



April 23, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Drug Shortages during COVID-19

Dear Secretary Azar:

Families USA is writing to urge the federal government to take action to reduce current drug shortages of hydroxychloroquine (HCQ) and chloroquine (CQ) and prevent future drug shortages related to the COVID-19 global pandemic. Families USA is a national, non-partisan health care policy and advocacy organization that supports policies and programs at the state and federal levels to ensure the best health and health care are equally accessible and affordable to all.

The Trump Administration is actively pushing the use of HCQ and CQ as a potential treatment for COVID-19, which has increased the demand for the drugs and resulted in shortages.ⁱ Currently, the efficacy of HCQ and CQ for the use of COVID-19 is merely anecdotal and usage of the drugs for COVID-19 may cause potentially fatal side effects.ⁱⁱ

These drugs are specifically approved by the Food and Drug Administration for the treatment of rheumatoid arthritis (RA), lupus and malaria. Due to a now discredited report from a French researcher and a barrage of media mentions on the possible efficacy of HCQ and CQ,ⁱⁱⁱ patients who need the medicine for chronic conditions are facing new barriers to access and many are being forced to ration their medication or go without it. It is especially critical that these patients have access to their prescribed medication at this time, especially as health care systems are stretched to their capacity with COVID-19 and patients with RA and lupus are immunocompromised making them more vulnerable to contracting COVID-19.

The Administration should address these directly with the following approaches and considerations:

The Department of Health and Human Services should exercise guidance around appropriate prescribing of HCQ and CQ, including prohibiting inappropriate prescribing of these medications.

The administration should ensure that patients who rely on these drugs, such as individuals with lupus, have access to their medication by making exceptions to quantity limits for patients with chronic diseases who take HCQ or CQ as part of their regular course of care and removing additional steps to obtaining their prescriptions.

HHS should also relax limitations on waiting periods between refills so that consumers can maintain at least a 30-day supply of medication on hand, while managing, in collaboration with pharmacists and providers, patient safety risk associated with early refills for certain drug classes. Since these drugs are taken by individuals who are immunocompromised, it is critical that those with RA and lupus are able to convert their 30-day prescriptions with multiple refills into a larger prescription such as a single 90-day-supply, which would minimize their trips to the pharmacy and thus their possible exposure to COVID-19. Finally, HHS should assure access by streamlining or eliminating processes for third party certification and specifically ensure access to HCQ and CQ for FDA-approved indications without requiring patients to take additional steps to obtain their prescriptions.

Guidelines should also be administered to providers and hospital systems to limit stockpiling and inappropriate prescribing. Despite the limited evidence of the effectiveness of HCQ and CQ in COVID-19 treatment,^{iv} hospitals, health systems, health plans, and providers have begun to stockpile large quantities of these drugs for future use of COVID-19^v and providers have begun prescribing the drugs to friends and family members.^{vi} In order to preserve the availability of the drugs for currently approved uses and possible treatment of COVID-19, there should be restrictions placed on the proper prescribing limits of HCQ and CQ.^{vii} In addition, the FDA should prepare to distribute its own stockpile for conditions the medicine is approved for, particularly if no strong clinical evidence emerges for the use of these drugs in response to COVID-19.

The Department of Health and Human Services should respond to shortages of prescription drugs by exercising march-in rights as laid out in the Bayh-Dole Act and increasing supply by pushing forward the Defense Production Act. In the past few weeks, the wholesale price for a key ingredient in HCQ has skyrocketed and some countries have threatened to implement export bans on the drug.^{viii} It is critical that the administration use their executive power to increase manufacturing and ensure that consumers are able to get the life-saving drugs they rely on.

For a drug developed with funds from a federal agency, the federal government may exercise march-in rights (as already defined in existing law: 35 U.S. Code § 203 - March-In Rights) to allow third parties to make and sell drugs to both increase quantities of the drug and lower prices. In the case where Bayh-Dole applies to a product with a shortage, the shortage qualifies, if the Secretary desires, as sufficient for the application of march-in rights. In the past, the mention of exercising march-in rights has pressured drug companies to lower their prices and/or provide more liberal licensing terms to third parties.^{ix} Alternatively, if march-in rights are unable to be exercised, executive leadership could exercise “government use” in patent law (28 U.S.C. 1498)^x in combination with the Defense Production Act. By invoking the Defense Production Act, the administration can issue mandatory contracts to drug manufacturers to produce drugs that are

currently in limited supply due to COVID-19 treatment or disruptions in the supply chain due to COVID-19.

The Department of Health and Human Services should work to prevent future shortages of prescription drugs caused by ruptures in the supply chain due to the spread of COVID-19. We were encouraged by language in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that addresses supply chain security by encouraging innovation within the private sector and establishes stronger reporting and warnings related to future drug shortages.^{xi} We urge HHS to work quickly to ensure appropriate implementation of the CARES Act as it relates to prescription drugs.

In order to ensure that we have adequate access to compounds for life saving drugs in the future, it is essential that the “Buy American” Executive order is not enacted. This Executive order aims to reduce U.S. dependency on foreign manufacturers for medicine.^{xii} During the COVID-19 crisis it is critical that we have a diverse supply chain for pharmaceutical ingredients, including from foreign manufacturers. Currently about 72% of pharmaceutical ingredient manufacturers supplying the U.S. are located overseas.^{xiii} Implementation of the Buy American EO during this severe economic and health crisis would disrupt established supply chains and lead to additional shortages.

Thank you for considering the above recommendations and working to keep Americans safe and healthy during this crisis. Please contact Jane Sheehan, Senior Federal Relations Manager at Families USA (jsheehan@familiesusa.org), for further information.

Sincerely,



Frederick Isasi, JD, MPH
Executive Director

ⁱ <https://www.lupus.org/news/state-pharmacy-boards-urged-to-ensure-availability-of-critical-lupus-medicines>

ⁱⁱ https://www.washingtonpost.com/politics/2020/04/13/how-false-hope-spread-about-hydroxychloroquine-its-consequences/?utm_campaign=wp_post_most&utm_medium=email&utm_source=newsletter&wpisrc=nl_most;https://www.nytimes.com/2020/04/09/health/coronavirus-remdesivir-kalil.html

ⁱⁱⁱ https://www.washingtonpost.com/politics/2020/04/13/how-false-hope-spread-about-hydroxychloroquine-its-consequences/?utm_campaign=wp_post_most&utm_medium=email&utm_source=newsletter&wpisrc=nl_most

^{iv} <https://www.phc.ox.ac.uk/covid-19/evidence-service/reviews/chloroquine-and-hydroxychloroquine-current-evidence-for-their-effectiveness-in-treating-covid-19>

^v <https://www.lupus.org/news/state-pharmacy-boards-urged-to-ensure-availability-of-critical-lupus-medicines>

^{vi} <https://www.propublica.org/article/doctors-are-hoarding-unproven-coronavirus-medicine-by-writing-prescriptions-for-themselves-and-their-families>

^{vii} <https://www.lupus.org/news/state-pharmacy-boards-urged-to-ensure-availability-of-critical-lupus-medicines>

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- viii https://www.statnews.com/pharmalot/2020/04/10/compound-pharmacies-hydroxychloroquine-price-hike/?utm_campaign=stat_plus_today&utm_source=hs_email&utm_medium=email&utm_content=86151370&hsenc=p2ANqtz--FmBEjRZooDKwTEb4rB9LhiX7KShALqhUQcnwJxCEj0qk_ttSsdkUIJjtBcGlyDlqMlimPY5PGDdcn04tQS9FpWrPew&hsmi=86151370
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- xi <https://www.congress.gov/bill/116th-congress/house-bill/748/text>
- xii <https://www.cnn.com/2020/03/19/coronavirus-trump-aide-peter-navarro-slams-big-pharma.html>
- xiii <https://www.cnn.com/2020/03/19/coronavirus-trump-aide-peter-navarro-slams-big-pharma.html>