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Dear Dr. Bharel, Attorney Engman and Dr. Sloane:

For the last several weeks, President Donald Trump has been touting chloroquine/hydroxychloroquine as a "game changer" in the prevention and treatment of the

Coronavirus.[1] This letter argues that, given the dubiousness of that claim and the *proven* importance of both drugs in treating rheumatological illnesses including lupus, that the Massachusetts Department of Public Health, the Board of Regulation in Pharmacy Board of Registration in Medicine should issue a statements regulating the prophylactic use and hoarding of antimalarials in the context of COVID-19.

Rationale

Lupus is a serious autoimmune disease that affects approximately 1.5 million people in the United States, 90% of whom are women and the vast majority of whom are women of color.[2] The impact of the failure to regulate the supply and use of chloroquine (Aralen or "CQ") and hydroxychloroquine (Plaquenil or "HCQ") is very real. According to the Lupus Foundation of America, chloroquine/hydroxychloroquine are "*critical to fighting the disease.*"[3] Because approximately two-thirds of lupus patients take chloroquine/hydroxychloroquine, the effects of drug shortages due to coronavirus are pressing and potentially life threatening.[4] Dr. Ashira Blazer, a rheumatologist at NYU Langone Health, called hydroxychloroquine "[t]he number one mainstay of lupus therapy."[5] The inability to receive lupus treatment can result in flares, which not only increase the need for immunosuppression and may increase susceptibility to infectious diseases such as COVID-19.[6] Given the already disproportionate impact of COVID-19 on Black and Latinx populations, this additional risk is potentially catastrophic.[7] Moreover, the FDA has approved the use of chloroquine/hydroxychloroquine for lupus, rheumatoid arthritis, and malaria. It is essential that individuals with these ailments be able to access this life-saving medication.

A growing consensus of medical experts insist that chloroquine/hydroxychloroquine are *not* miracle drugs for COVID-19.[8] Moreover, the false belief in their use for prophylactic treatment

[1] See e.g., ABC News, "Fauci Throws Cold Water on Trump's Declaration that Malaria Drug Chloroquine is a "Game Changer," March 20, 2020, https://abcnews.go.com/Politics/fauci-throws-cold-water-trumps-declaration-malaria-drug/story?id=69716324.
[2] Lupus Foundation of America, "Lupus Facts and Statistics," 2020, https://www.lupus.org/resources/lupus-facts-and-statistics.
[3] Lupus Foundation of America, "State Action on Hydroxychloroquine and Chloroquine Access," 2020, lupus.org/advocate/state-action-on-hydroxychloroquine-and-chloroquine-access.
[4] Olga Lucia Torres, "Trump Keeps Putting the Lives of Lupus Patients at Risk," April 6, 2020, https://www.nytimes.com/2020/04/06/opinion/coronavirus-hydroxychloroquine-lupus.html.
[5] Lauren Gelman, "A Lupus Patient Explains Why a Hydroxychloroquine Shortage is Terrifying to Lupus and Rheumatoid Arthritis Patients," March, 22, 2020, https://creakyjoints.org/treatment/hydroxychloroquine-shortage-coronavirus-impact-lupus-rheumatoid-arthritis/.
[6] Id. Similarly the absence of these medication can cause intense pain for people with RA. *CNN*, "Americans Battle to Cope With Life's Challenges Amid Virus," 2020, https://www.cnn.com/videos/us/2020/04/07/fabric-of-america-coronavirus-daily-struggles-savidge-pkg-vpx.cnn/video/playlists/coronavirus/,
[7] Charles M. Blow, "The Racial Time Bomb in the COVID-19 Crisis," *New York Times*, April 1, 2020, https://www.nytimes.com/2020/04/01/opinion/coronavirus-black-people.html.
[8] *See e.g.* Jinoos Yazdany and Alfred H.J. Kim, "Use of Hydroxychloroquine and Chloroquine During the COVID-19 Pandemic: What Every Clinician Should Know," *Annals of Internal Medicine*, March 31, 2020, https://annals.org/aim/fullarticle/2764199/use-hydroxychloroquine-chloroquine-during-covid-19-

is not harmless. Rather, it prevents focus on more effective treatments for COVID-19 and risks the lives of lupus patients without cause.[9] President Trump continues to make dangerous statements about chloroquine/hydroxychloroquine that increase risk to vulnerable populations. He has falsely claimed that lupus patients that take the medications "aren't catching this horrible virus,"[10] a fact which is simply unproven by the evidence. There is no basis for the belief that HCQ or CQ will prevent illness from COVID-19.[11] In fact, an international registry of patients with rheumatic diseases and COVID-19 reported that 25% of patients were taking hydroxychloroquine prior to the development of the illness. The investigators concluded that they could not report any protective effect of hydroxychloroquine against COVID-19.[12] Further, HCQ/CQ can, in the hands of unskilled clinicians, produce risk of cardiac arrhythmia and cardiac arrest. When used in combination with azithromycin, as suggested by President Trump, such risks are amplified considerably.[13]

pandemic-what-every-clinician; University of Michigan Health Lab, "Chloroquine, Ibuprofen, and Beyond: Doctors Discuss Latest Treatments, and Treatment Rumors, For COVID-19, April 2, 2020, https://labblog.uofmhealth.org/rounds/chloroquine-ibuprofen-and-beyond-doctors-discuss-latest-treatments-and-treatment-rumors-for.

[9] Jonathan Chait, "Why Trump is Overruling Scientists to Pursue His Pet Coronavirus Drug," *New York Mag*, April 6, 2020, https://nymag.com/intelligencer/2020/04/trump-fauci-navarro-giuliani-scientists-coronavirus-hydroxychloroquine.htm.

[10] Factcheck.org, "Trump's False Coronavirus Claim About Lupus Patients," April 6, 2020, https://www.factcheck.org/2020/04/trumps-false-coronavirus-claim-about-lupus-patients/

[11] Lupus Foundation of America, "Are People With Lupus Protected Against COVID-19?" April 4, 2020, https://www.lupus.org/blog/are-people-with-lupus-protected-against-covid19. In fact, recent articles have indicated that the administration's fervent push for use of the drugs, against the advice of Dr. Anthony Fauci, may even be related to the President's political interests. *Washington Post*, "Trump's Promotion of Hydroxychloroquine is Almost Certainly About Politics, Not Profits, April 8, 2020, https://www.washingtonpost.com/politics/2020/04/07/trumps-promotion-hydroxychloroquine-is-almost-certainly-about-politics-not-profits/.

[12] Lauren Gelman, "There is No Study Proving That 'Lupus Patients Don't Get Coronavirus' Because They Take Hydroxychloroquine," April 5, 2020, https://creakyjoints.org/symptoms/lupus-patients-do-get-coronavirus/.

[13] American College of Cardiology, "Ventricular Arrhythmia Risk Due to Hydroxychloroquine-Azithromycin Treatment For COVID-19," March 29, 2020, https://www.acc.org/latest-in-cardiology/articles/2020/03/27/14/00/ventricular-arrhythmia-risk-due-to-hydroxychloroquine-azithromycin-treatment-for-covid-19.

Recommendations

We appreciate that the Commonwealth has already taken some initial steps to address the concerns we raise, including an advisory issued by MassHealth[14] and the Division of Insurance.[15] However, in light of the evidence described above, we recommend that that the state's regulatory organizations take further initiative to counteract hoarding and off-label usage of HCQ and CQ. According to the *Wall Street Journal*,[16] at least 20 jurisdictions have already acted to implement emergency regulations or guidelines to ease pressure on the supply of HCQ and CQ for autoimmune patients.[17] In most cases, states have acted through their boards of pharmacy, public health departments, and/or boards of registration in medicine.

For example, the Rhode Island Department of Health (DOH) issued an emergency regulation to restrict the prescribing and dispensing of hydroxychloroquine or other drugs for COVID-19 or off-label purposes until such point that there is peer-reviewed evidence establishing their safety and effectiveness to justify the clinical decision. Oregon has acted similarly. See also policies in states such a Arizona, Arkansas, Delaware, Georgia, Hawa'ii, Idaho, Kansas, Kentucky, Michigan, Minnesota, Nevada, New Jersey, New York, North Carolina, Ohio, Texas, Virginia

[14] MassHealth, "Pharmacy Facts," March 25, 2020, https://www.mass.gov/doc/pharmacy-facts-143-march-25-2020-0/download. This provides as follows: "Individuals who have or are suspected to have COVID-19, or who have new prescriptions for lupus, malaria, or rheumatic conditions, must go through a PA process before chloroquine and hydroxychloroquine can be dispensed. If a MassHealth member or HSN patient is approved for COVID-19, pharmacies must dispense up to a 14-day supply. If a MassHealth member or HSN patient is approved for other diagnoses, pharmacies may dispense up to a 90-day supply if requested by the MassHealth member, HSN patient, or prescriber as long as sufficient quantity remains on the prescription to support the quantity being filled."

[15] Office of Consumer Affairs and Business Regulation, "Bulletin 2020-06," March 26, 2020, https://www.mass.gov/doc/bulletin-2020-06-administration-of-precription-drug-benefits-during-COVID-19-coronavirus-public/download. This policy notes that these drugs have been used inappropriately and expresses concern over the possibility of overdosing and death. The Division imposes more flexible quantity limits for those with rheumatologic conditions, but does not prohibit carriers from filing prescriptions for preventative purposes, and notes that it expects health carriers to impose prior authorization on all users of HCQ and CQ in order to "avoid inappropriate prescribing behaviors."

[16] *The Wall Street Journal*, "States Try Reducing Malaria-Drug Hoarding Amid Unproven Coronavirus Benefit," April, 5, 2020, https://www.wsj.com/articles/states-try-reducing-malaria-drug-hoarding-amid-unproven-coronavirus-benefit-11586095200. As of April 7, 2020, CNN now places this number at 22 states. *CNN*, *supra* note 6.

[17] *See also*, fifty state surveys available through the National Association of Boards of Pharmacy, https://nabp.pharmacy/wp-content/uploads/2020/03/COVID-19-Board-of-Pharmacy-Status.pdf, and the Lupus Foundation of America, https://www.lupus.org/advocate/state-action-on-hydroxychloroquine-and-chloroquine-access. See also the Joint Statement of the Lupus Foundation of America, the American College of Rheumatology, the American Academy of Dermatology Association and the Arthritis Foundation, sent to Vice President Mike Pence https://www.arthritis.org/getmedia/ef17ecf8-a13e-4265-94bd-ccc7971d60b5/Joint-Statement-on-HCQ-LFA-ACR-AADA-AF.pdf

and West Virginia all of which have also taken measures to prevent the hoarding or misuse of chloroquine/hydroxychloroquine.[18]

There is considerable historical support for such interventions, including the anthrax attacks of 2001.[19] Indeed, it is the responsibility of professional organizations to make strong statements against the ableist, sexist, and racist preferences for the good of the whole over the good of individuals with chronic illnesses.[20] The Lupus Foundation of America has already begun identifying critical policy issues,[21] which we incorporate into the following recommendations for the Commonwealth of Massachusetts:[22]

- **COVID-related restrictions:** Patients across the country are reporting that they are unable to fill prescriptions for RA or lupus because the drugs are set aside only for use in COVID-19. In some cases, the medications are even being set aside for the future use for COVID-19. Similarly, patients are reporting that even if the medications are available for RA and lupus, they face new requirements to first obtain approval from a third party certifying that they are eligible to receive the medication. This delays patient access to their medication and places an unnecessary administrative burden on rheumatology and other practices, which are already struggling to care for patients amid this public health

[18] Elizabeth Cohen, "States Try to Stop Hoarding of Possible Coronavirus Treatments," *CNN*, March 23, 2020, https://www.cnn.com/2020/03/23/health/states-drug-stockpile-coronavirus/index.html.
[19] Id.
[20] American College of Rheumatology, "Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic," April 2, 2020, https://www.rheumatology.org/Portals/0/Files/Guiding-Principles-Scarce-Resource-Allocation-During-COVID-19.pdf.
[21] Lupus Foundation of America, "State Pharmacy Boards Urged to Ensure Availability of Critical Lupus Medicines," March 26, 2020, https://www.lupus.org/news/state-pharmacy-boards-urged-to-ensure-availability-of-critical-lupus-medicines
[22] Anjali Vats is an attorney and an Associate Professor at Boston College and Boston College Law School. She was diagnosed with systemic lupus erythematosus at the age of four. She has been attempting to fill her HCQ prescription since March 20, 2020. Maureen Dubreuil MD MSc is a rheumatologist and Assistant Professor of Medicine at Boston University School of Medicine. The Disability Law Center (DLC) is the Protection and Advocacy ("P&A") system for Massachusetts, pursuant to authority provided under federal law. Under the Protection and Advocacy in Individual Rights (PAIR), DLC is directed to "legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of eligible individuals with disabilities within the State…" 34 C.F.R sec. 381.3(a)(2). The Lupus Foundation of New England is a 501 c3 not-for-profit organization serving the lupus community since its incorporation in May of 1974, now serving the lupus communities of Massachusetts, Rhode Island and New Hampshire. Our Foundation is receiving dozens of calls per week seeking guidance and information on medication supply and availability.

crisis.[23] We strongly oppose these restrictions and urge states and other stakeholders not to impose them, and to rescind such policies that have already been implemented. Instead, we support polices that specifically ensure access to HCQ and CQ for FDA approved indications (or for off-label uses supported by regulatory agencies and/or the scientific literature[24]), without requiring these patients to take additional steps to obtain their prescriptions. One method for doing so is allowing patients with pre-existing prescriptions and an FDA-approved indication receive refills without need for any further documentation/approval of their conditions or needs.

- **Stockpiling:** There are reports of hospitals, health systems, health plans, and providers stockpiling large quantities of HCQ and chloroquine. In some cases, these stockpiles are for exclusive use for COVID-19 or even the potential use of the drugs for COVID-19. While we recognize the urgent global need to have treatments for COVID-19 like HCQ and CQ available for that use, we should not deny access to these medications for the people who already rely on them to save their kidneys and their lives and for whom they are proven to work.
- **Quantity limits:** Increasingly HCQ prescriptions are being limited to 7 or 14 days, even for patients with lupus and RA. Not only does this place an additional barrier for people with chronic diseases to receive needed medications, but it also puts them at greater risk for exposure to COVID-19 by requiring them to travel outside their home more frequently to fill their prescriptions. Exceptions to quantity limits should be made for patients with chronic diseases such as lupus and RA who take HCQ as part of their regular course of care.
- **Off-label restrictions:** We support polices that restrict HCQ and chloroquine access to those who take it for FDA-approved indications. However, we encourage stakeholders to provide flexibility to allow for off-label use when those uses are supported by the scientific literature and when those medications are already part of a patient's treatment plan. For example, people with conditions like juvenile idiopathic arthritis, Sjogren's Syndrome, sarcoidosis, Q fever, and porphyria cutanea tarda are routinely prescribed HCQ as an effective treatment. Those patients should continue to have access to these medications.

[23] This is currently an issue in Massachusetts that needs to be corrected. See MassHealth, "Pharmacy Facts," March 25, 2020, https://www.mass.gov/doc/pharmacy-facts-143-march-25-2020-0/download.

[24] Neither HCQ nor CQ have been approved by the FDA for treatment of COVID-19. Last week, the FDA left the door open to hospitals using HCQ to treat COVID-19 when clinical trials are not otherwise available or when participation is not feasible. Food and Drug Administration, March 28, 2020, https://www.fda.gov/media/136534/download. HHS has also granted permission for donations of HCQ and CQ to be given to states for COVID-19 treatment. US Department of Health and Human Services, "HHS Accepts Donations of Medicine to Strategic National Stockpile as Possible Treatments for COVID-19 Patients," March 29, 2020, https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html.
The FDA has also issued a notice of the shortage of HCQ and CQ. See Food and Drug Administration, "Drug Shortages," March 31, 2020, https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Hydroxychloroquine%20Sulfate%20Tablets&st=c&tab=tabs-1.

- **Inappropriate and unreasonable prescribing:** Reports also indicate that clinicians, including dentists and surgeons are self-prescribing HCQ and chloroquine or prescribing it for their friends and family.[25] Moreover, in many parts of the country there are no restrictions limiting the prescribing of HCQ and chloroquine. For example, the drugs are being prescribed to prevent COVID-19 even though no studies show efficacy for this use. Such examples of unreasonable prescribing must be stopped in order to preserve the availability of the drug for currently approved uses, scientifically accepted uses and, potentially, for use to treat COVID-19.

We encourage you to take these steps to protect vulnerable populations during this pandemic. Already we are receiving reports from rheumatologists in Massachusetts of large numbers of calls from distressed patients, often in pain, who are unable to secure their medication or must apportion a limited supply over a period that far exceeds their prescription cycle. And it will not be long before rheumatologists start seeing patients with lupus flares, including irreversible kidney damage, because they cannot access HCQ. This is an ethically unacceptable and easily avoidable issue that can be managed via regulation, with no repercussions for COVID-19 patients.

Specifically, we ask that you adopt emergency regulations or a binding sub-regulatory directive to do the following:

1. For current and future lupus and RA patients instruct pharmacies to prioritize HCQ and CQ prescriptions written with a diagnosis code reflecting lupus or RA;
2. Remove new requirements of prior approval for new patients with a lupus or RA diagnosis where the prescription is written with the appropriate diagnosis code.[26]
3. For COVID-19 patients, In the absence of new, emerging clinical evidence to the contrary, limit prescriptions of HCQ and CQ to a 7-day supply maximum for those individuals with current positive testing or a presumed COVID-19 diagnosis.[27] This is the currently accepted dosage for COVID-19 patients in the ICU;
4. In the absence of new, emerging clinical evidence to the contrary, instruct pharmacies to decline prescriptions for the purported preventative use of HCQ or CQ by persons not infected by the coronavirus, and prohibit prescribers from issuing such prescriptions in

[25] In Massachusetts, under BORIM's Interim Policy 20-02, physicians may now self-prescribe or prescribe for members of their families. Board of Registration in Medicine, "Interim Policy on Prescribing," April 2, 2020, https://www.mass.gov/lists/physician-regulations-policies-and-guidelines#new-policies-and-guidelines-.

[26] Recommendations 1 and 2 should also apply to patients with juvenile idiopathic arthritis, Sjogren's Syndrome, sarcoidosis, Q fever, and porphyria cutanea tarda, conditions for which HCQ is routinely prescribed HCQ as an effective treatment.

[27] The Board of Registration in Pharmacy has currently only clarified that hydroxychloroquine prescribed for COVID-19 should be limited to a 14-day supply. Board of Registration in Pharmacy, "Coronavirus Disease 2019 Frequently Asked Questions," April 7, 2020, https://www.mass.gov/news/coronavirus-disease-2019-covid-19-frequently-asked-questions.

the absence of a current or presumed COVID-19 diagnosis based upon testing or clinical findings;

If you have any questions regarding our request, please contact us at rglassman@dlc-ma.org. Thank you in advance for consideration of our concerns.

We look forward to receiving your reply.

Respectfully,

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