



March 26, 2020

Commissioner Stephen Hahn, MD
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Janet Woodcock, MD
Center Director, Center for Drug Evaluation and Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn & Dr. Woodcock:

The Sjögren's Foundation is writing in support of the recent public statement made by the American College of Rheumatology, Lupus Foundation and the Arthritis Foundation regarding hydroxychloroquine.

Our Foundation continues to hear daily from hundreds of patients about the inability to obtain refills at their local pharmacies due to shortages of the medication. We have also heard from several patients that their medical networks are disallowing renewal of this drug, thus causing and creating dire ramifications for many Americans.

Sjögren's is a systemic autoimmune disease that affects the entire body and can severely impair quality of life and lead to disability and sometimes death. Sjögren's affects as many as 4 million Americans, with the average age of diagnosis being 42 years old. According to the Sjögren's Foundation 2017 national survey executed by Harris Poll, 43% of those patients depend on hydroxychloroquine (the generic) and Plaquenil® (name brand) to treat their disease.

Clinical Practice Guidelines for Sjögren's recommend the use of hydroxychloroquine as a standard of care and first-line treatment of Sjögren's. Published by the American College of Rheumatology (ACR) journal, *Arthritis, Care & Research*, these guidelines were developed using a rigorous methodology as devised by leading groups such as the Institute of Medicine and the ACR. In addition, hydroxychloroquine/Plaquenil® have been used in the treatment of Sjögren's for over 30 years.

This is why we echo yesterday's statement calling for the White House Coronavirus Task Force to work with the FDA, pharmaceutical industry and pharmacies to:

- increase monitoring and timely reporting of shortages
- increase production and supply of these drugs
- take action to ensure current supplies are allocated for patients already taking them

Ensuring that patients have continued access to these life-saving drugs to treat their Sjögren's, lupus, rheumatoid arthritis and related diseases is critical. Without continued stable dosing, Sjögren's patients will experience an incapacitating exacerbation of the disease, including debilitating fatigue as well as other devastating complications that will not allow them to work or function, thus driving up healthcare costs and disability claims. In addition, a lapse in medication can cause a patient to revert in their disease progression, causing long-term consequences to their health.

We know, Dr. Woodcock, that as a fellow rheumatologist, and through our work together in Sjögren's-related clinical trials, you understand the extremely limited treatment options for our patients. In the current environment, we wish to emphasize how important hydroxychloroquine is to our patient population that depends on it to function day in and day out. And while we absolutely recognize the profound and urgent global need to find safe and effective treatments for COVID-19, we want to ensure that there is awareness and consideration of the lives of Sjögren's and other autoimmune disease patients who will suffer harmful or life-threatening consequences if they experience a lapse in treatment or in their stable dosing of hydroxychloroquine.

We thank you for considering our concerns on this issue, and for all of your important work, particularly during this critical time. If you have any questions, please do not hesitate to contact us at 301-530-4420, ext. 211 or by email at staylor@sjogrens.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Taylor".

Steven Taylor
President & CEO
Sjögren's Foundation

A handwritten signature in black ink, appearing to read "Theresa Lawrence Ford".

Theresa Lawrence Ford, MD, FACR
Medical & Scientific Advisors Chairperson
Sjögren's Foundation