Congress of the United States
Washington D.C. 20515

April 8, 2020

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hahn:

I am writing regarding concerns I have about reports of hoarding and utilizing certain medications to treat COVID-19, without adequate clinical data that point to their efficacy. Additionally, I am concerned that the publicity certain treatments are receiving are putting the populations that rely on them to survive at extreme risk.

Specifically, hydroxychloroquine (HCQ) and chloroquine (CQ) are currently used by tens of thousands of Americans to treat lupus, rheumatoid arthritis (RA), and malaria. As you know, these three conditions are the only indications for which these drugs are approved by the Food and Drug Administration (FDA). In fact, HCQ and CQ are often the only course of treatment for these patients.[1]

On March 28, 2020, FDA issued an emergency use authorization (EUA)[2] for both HCQ and CQ despite the limited in-vitro and "anecdotal" evidence of efficacy for the treatment of the coronavirus disease (COVID-19). The Centers for Disease Control and Prevention note "there are no currently available data from Randomized Clinical Trials (RCTs) to inform clinical guidance on the use, dosing, or duration of hydroxychloroquine for prophylaxis or treatment of [COVID-19]." [3]

Since the above-referenced EUA was issued, patients with lupus and RA have already been reporting the inability to access their medications. Shortages continue to be reported across the country, including in my home state of Colorado, and on March 31, 2020 FDA added both HCQ CQ[4] on their drug shortage list. I am particularly concerned about anecdotes of hoarding practices of these drugs to have "just in case" as well as inappropriate prescribing of these experimental treatments which seem to be exacerbating the drug shortage issue.

To mitigate this fast-growing problem, a number of states have already begun imploring providers to restrict dispensing of HCQ and CQ solely for FDA-approved indications of use or as

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[1] https://www.lupus.org/news/joint-statement-urging-white-house-coronavirus-task-force-and-nation-s-governors-to-ensure#
[2] https://www.fda.gov/media/136534/download
[3] https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html#r1
[4] https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

a part of a state-approved clinical trial.[5] Until further information can be ascertained to prove the efficacy of these drugs for the treatment of COVID-19, I urge FDA to issue a Dear Health Care Provider Letter to warn providers against prescribing HCQ or CQ for non-FDA-approved indications for use. This would help alleviate the current drug shortage, ensure patients who rely on these medications can access their treatments, and address the misuse of these important therapeutics.

Lastly, the following information would be helpful:

- What immediate and proactive actions is FDA taking to ensure current supplies of HCQ and CQ are allocated for patients taking them for FDA-approved indications?
- What is FDA doing to address the current HCQ shortage?
- Are disbursed SNS supplies of HCQ and CQ able to be used to treat patients with FDA-approved indications in addition to COVID-19 patients?
- If so, is FDA coordinating with the Assistant Secretary for Preparedness and Response (ASPR) to use the SNS supplies to alleviate the drug shortage of HCQ?

While I support continued research to study HCQ, CQ, and any other drug as a potential treatment to COVID-19, it is imperative that patients with FDA-approved indications for use are able to access their medications. Their lives depend on it.

Your swift response is appreciated.

Sincerely,

Diana DeGette
Member of Congress

[5] https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency