United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

April 16, 2020

The Honorable Stephen M. 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 write to seek assurances that the Food and Drug Administration's (FDA) response to the COVID-19 outbreak is driven by unbiased scientific decision-making alone. A number of reports have raised serious concerns about whether political pressure has influenced FDA actions in recent weeks. FDA must act with speed and flexibility in its response to this extraordinary public health crisis but must do so in a manner that upholds scientific integrity over political influence.

In particular, I have questions about the effects of political pressure on FDA's Emergency Use Authorization (EUA) review process during the pandemic. FDA is authorized to issue an EUA to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases when there are no adequate, approved, and available alternatives.[1] Although the EUA mechanism is designed to provide flexibility in agency decision-making during an emergency, it still requires FDA to meet certain statutory criteria related to safety and effectiveness before the authorization can be granted.[2]

Under the Federal Food, Drug, and Cosmetic Act, a product may be considered for an EUA if the Commissioner determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product.[3] That risk-benefit analysis relies on the totality of the scientific evidence, while taking into account the quantity and quality of such evidence.[4] Over the past two months,

[1] 21 U.S.C. 360bbb-3(c); FDA Guidance for Industry and Other Stakeholders, Emergency Use Authorization of Medical Products and Related Authorities (Jan. 2017) ("EUA guidance"), Section III.B.; https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[2] 21 U.S.C. 360bbb-3(c); *see also* EUA guidance, Section III.B.
[3] *Id*.
[4] *Id*.

FDA has issued a number of EUAs as part of its response to COVID-19, including for in vitro diagnostic products, personal protective equipment, ventilators, and therapeutics.[5]

I am concerned about reports that President Trump pressured officials at FDA to issue an EUA authorizing the use of the drugs hydroxychloroquine sulfate and chloroquine phosphate for the treatment of certain patients with COVID-19.[6] On March 28, FDA issued an EUA authorizing both drugs to be distributed from the Strategic National Stockpile (SNS) "and used for certain hospitalized patients with COVID-19."[7] FDA's decision to grant this EUA has been widely criticized for a lack of quality evidence supporting the safety and effectiveness of the drugs in treating COVID-19, including by former FDA commissioner Dr. Margaret Hamburg and former FDA chief scientist Dr. Luciana Borio.[8] Dr. Hamburg has expressed fears that, in issuing this EUA, FDA has taken "a step away from scientific rigor, to a system that is much more subject to all kinds of interference, from wishful thinking to frank political and economic motivations."[9]

Reports of political pressure on FDA to issue this EUA are all the more concerning given the consequences. Although the EUA is limited to the use of hydroxychloroquine sulfate and chloroquine phosphate that are distributed from the SNS, the President's statements in support of the drugs have likely driven a spike in purchasing and prescribing the drugs on the commercial market, resulting in drug shortages; preventing patients who take these drugs for chronic conditions, such as lupus, from accessing them; and exposing thousands more patients to the drugs, which will lead to an increased incidence of even rare side effects associated with their use, including potentially serious cardiovascular events.[10] Moreover, according to researchers and multiple former FDA officials, including Dr. Hamburg, assessing the safety and effectiveness of these drugs for the treatment of COVID-19 will be difficult outside of the clinical trial context, and FDA's issuance of the EUA may have made it more difficult to recruit

[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas.

[6] https://www.reuters.com/article/us-health-coronavirus-usa-guidance-exclu/exclusive-pressed-by-trump-u-s-pushed-unproven-coronavirus-treatment-guidance-idUSKBN21M0R2; https://thehill.com/policy/healthcare/public-global-health/491251-trump-pushed-health-officials-to-make-anti-malaria.

[7] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics; https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html

[8] https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus#; https://www.politico.com/news/2020/03/29/fda-emergency-authorization-anti-malaria-drug-155095; *see also* https://thehill.com/homenews/administration/488796-trump-steps-up-effort-to-tout-malaria-drug-as-coronavirus-game.

[9] https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus#.

[10] https://newsroom.heart.org/news/caution-recommended-on-covid-19-treatment-with-hydroxychloroquine-and-azithromycin-for-patients-with-cardiovascular-disease-6797342; https://www.nejm.org/doi/full/10.1056/NEJMp2009457?af=R&rss=currentIssue; https://www.washingtonpost.com/business/2020/03/30/coronavirus-drugs-hydroxychloroquin-chloroquine/; https://www.nbcnews.com/politics/donald-trump/mayo-clinic-cardiologist-inexcusable-ignore-hydroxychloroquine-side-effects-n1178776; https://www.newsweek.com/swedish-hospitals-chloroquine-covid-19-side-effects-1496368.

participants in controlled clinical trials for these drugs, as well as for other potential treatments for COVID-19.[11]

In addition, Trump Administration officials have reportedly made similar efforts to pressure FDA to authorize the use of other potential COVID-19 treatments. For example, officials within the National Security Council (NSC) are reportedly pushing FDA to issue an EUA for Avigan (favipiravir), an antiviral drug approved for use in Japan for the treatment of influenza, despite concerns raised by other U.S. officials about risks, including birth defects, associated with the use of the drug.[12]

FDA's review of products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID-19 must be based solely on science, data, and the best interests of the public health, and not on political pressure from President Trump or other officials in the Administration. We rely on the expertise and judgment of FDA scientists and medical professionals to evaluate carefully the safety, effectiveness, and quality of medical products. Now more than ever, it is critical that FDA shield its experts from political influence. If the agency fails to do so, it risks unnecessarily exposing patients to potentially severe adverse health effects and losing the public trust in the tests, drugs, and vaccines that are — and will be — critical for addressing the COVID-19 pandemic.

I am committed to doing everything I can to ensure science drives all public health decisions around the health and safety of patients and families during this pandemic. To help me understand FDA's position on evidence-based policymaking in the agency's response to COVID-19, please provide a staff briefing on the following topics by no later than April 30, 2020:

1. Mechanisms in place to ensure political pressure does not interfere with the integrity of the agency's scientific decision-making process, including when and whether to grant EUAs for medical products;

2. Guidance from FDA to Trump Administration officials and advisors on the integrity of the agency's scientific decision-making process, including the process and standards for review of EUA requests;

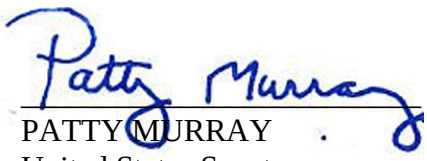
3. Guidance from FDA to Trump Administration officials and advisors on public communications about unapproved and unauthorized uses of medical products for the diagnosis, cure, mitigation, treatment, or prevention of COVID-19; and

4. The FDA officials and offices responsible for investigating and responding to political pressure on FDA scientific and medical staff concerning matters pending before the agency.

[11] https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus; https://www.nejm.org/doi/full/10.1056/NEJMp2009457?af=R&rss=currentIssue.
[12] https://www.politico.com/news/2020/03/31/white-house-pressures-fda-japanese-drug-157587 ("National Security Council officials seem determined to help Trump work around the regulatory system to achieve his goal of finding a coronavirus cure, while other U.S. officials feel caught in the middle.").

Thank you in advance for your attention to this critical matter. If you have any questions, or would like to further discuss compliance with this request, please contact Kathleen Borschow and Katlin McKelvie Backfield with my Health, Education, Labor, and Pensions Committee Staff at (202) 224-0767.

Sincerely,



PATTY MURRAY
United States Senator
Ranking Member, Senate Health, Education,
Labor, and Pensions Committee