

Congress of the United States
Washington, DC 20515

April 8, 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 to express concern with the U.S. Food and Drug Administration's (FDA) recent grants of emergency use authorization (EUA) to drugs and the approval of potential treatments for clinical trials. We are in the midst of the greatest test of our time, and as such our duty to ensure the safety, health, and well-being of Americans is more important than ever. The FDA is the gold standard worldwide for scientific review of medical products and we must maintain superior scientific judgement at this perilous time.

Specifically, we are concerned about two recent moves to fast-track drugs. First, the FDA issued emergency approval of hydroxychloroquine and chloroquine to treat COVID-19. While there is anecdotal evidence showing some initial positive outcomes from this decades-old malaria drug, there has been no adequate and well-controlled trial demonstrating safety and efficacy for COVID-19 patients. Second, the FDA approved a clinical trial for an experimental stem cell therapy, CYNK-001, whose objective is to prevent the severe symptoms of COVID-19 by using "natural killer" cells to boost the immune system of infected patients. There is very little evidence that this approach will work as intended. In both cases, we are concerned the FDA acted in the absence of scientific data, raising questions about whether the agency faced political pressure to act.

Former FDA officials have questioned the EUA as well, noting the total lack of scientific evidence that hydroxychloroquine and chloroquine are beneficial in the treatment of COVID-19 and that an EUA should only be issued when the evidence indicates that benefits outweigh the risks.¹ A leading stem cell researcher also observed that therapies like CYNK-001, which uses "natural killer" cells derived from the placenta, presents serious risks, including exacerbating respiratory issues – a particularly serious complication given COVID-19's threat to respiratory function.²

In addition to the FDA's actions, there are other consequences to Administration officials and advisors promoting drugs and therapeutics in contravention of scientific data and process. As a result of non-scientific promotion of hydroxychloroquine and chloroquine as therapeutic options for COVID-19 patients, individuals who take these medications regularly for autoimmune diseases like rheumatoid arthritis and lupus have faced severe barriers getting their prescriptions. Now, these patients face a nationwide shortage of these critical drugs because the drugs were promoted at a press conference despite a clear lack of evidence of their safety and efficacy in treating

COVID-19.³ Additionally, we are seeing evidence that providers are using their prescription authority to acquire and hoard the products for themselves, further straining the supply for patients who take the drug.⁴

While we understand the FDA is under immense pressure to quickly evaluate therapies for COVID-19, it is more important than ever that the FDA remain true to its standard processes in issuing EUAs. There is a chance that these two potential therapies could be more harmful than helpful. The FDA and the administration must also consider the damage done in the form of giving false hope to the American people. We represent a state on the frontlines of this pandemic. Statements promoting a therapy with no evidence, combined with the FDA's issuance of an EUA outside of its standard process, may cause many Americans to believe that these experimental drugs are a cure-all, and worse over may inspire some to abandon social distancing and other proven preventative measures critical to controlling this virus.

The FDA must maintain its global status as the gold standard for drug approval and review. It must not cede its responsibility to base decisions on rigorous scientific evidence. As this pandemic grows exponentially, your agency's decision-making process must not succumb to political pressure. An agency charged with protecting the public health can only do so by total dedication to the safety, efficacy, and security of human drugs and biological products. We look forward to your response.

Sincerely,



Bill Pascrell, Jr.
Member of Congress



Robert Menendez
United States Senator

¹ Borio, L. (2020). I would like to see who @FDA_MCMi signed off on this EUA despite the total lack of scientific evidence that chloroquine/hydroxychloroquine are beneficial in the treatment of COVID-19. EUA is supposed to be issued when the evidence indicates that benefits outweigh the risks. Retrieved from <https://twitter.com/lborio/status/1244450631491911688>

² Katie Thomas. (2020, Apr 2,). Unproven stem cell therapy gets OK for testing in coronavirus patients. *New York Times (Online)* Retrieved from <https://search.proquest.com/docview/2385245243>

³ Ornstein, C. (2020-03-22T16:41:00+0000). Lupus patients can't get crucial medication after president trump pushes unproven coronavirus treatment. Retrieved from <https://www.propublica.org/article/lupus-patients-cant-get-crucial-medication-after-president-trump-pushes-unproven-coronavirus-treatment>

⁴ Topher Sanders, D. A. (2020-03-24T13:45:00+0000). Doctors are hoarding unproven coronavirus medicine by writing prescriptions for themselves and their families. Retrieved from <https://www.propublica.org/article/doctors-are-hoarding-unproven-coronavirus-medicine-by-writing-prescriptions-for-themselves-and-their-families>