



March 30, 2020

The Honorable Mike Pence
Vice President of the United States
Chair, White House Coronavirus Task Force
The White House
Washington, DC 20500

Stephen Hahn, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Reported Shortages of Essential Drugs

Dear Vice President Pence and Commissioner Hahn,

On behalf of the American College of Physicians (ACP), I am writing to express concern about the negative impact drug shortages have on the health of the public and urge federal government action over the reported shortages of several drugs that have been exacerbated by the COVID-19 pandemic. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The American health system experiences hundreds of new drug shortages each year, and this trend has been on the rise in past decades.¹ These shortages can arise from a variety of causes, including manufacturing issues, supply and demand issues, issues with raw materials, and discontinuation, amongst other and unknown causes. Drug shortages can dramatically impact the health care system, resulting in higher hospital expenses, increased labor costs, and heightened safety risks.² Hospitals must seek out more expensive alternative therapies, estimated to cost about \$200 million annually. Additional labor is needed to make the operational changes associated with the alternative treatments, resulting anywhere from an extra 2.5 to 3 hours up to 9 hours per week on average spent by pharmacists and pharmacy

¹ "Drug Shortages Statistics." ASHP, 2020. <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>.

² Vail et al. Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 2017.

technicians and \$216 million in labor costs.³ Another estimate places additional labor costs at roughly \$360 million per year.⁴ There are reports of cancer treatment being rationed and delayed due to chemotherapy drug shortages. Further, patients are more prone to medication errors due to unfamiliarity with alternative treatments or unknown conversion factors for dosage adjustments for generic drugs. At the extreme end of the spectrum, shortages can result in the deaths of patients with conditions where there is not an alternative treatment, such as cytarabine for patients with leukemia and lymphoma.⁵

This issue of drug shortages is particularly important to physicians because prescription drugs are a key part of a physician's comprehensive toolkit and have been crucial in improving the health and lives of millions of our patients. **ACP is concerned that under the status quo, a lack of strategy to mitigate drug shortages will result in the development of more serious health issues and, in turn, lead to diminished quality of life, poorer outcomes, and additional financial burden to the health care system.**

In recent days, there has been a rush to procure the antimalarial medications chloroquine and hydroxychloroquine amidst viral claims that the drugs are a potential treatment for COVID-19. Additionally, the Food and Drug Administration (FDA) recently issued emergency authorization to allow the donation of chloroquine and hydroxychloroquine to the Strategic National Stockpile for distribution to patients with COVID-19 when clinical trials are not available or feasible. Both of these drugs are currently approved for use to treat malaria, while tens of thousands of patients rely on the immunosuppressive hydroxychloroquine to treat diseases like rheumatoid arthritis, lupus, and porphyria cutanea tarda. As a result of the speculative and pandemic-induced increased demand for the drugs, shortages have been reported and those who have been taking the drugs for years in order to productively conduct their lives have been faced with inconsistent access to these vital medications. Some have had to rely on the name brand version of the medication,⁶ which can cost upwards of 44 times as much as the generic and often is not covered by insurance, while others have received notice from their providers that their prescriptions will no longer be filled due to COVID-19 demand.⁷

It is important to note that use of chloroquine and hydroxychloroquine as a COVID-19 treatment is still early in the clinical trial testing stage and there is very limited clinical data available to suggest its efficacy in treating the virus. While we recognize the urgent need to

³ Kaakeh, Rola, Burgunda V. Sweet, Cynthia Reilly, Colleen Bush, Sherry DeLoach, Barb Higgins, Angela M. Clark, and James Stevenson. "Impact of drug shortages on US health systems." *American Journal of Health-System Pharmacy* 68, no. 19 (2011): 1811-1819.

⁴ Kacik, Alex. "Drug Shortages Drain at Least \$359M from Health Systems." *Modern Healthcare*, June 26, 2019. <https://www.modernhealthcare.com/finance/drug-shortages-drain-least-359m-health-systems>.

⁵ Stein, Rob. "Shortages of Key Drugs Endanger Patients." *The Washington Post*, May 1, 2011. https://www.washingtonpost.com/national/shortages-of-key-drugs-endanger-patients/2011/04/26/AF1aJJVF_story.html.

⁶ Hernandez, Salvador. "Trump Touted Chloroquine As A Possible Coronavirus Treatment. Now She Can't Find The Drug For Her Autoimmune Disease." *BuzzFeed News*, March 24, 2020. <https://www.buzzfeednews.com/article/salvadorhernandez/coronavirus-chloroquine-patient-shortage>.

⁷ Chen, Tanya. "A Woman With Lupus Said Her Health Care Provider Is Stopping Her Chloroquine Prescription And Thanked Her For The 'Sacrifice.'" *BuzzFeed News*, March 25, 2020. <https://www.buzzfeednews.com/article/tanyachen/kaiser-permanente-lupus-chloroquine>.

identify a cure and support clinical trials, the federal government must concurrently actively monitor and report shortages and take action to ensure that those who need these drugs for existing approved conditions can access them with minimal barriers. **The College strongly believes that to address current and looming shortages, the federal government should work with pharmaceutical companies to ensure there is an adequate supply of pharmaceutical therapies and vaccines to protect and treat the U.S. population.** Specifically, if necessary to mitigate an existing shortage and protect the general welfare of the public, ACP supports the government invoking federal law to allow generic drugmakers to bypass a drug manufacturer's patent to produce a drug for the government.

Not only must these and other essential medications and COVID-19 treatments be readily available, they also must be affordable to all who need them. Research has shown that rising costs make prescription drugs less accessible for patients, making them more likely to forego their medications and posing a barrier to the adherence of recommended treatment plans. This can have negative downstream effects, placing lives at risk and increasing costs throughout the health care system. It is estimated that medication non-adherence causes roughly 125,000 deaths, 10 percent of hospitalizations, increased morbidity and mortality rates, and costs the health care system anywhere from \$100-\$300 billion a year in the United States.⁸ This threat is exacerbated in light of the current viral pandemic at hand. **The Administration should utilize its authority under the Defense Production Act to designate essential medications and protect them from hoarding and price gouging, particularly for those medications that were in-part developed using taxpayer funds.** The Administration should also examine ways to minimize cost sharing for the drugs in question as well as mechanisms to prevent unreasonable price increases.

In addition to increasing supply and ensuring affordable access to treatments, this also means taking action to prohibit the inappropriate prescribing and stockpiling of chloroquine and hydroxychloroquine and diversion for use in COVID-19. The Centers for Disease Control and Prevention (CDC) and the FDA, as well as other public health agencies, also have a duty and a responsibility to adequately and effectively communicate to the public and health care industry clinically accurate and up-to-date information of the safety, efficacy, and status of these drugs for use in COVID-19 cases. This is particularly important as there have been several reported deaths from improper consumption⁹ and claims of hoarding of the medication.¹⁰

⁸ Viswanathan, Meera, Carol E. Golin, Christine D. Jones, Mahima Ashok, Susan J. Blalock, Roberta CM Wines, Emmanuel JL Coker-Schwimmer, David L. Rosen, Priyanka Sista, and Kathleen N. Lohr. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." *Annals of internal medicine* 157, no. 11 (2012): 785-795.

⁹ McLaughlin, Elliott C. "Chloroquine and Hydroxychloroquine: What to Know about the Potential Coronavirus Drugs." CNN, March 24, 2020. <https://www.cnn.com/2020/03/23/health/chloroquine-hydroxychloroquine-drugs-explained/index.html>.

¹⁰ Sanders, Topher, David Armstrong, and Ava Kofman. "Doctors Are Hoarding Unproven Coronavirus Medicine by Writing Prescriptions for Themselves and Their Families." ProPublica, March 25, 2020. <https://www.propublica.org/article/doctors-are-hoarding-unproven-coronavirus-medicine-by-writing-prescriptions-for-themselves-and-their-families>.

Thank you for considering our concerns. ACP appreciates that the Administration has already undertaken efforts to address some of these concerns, including the issuance of an executive order to prevent hoarding and price gouging of critical medical supplies and a provision in the Coronavirus Aid, Relief, and Economic Security (CARES) Act to require Medicare Part D plans to provide a 90-day supply of prescription drugs when requested. The College shares the Administration's goal of impeding the spread of the virus and ensuring appropriate access to medications, if shown to be safe and effective by the FDA in treating COVID-19. It is also essential that patients who have not been diagnosed with COVID-19 also have access to medications that have been shown to be safe and effective in treating their conditions. ACP contends that both goals must be accomplished in a manner that also promotes patient access, ensures a stable supply, and prevents unreasonable pricing of essential medications and treatments. Please contact Josh Serchen, Senior Analyst, Health Policy at jserchen@acponline.org if the College can be of any assistance or if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert M. McLean". The signature is fluid and cursive, with the first name "Robert" being the most prominent.

Robert M. McLean, MD, FACP
President