

April 1, 2020

Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hahn:

I am writing to request information about steps the U.S. Food and Drug Administration (FDA) is taking to address the sudden shortage of drugs touted as potential treatments for the novel coronavirus disease 2019 (COVID-19). In recent weeks, President Trump has repeatedly promoted the use of hydroxychloroquine and chloroquine—antimalarial drugs typically used to treat lupus, malaria, and rheumatoid arthritis—as treatments for COVID-19, despite neither drug being tested in appropriate clinical studies.¹ While the FDA issued an Emergency Use Authorization (EUA) for these drugs on March 28, 2020, limited studies on the drugs' effectiveness against COVID-19 remain inconclusive and neither drug has been fully approved by the FDA for this purpose.² President Trump's unproven claims about the drug have fueled an increased demand for them, leaving physicians and patients that already rely on them to grapple with shortages of these essential medications.

Though scientists have begun testing hydroxychloroquine and chloroquine as candidates for potential COVID-19 treatments³ and the FDA issued an EUA to allow these drug products to be “donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19,”⁴ public health experts have cautioned against their wide distribution.⁵ When asked about the effectiveness of hydroxychloroquine to treat COVID-19,

¹ Vox, “Trump’s reckless promotion of hydroxychloroquine to fight coronavirus, explained,” Nicole Narea, March 26, 2020, <https://www.vox.com/2020/3/26/21193912/trump-hydroxychloroquine-coronavirus-treatment>.

² U.S. Food and Drug Administration, “Emergency Use Authorization,” March 31, 2020, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

³ Vox, “Trump’s reckless promotion of hydroxychloroquine to fight coronavirus, explained,” Nicole Narea, March 26, 2020, <https://www.vox.com/2020/3/26/21193912/trump-hydroxychloroquine-coronavirus-treatment>.

⁴ U.S. Food and Drug Administration, “Emergency Use Authorization,” March 31, 2020, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

⁵ New York Times, “Trump’s Embrace of Unproven Drugs to Treat Coronavirus Defies Science,” Katie Thomas and Denise Grady, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>.

Director of the National Institute of Allergy and Infectious Diseases Dr. Anthony Fauci, stated existing evidence is “anecdotal” and that we “can’t make any definitive statement about it.”⁶

Despite these warnings, President Trump continues to use his platform to tout unproven treatments directly to the American people based on his belief that he is “a smart guy” and that he “feel[s] good about it.”⁷ On Twitter, President Trump tweeted:

“HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine,” irresponsibly referencing a small, inconclusive study of less than 40 patients.⁸ He has also falsely suggested that hydroxychloroquine had already been immediately approved by the FDA and that his administration will make hydroxychloroquine “available almost immediately” because there have been “very, very encouraging early results.”⁹ In reality, the drug had only been approved for non-COVID-19 related uses and the FDA has made it available for clinical studies or otherwise appropriate when clinical trials are not available, not mass consumption.

President Trump has even directly encouraged Americans to ask for prescriptions from their providers and downplayed any risks, saying, “If you wanted, you can have a prescription. You get a prescription. You know the expression, what the hell do you have to lose?”¹⁰ In Arizona, a man died and a woman is under critical care after incorrectly self-medicating with chloroquine, ingesting a form of the drug that is typically used for treating fish tanks.¹¹

Reports now indicate that, as a result of heightened attention on these anti-malaria drugs, some prescribers have already “begun writing prescriptions for these drugs for family, friends, and coworkers in anticipation of Covid-19 related illness,” – contributing to a shortage.¹² These drugs are now close to being completely depleted with four of eight manufacturers of

⁶ Vox, “Trump’s expert urged caution about a coronavirus treatment. Trump hyped it up anyway,” German Lopez, March 20, 2020, <https://www.vox.com/policy-and-politics/2020/3/20/21188397/coronavirus-trump-press-briefing-covid-19-anthony-fauci>.

⁷ New York Times, “Trump’s Embrace of Unproven Drugs to Treat Coronavirus Defies Science,” Katie Thomas and Denise Grady, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>.

⁸ Stat News, “Why President Trump is at odds with his medical experts over using malaria drugs against COVID-19,” Matthew Herper, March 22, 2020, <https://www.statnews.com/2020/03/22/why-trump-at-odds-with-medical-experts-over-malaria-drugs-against-covid-19/>; Tweet from President Donald Trump, March 21, 2020, <https://twitter.com/realDonaldTrump/status/1241367239900778501>.

⁹ Tweet from President Donald Trump, March 21, 2020, <https://twitter.com/realDonaldTrump/status/1241367239900778501>; White House, “Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing,” March 19, 2020, <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/>.

¹⁰ New York Times, “Trump’s Embrace of Unproven Drugs to Treat Coronavirus Defies Science,” Katie Thomas and Denise Grady, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>.

¹¹ Business Insider, “Trump touts unproven coronavirus treatment hours after reports that a man in Arizona died trying to use it,” Jake Lahut, March 23, 2020, <https://www.businessinsider.com/trump-touts-unproven-coronavirus-treatment-hours-after-it-killed-man-2020-3>.

¹² CNN, “States try to stop hoarding of possible coronavirus treatments,” Elizabeth Cohen, March 23, 2020, <https://www.cnn.com/2020/03/23/health/states-drug-stockpile-coronavirus/index.html>.

hydroxychloroquine reporting a shortage.¹³ Six states—Idaho, Nevada, Texas, Ohio, Oklahoma and West Virginia — have already taken strict measures to make sure the drugs are not being prescribed unnecessarily.¹⁴

Pharmacists are turning away some patients or providing them only with limited supplies because of this shortage, exacerbating existing health problems.¹⁵ Hydroxychloroquine has been shown to “lower the risk of dying from lupus and prevent organ damage, and is considered the standard of care.”¹⁶ One lupus patient having difficulties obtaining hydroxychloroquine explained how she is likely “going to go into a flare” or “increase other, more dangerous medicines” if she cannot get the drug.¹⁷ This is extremely disturbing because a disruption in access to these drugs presents serious risks for patients with autoimmune disorders, making them more susceptible to complications from COVID-19 should they get the virus. It is imperative that we ensure these drugs remain available for patients who rely on them to avoid illness and disability.

The FDA typically responds to drug shortages by “taking actions to address their underlying causes and to enhance product availability” when necessary – as well as to communicate to the public “information about shortages” on its website. Moreover, in shortages involving critical drugs, the FDA “may look for a firm that is willing and able to redirect product into the U.S. market to address a shortage.”¹⁸

On February 27, 2020, the FDA warned the American public that the COVID-19 outbreak “would likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products.”¹⁹ And the agency has been monitoring the drug supply for “potential shortages,” including identifying 20 drugs which solely source their active pharmaceutical ingredient or finished drug product from China and 63 manufacturers that produce essential medical devices.²⁰ But due to the unprecedented nature of this pandemic,

¹³ Washington Post, “As Trump touts an unproven coronavirus treatment, supplies evaporate for patients who need those drugs,” Christopher Rowland, March 23, 2020, <https://www.washingtonpost.com/business/2020/03/20/hospitals-doctors-are-wiping-out-supplies-an-unproven-coronavirus-treatment/>; Reuters, “States work to limit prescriptions of potential coronavirus drugs,” Michael Erman, March 22, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-pharmacies/states-work-to-limit-prescriptions-of-potential-coronavirus-drugs-idUSKBN2190XC>.

¹⁴ CNN, “States try to stop hoarding of possible coronavirus treatments,” Elizabeth Cohen, March 23, 2020, <https://www.cnn.com/2020/03/23/health/states-drug-stockpile-coronavirus/index.html>.

¹⁵ ProPublica, “Lupus Patients Can’t Get Crucial Medication After President Trump Pushes Unproven Coronavirus Treatment,” Charles Ornstein, March 22, 2020, <https://www.propublica.org/article/lupus-patients-cant-get-crucial-medication-after-president-trump-pushes-unproven-coronavirus-treatment>.

¹⁶ New York Times, “Trump’s Embrace of Unproven Drugs to Treat Coronavirus Defies Science,” Katie Thomas and Denise Grady, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>.

¹⁷ ProPublica, “Lupus Patients Can’t Get Crucial Medication After President Trump Pushes Unproven Coronavirus Treatment,” Charles Ornstein, March 22, 2020, <https://www.propublica.org/article/lupus-patients-cant-get-crucial-medication-after-president-trump-pushes-unproven-coronavirus-treatment>.

¹⁸ Food and Drug Administration, “Frequently Asked Questions about Drug Shortages,” last updated July 05, 2018, <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>.

¹⁹ U.S. Food and Drug Administration, “Coronavirus (COVID-19) Supply Chain Update,” February 27, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>.

²⁰ *Id.*

questions remain as to how the FDA may be handling shortages due in part to misinformation from the President.

The Department of Health and Human Services has announced that it “accepted 30 million doses of hydroxychloroquine sulfate donated by Sandoz, the Novartis generics and biosimilars division, and one million doses of chloroquine phosphate donated by Bayer Pharmaceuticals, for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials.”²¹ However, it is not clear whether and how HHS is working to mitigate shortages of hydroxychloroquine and chloroquine for non-COVID-19 uses, including for lupus and rheumatoid arthritis patients who rely on these drugs.

In order to address reports of shortages of hydroxychloroquine and chloroquine caused by increased demand, I ask for an update on how the agency is working to guarantee that patients that rely on these drug will continue to have access during this crisis, how the agency is working to combat misinformation about the effectiveness of drug treatments for COVID-19, and about how the agency may be working with providers to ensure safe prescription practices for these drugs.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Warren", written over a horizontal line.

Elizabeth Warren
United States Senator

²¹ Department of Health and Human Services, “HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients,” Press Release, March 29, 2020, 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.