

United States Senate
WASHINGTON, DC 20510

April 22, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to express serious concerns with recent shortages of hydroxychloroquine and chloroquine and the severe impact these shortages could have for patients in Virginia. We are concerned that the recent attention given to these drugs as potential treatments for the novel coronavirus (COVID-19) has severely diminished the supply and may prevent patients with chronic conditions from accessing life-saving care. We urge you to work to ensure patients have access to these drugs, on which they have long depended.

Millions of Americans with lupus, rheumatoid arthritis, and malaria depend on hydroxychloroquine and chloroquine for treatment.¹ According to the Johns Hopkins Lupus Center, hydroxychloroquine helps reduce flareups in lupus patients by “as much as 50%” and some patients depend on the drug their entire lives to control their symptoms.² If these drugs were to become unavailable for lupus patients, the impact could be devastating. Hydroxychloroquine is often the only medication that works to increase survival for lupus patients. Shortages could be especially deadly for minority women, as lupus is the fifth leading cause of death in African American and Hispanic-American women.³

On March 28, your agency issued an Emergency Use Authorization to allow these drugs to be distributed from the Strategic National Stockpile to states for doctors to prescribe to patients when a clinical trial is not feasible.⁴ The Department of Health and Human Services cited “anecdotal reports suggesting that these drugs may offer some benefit in the treatment of hospitalized COVID-19 patients.”⁵ However, members in the Administration have also touted hydroxychloroquine as a “miracle drug,” and soon after, shortages of the drug were reported by

¹ <https://www.wsj.com/articles/states-try-reducing-malaria-drug-hoarding-amid-unproven-coronavirus-benefit-11586095200>

² <https://www.hopkinslupus.org/lupus-treatment/lupus-medications/antimalarial-drugs/>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6105528/>

⁴ <https://www.fda.gov/media/136534/download>

⁵ <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>

health care providers and patients will chronic illnesses.⁶ In fact, the FDA announced just days later that these drugs were “currently in shortage... due to a significant surge in demand.”⁷

To our knowledge, 30 million doses of hydroxychloroquine and 1 million doses of chloroquine have been donated to the Strategic National Stockpile for use in treating patients hospitalized with COVID-19.⁸ According to a joint statement from the American Medical Association, the American Pharmacists Association, and the American Society of Health-System Pharmacists, many pharmacies and hospitals have also purchased “excessive amounts” of the medication.⁹

Unfortunately, as a result, we have heard from patients across the Commonwealth who are fearful they will not be able to access these drugs, many of whom have depended on them for many years. We have also heard from prescribers who expressed the local supply of the drug is currently depleted. We fear that if this continues we will have a new public health crisis on our hands on top of the pandemic.

Patients cannot – and should not – simply stop taking their medication. Our understanding is that if lupus patients stop taking the medication, they may develop withdrawal symptoms that may require hospitalization.¹⁰ If unable to take the drugs they rely on, there may be a spike in hospitalized lupus patients at a time when hospital beds are already at capacity with COVID-19 patients, further overwhelming our health care system.

We understand that you have posted a statement on the FDA’s website, saying your agency is “working with manufacturers to assess their supplies and actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus, and rheumatoid arthritis.”¹¹ We also appreciate that you published product-specific guidances to support the development of generic counterparts for these drugs.¹² However, while we appreciate your attention to this serious matter, we implore your agency to consider implementing more tangible steps to mitigate drug shortages. We respectfully request that your agency answer the following questions:

- By when will the FDA’s assessment of supply shortages and evaluation of market demand be completed?
- What is the current estimated timeline for the development of generic counterparts for these medications?
- What else is the FDA doing to truly address this shortage?

⁶ <https://www.npr.org/sections/coronavirus-live-updates/2020/04/07/829302545/trump-tells-the-story-of-a-miracle-cure-for-covid-19-but-was-it>

⁷ <https://www.newsweek.com/fda-shortage-hydroxychloroquine-chloroquine-1495555>

⁸ <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>

⁹ <https://www.pharmacist.com/sites/default/files/files/Apha%20Coronavirus/Apha%20Coronavirus/2020/03/ama-apha-ashp-statement-ensuring-access-to-medicines-covid-19.pdf>

¹⁰ <https://www.cnn.com/2020/04/07/health/hydroxychloroquine-shortage-lupus-arthritis/index.html>

¹¹ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-7-2020>

¹² <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-13-2020>

- In addition to the items mentioned in the April 13th press release, what other steps is the FDA taking to ensure that patients who previously depended on hydroxychloroquine and chloroquine have access to the drugs for treatment of chronic conditions?

Thank you again for your attention to this matter. We look forward to your response on this issue for the health and wellbeing of our nation's patients.

Sincerely,

/s/Mark R. Warner
United States Senator

/s/Tim Kaine
United States Senator