founder and CEO Mike Lindell, who, to be clear, is not a public health expert, and has a financial stake in the company that develops oleandrin, promoted the drug to President Trump in July along with Secretary of Housing and Urban Development Ben Carson, and President Trump agreed that "the FDA should be approving it" even though there is no public data regarding oleandrin's testing in animals or humans for efficacy against COVID-19.[24] Despite this pressure, the FDA announced last week that it would not approve oleandrin to be marketed as dietary supplement.[25]

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[17] Tweet by Donald J. Trump, March 21, 2020, https://twitter.com/realDonaldTrump/status/1241367239900778501?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1241367245143642113%7Ctwgr%5Eshare_3&ref_url=https%3A%2F%2Fabcnews.go.com%2FHealth%2Ftimeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine%2Fstory%3Fid%3D72170553.

[18] Food and Drug Administration, letter to Dr. Rick Bright, March 28, 2020, https://www.fda.gov/media/136534/download.

[19] Food and Drug Administration, "FDA Drug Safety Communication: FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems," April 24, 2020, https://www.fda.gov/media/137250/download

[20] ABC News, "Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine," Libby Cathey, August 8, 2020, https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553.

[21] New York Times, "A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing," Sheryl Gay Stolberg, June 16, 2020, https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html?smid=tw-share.

[22] U.S. Office of Special Counsel Complaint of Prohibited Personnel Practice or Other Prohibited Activity, filed by Dr. Rick Bright, https://context-cdn.washingtonpost.com/notes/prod/default/documents/6bfde4d6-4c3d-4671-8eeb-6b3d39e47c03/note/26f73d7a-d060-4c25-af4c-a58a167ee2c7.#page=1.

[23] Axios, "Trump eyes new unproven coronavirus 'cure'," Jonathan Swan, August 16, 2020, https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html.

[24] *Id.*

[25] CNN, "FDA rejects oleandrin, an unproven coronavirus therapeutic pushed by MyPillow CEO, as a dietary supplement ingredient," Jen Christensen and Jamie Gumbrecht, September 4, 2020, https://www.cnn.com/2020/09/04/health/oleandrin-coronavirus-fda-mypillow/index.html.

Perhaps in part due to this politicization of scientific review process, polling unfortunately shows significant public skepticism about a future vaccine. A recent poll found that only 49% of American adults plan to accept a coronavirus vaccine, with 20% not planning to be vaccinated and 31% unsure.[26] The same poll found that only 25% of Black Americans and 37% of Hispanic Americans plan to be vaccinated.[27] A poll released last week from the Kaiser Family Foundation found that 62% of Americans are worried that "the political pressure from the Trump administration will lead the FDA to rush to approve a coronavirus vaccine without making sure that it is safe and effective."[28] In order to achieve broad acceptance with the public, a future vaccine for COVID-19 will need to overcome public skepticism about the speed of the process, underlying doubts about vaccine safety,[29] long-standing mistrust of the medical system among communities of color[30] – and the effects of the President's ongoing political interference.

Full transparency throughout the review and authorization process is thus essential to countering real or perceived politicization and building public confidence in any approved vaccine. Despite promises of transparency, many vaccine developers have not yet released their trial protocols, and in some cases they have disclosed information about the trials in closed-door meetings with investors that has not been made available to the general public.[31] In addition to the efforts FDA has already made to publish its recommendations regarding data needed for clinical development and licensure of vaccines, a transparent review process will require that FDA (1) make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public; (2) make the deliberations of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) open to the public; and, (3) publish in advance the details of each Phase 3 trial design, including how participants are recruited, how they will be monitored for severe side effects on an ongoing basis, and under what circumstances the trial would be terminated early.[32] Furthermore, given the disproportionate impact of the pandemic on communities of color and the history of racism in clinical trials,[33] the

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[26] Associated Press, "AP-NORC poll: Half of Americans would get a COVID-19 vaccine," Lauran Neergaard and Hannah Fingerhut, May 27, 2020, https://apnews.com/dacdc8bc428dd4df6511bfa259cfec44.
[27] *Id.*
[28] Kaiser Family Foundation, "KFF Health Tracking Poll - September 2020: Top Issues in 2020 Election, The Role of Misinformation, and Views on A Potential Coronavirus Vaccine," Liz Hamel, Audrey Kearney, Ashley Kirzinger, Lunna Lopes, Cailey Muñana, and Mollyann Brodie, September 10, 2020, https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/.
[29] Pediatrics, "Countering Vaccine Hesitancy," Kathryn M. Edwards, Jesse M. Hackell, and the Committee on Infectious Diseases, The Committee On Practice And Ambulatory Medicine, August 2016, https://pediatrics.aappublications.org/content/early/2016/08/25/peds.2016-2146.
[30] Am J Public Health, "Racial/Ethnic Differences in Physician Distrust in the United States," Katrina Armstrong, Karima Ravenell, Suzanne McMurphy, and Mary Putt, July 2007, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1913079/; Behav Med., "Medical Mistrust, Racism, and Delays in Preventative Health Screening Among African-American Men," Wizdom Powell, Jennifer Richmond, Dinushika Mohottige, Irene Yen, Allison Joslyn, and Giselle Corbie-Smith, Apr-Jun 2019, https://pubmed.ncbi.nlm.nih.gov/31343960/.
[31] New York Times, "Vaccine Makers Keep Safety Details Quiet, Alarming Scientists," Katie Thomas, September 13, 2020, https://www.nytimes.com/2020/09/13/science/coronavirus-vaccine-trials.html.
[32] Letter to FDA Commissioner Stephen Hahn from Lilian Abbo, et al., https://cspinet.org/sites/default/files/COVID_Vaccine_Letter_to_FDA_8.5.2020.pdf.
[33] J Health Care Poor Underserved, "More Than Tuskegee: Understanding Mistrust about Research Participation," Darcell P. Scharff, Katherine J. Mathews, Pamela Jackson, Jonathan Hoffsuemmer, Emeobong Martin, and Dorothy Edwards, March 10, 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4354806/; USA Today, "'Sign me up':

FDA has a responsibility to actively involve communities of color in the review and authorization process for any treatment or vaccine. The same is true for other populations that are at elevated risk from COVID-19, including older Americans and people with disabilities.

In order to understand how the FDA is addressing these concerns, we request answers to the following questions by September 28, 2020:

1. Will all meetings of the VRBPAC to discuss COVID-19 vaccine products, as well as documents reviewed during these meetings, be open to the public?

2. What steps has the FDA taken to prevent political interference in the agenda or discussions at the October 22 meeting of the VRBPAC, in light of its timing shortly before the presidential election?

3. Will data generated by COVID-19 vaccine clinical trials be made available to the public? What steps will the FDA take to ensure that enough data are made available to allow the public to evaluate the outcome of the clinical trials, including data used to inform a decision to issue an EUA, while protecting participant privacy?

4. Will the FDA require public disclosure of the design details of Phase 3 clinical trials for a COVID-19 vaccine, including the procedure for ongoing monitoring of severe side effects and the criteria under which the trial would be ended early?

5. How will the FDA assess safety and efficacy for groups with limited participation in early stage clinical trials, including pediatric patients and pregnant people?

6. What steps has the FDA taken to involve representatives of communities of color, people with disabilities, older Americans, and other groups at elevated risk from COVID-19 in the review process for vaccines?

Thank you for your consideration of this urgent matter.

Sincerely,

Elizabeth Warren
United States Senator

Margaret Wood Hassan
United States Senator

Dianne Feinstein
United States Senator

Kirsten Gillibrand
United States Senator

Why people of color are vital to getting a successful COVID-19 vaccine," Karen Weintraub, August 20, 2020, https://www.usatoday.com/story/news/health/2020/08/20/covid-19-vaccine-trials-need-diverse-volunteers/3297954001/.

Richard Blumenthal
United States Senator

Tina Smith
United States Senator

Jeffrey A. Merkley
United States Senator

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United States Senator

Jack Reed
United States Senator

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