

Congress of the United States
Washington, DC 20515

August 2, 2016

Robert M. Califf, M.D., Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Access to Quinacrine for Patients with Lupus

Dear Commissioner Califf,

Patient organizations in the lupus community have brought to our attention that the Food and Drug Administration (FDA) is currently reviewing whether the active ingredient in quinacrine, a drug often used to treat lupus patients, will continue to be available to compounding pharmacies. As Co-chairs of the Congressional Lupus Caucus, we share their concerns regarding the adverse impact of a decision by the FDA to restrict access to quinacrine, which for over fifty years has been a critical treatment for numerous symptoms of lupus and other autoimmune diseases.

As Dr. Keith M. Hull, Medical Officer in the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) within the Center for Drug Evaluation and Research (CDER) noted during his presentation to the FDA's Pharmacy Compounding Advisory Committee, quinacrine's effectiveness has been documented extensively, and its safety profile is consistent with those of other lupus treatments. Importantly, quinacrine is a treatment option for patients who cannot tolerate hydroxychloroquine or for whom hydroxychloroquine is not effective. Should quinacrine become unavailable, the only alternative for these patients would be to escalate immunosuppressive or other more toxic and expensive therapies that result in more frequent and serious side effects. Unlike quinacrine, these immunosuppressive medications also require frequent blood monitoring.

Although the number of patients that rely on quinacrine is comparatively small, the treatment is so effective that patients frequently pay the entire out-of-pocket cost to have access to the drug. Loss of access to quinacrine, particularly when there are no comparable alternatives, is unfair to patients and to the physicians who treat them. One proposed solution for the thousands of patients on quinacrine—the use of the Expanded Access Pathway for Investigational Drugs for Treatment—is a burden that most physicians would not be able to perform, even if there was a compounding pharmacy that could supply the medication.

Given the demonstrated safety and efficacy of quinacrine, the use of the investigational new drug pathway is an unfunded mandate that we fear will result in the loss of access to quinacrine for patients in the United States. Furthermore, we are concerned that many patients would be left without adequate therapeutic options at a time when there are already so few

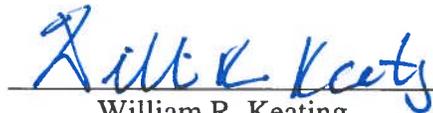
treatments for patients with lupus, and that patients may resort to potentially unsafe tactics and sources to obtain the drug.

On behalf of the lupus patient community, we strongly urge you to consider DPARP's recommendation that quinacrine hydrochloride be placed on the list of bulk drug substances that can be used in compounding, and we encourage you to work closely with lupus patient advocacy groups to address this potentially severe, yet avoidable, problem.

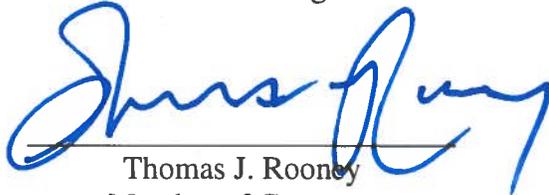
Sincerely,



Ileana Ros-Lehtinen
Member of Congress



William R. Keating
Member of Congress



Thomas J. Rooney
Member of Congress



Eddie Bernice Johnson
Member of Congress

CC: Janet Woodcock, M.D., Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993