Congress of the United States
Washington, DC 20515

July 2, 2020

Dr. Stephen Hahn, MD
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn,

We write today regarding reports that the U.S. Food and Drug Administration (FDA) has made decisions that have put Americans at risk. We previously wrote to the FDA and the Department of Health and Human Services Office of the Inspector General about one of these decisions, the FDA's April 27, 2020 Emergency Use Authorization (EUA) for hydroxychloroquine and chloroquine, leading to confusion about the drugs' efficacy in treating COVID-19. On Monday, June 15, 2020, the FDA withdrew their EUA for these two products, but real and irreversible harm was done because of the FDA's rushed rubber stamp approval. We request the FDA improve transparency and communications on the vaccine-development process, including information on the rationale of the approval of certain candidates over others.

Reports that FDA officials had knowledge of and allowed faulty COVID-19 antibody tests to flood the market have also surfaced.[1] In April 2020, the FDA made the decision to allow antibody tests to enter the U.S. market with no formal review. In May, 50 days later, the FDA finally reversed course and required test developers to show their data and apply for an Emergency Use Authorization (EUA). After nearly three months, the FDA started removing tests from the market, but the damage was done. By that point, municipalities had relied upon those faulty tests to determine how and when to send essential workers, like police, EMTs, and firefighters to work.

A concerning pattern is beginning to emerge of non-scientific based decision making at the FDA. We have seen reports that undue political considerations, rather than the FDA's rigorous scientific process, are playing a role in the ongoing development of a COVID-19 vaccine candidate.[2] We recognize and appreciate the need for expediency during the ongoing pandemic to provide a vaccine that will allow Americans to return to some semblance of normalcy. However, decisions regarding the development and distribution of a vaccine should be based on sound science only, not political pressure. In your search for a viable vaccine candidate, we ask that the FDA commit to regular agency procedures that demonstrate safety, efficacy, and effectiveness.

The failure to maintain the FDA's independence and scientific rigor will ultimately prove to be detrimental in the development of a COVID-19 vaccine. Advancing candidates for any reason other than scientific data and evidence may lead to public harm and further exacerbate growing public distrust of the FDA's work and integrity. EUAs play an important role in advancing the availability of new tools to cope with the onslaught of the pandemic, and we are fully aware of the

immense pressures to deliver a vaccine. However, safety and efficacy cannot be sacrificed in the urgency to present the nation with a rushed vaccine candidate to score political points. EUAs only require that the FDA finds it "reasonable to believe" that a vaccine or drug "may be effective" in preventing a disease to be marketed without being licensed.[3] The FDA should not grant EUAs to one or multiple vaccine candidates before completion of a rigorous and well-controlled study that determines infection prevention. No vaccine since the 1950s has been approved and licensed without completing large clinical studies of safety and effectiveness. With the understanding that many vaccine developers are merging clinical trials for efficiency, the FDA must remain vigilant and committed to the standards of safety and efficacy.

The nation's health and safety remain in the FDA's hands. Without a continued commitment to relying on science as the cornerstone of the decision-making process, a lackluster vaccine candidate will keep the American people from returning to any sense of normalcy. The lessons learned from the EUAs granted for hydroxychloroquine and allowing dozens of faulty COVID-19 antibody tests on the market must serve as a warning for the consequences of failing to remain true to the FDA's mission. We request that you publicly commit to advancing only the most viable of vaccine candidates and to running adequate and well-controlled trials to ensure there is public trust in any eventual COVID-19 vaccine. We also ask that you work with your interagency partners at the Centers for Disease Control and Prevention to educate the American public concerning the necessity of a future COVID-19 vaccine. We understand and support expediency for a vaccine against COVID-19, but we must support the scientific process over expediency.

Thank you for your consideration of this critical issue. We look forward to hearing from you and working with you going forward on this important issue.

Sincerely,

Robert Menendez
United State Senator

Bill Pascrell, Jr.
Member of Congress

CC: Director Robert R. Redfield, Centers for Disease Control and Prevention

[1] Federal officials allowed distribution of COVID-19 antibody tests after they knew many were flawed. (June 28, 2020). Retrieved from https://www.cbsnews.com/news/federal-officials-allowed-flawed-covid-19-antibody-tests-2020-06-25/

[2] Owermohle, S. (June 15, 2020). White house pressure for a vaccine raises risk the U.S. will approve one that doesn't work. *Politico* Retrieved from https://www.politico.com/news/2020/06/15/pressure-coronavirus-vaccine-risk-approval-316094

[3] Emergency use authorization of medical products and related authorities. (2017). Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities