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March 31, 2020

**Stephen M. Hahn, MD, FASTRO**  
Commissioner  
Office of the Commissioner  
Food and Drug Administration  
United States Department of Health and Human Services  
10903 New Hampshire Avenue  
White Oak Building One, Room 2217  
Silver Spring, Maryland 20993

Dear Commissioner Hahn:

We write you today on behalf of the American Society of Tropical Medicine and Hygiene (ASTMH), the largest international scientific organization of experts dedicated to reducing the worldwide burden of tropical infectious diseases and improving global health. Since our founding in 1903, malaria has been a central focus for ASTMH.

The ongoing pandemic of COVID-19 understandably has the world and the scientific community searching desperately for solutions, including effective treatments. We understand that the FDA has acted under its authority through the Emergency Use Authorization to provide assistance in a public health emergency and thereby approved the antimalarial and anti-inflammatory 4-aminoquinolines chloroquine and hydroxychloroquine for the treatment or prevention of COVID-19. Given the known side effects, we urge extreme caution and strong monitoring with their use. In addition, we remind you that as a member of FDA's Network of Experts, you have access to leading ASTMH member malariologists who have specialized scientific or medical expertise to offer during this rapidly evolving public health emergency. We are eager to help.

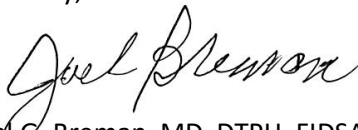
The two randomized clinical trials of hydroxychloroquine for COVID-19 reported to date had small numbers of patients and methodological limitations, and they produced conflicting results. In addition, two small non-randomized studies of treatment with the combination of hydroxychloroquine and azithromycin have been reported. In both of these studies, many of the enrolled patients had mild disease, so the need for treatment was unclear. Side effects of chloroquine and hydroxychloroquine can be substantial, with pre-existing, especially cardiovascular conditions, notably arrhythmias. The combination of hydroxychloroquine and azithromycin may increase risk of arrhythmia.

Furthermore, surging demand for hydroxychloroquine for management of COVID-19 risks loss of drug availability for many patients with systemic lupus erythematosus or rheumatoid arthritis, for which the drug is clearly indicated. Evidence from carefully designed, randomized treatment and prevention trials with both new and old compounds is urgently needed before any regimen should be endorsed for widespread use.


Evidence must always guide our drug and vaccine treatment and prevention strategies, as learned recently in combating Ebola virus disease in eastern Democratic Republic of the Congo. Adhering to this sound scientific principle is our compass.

We are all in this together.

Sincerely,



Joel G. Breman, MD, DTPH, FIDSA, FASTMH  
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