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Allison Vordenbaumen Benz R.Ph., M.S.
Executive Director, Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500
333 Guadalupe Street
Austin, Texas 78701

Submitted via Electronic Mail

Re: Request to clarify guidelines for prescribing hydroxychloroquine (also known as hydroxychloroquine sulfate) for COVID-19

August 26, 2020

Ms. Vordenbaumen Benz:

We write to you today to both express our relief that the Texas State Board of Pharmacy (TSBP) was not—as was rumored—restricting the prescription of hydroxychloroquine (also known as hydroxychloroquine sulfate) as a treatment for someone who has been diagnosed with COVID-19,¹ and to request that the TSBP clarify the guidelines to all pharmacists and physicians in Texas regarding its use. We understand that the use of hydroxychloroquine, coupled with other drugs, can be a very effective treatment against some of the more severe cases of COVID-19, and we believe that every Texan deserves an honest assessment of the potential risks and benefits that is free of the hyper-politicized sentiments we have seen on the drug over the last few months. Our main concern, as it should be, is the lives and livelihoods of Texans. The sooner we can eradicate the complications associated with this virus, the faster we can get back to normal life.

I. The Use of Hydroxychloroquine Has Become Overly Politicized

Almost immediately after President Trump began to tout hydroxychloroquine as an effective treatment for COVID-19, its use became controversial. Dr.

¹ 45 Tex Reg. 2278 (2020) (emerg. amend. To 22 Tex. Admin. Code § 291.30) (adopted Mar. 20, 2020, expired July 17, 2020) (Tex. State Bd. of Pharm.).

Harvey Risch, an epidemiologist at Yale University, recently said that hydroxychloroquine is “a political drug now, not a medical drug And I think we’re basically fighting a propaganda war against the medical facts, and that colors not just the population of people and how they think about it, but doctors as well.”² Further evidence that the scientific assessments used to determine the drug’s supposed ineffectiveness were rushed and biased surfaced when *The Lancet*, a popular peer-reviewed medical journal, had to embarrassingly retract its study claiming hydroxychloroquine’s ineffectiveness in treating COVID patients.³ It is clear that heightened political unrest has bled into the medical debate on the use of hydroxychloroquine. Notwithstanding that, we admit that we are not scientists and we encourage further studies on its use. But there is one thing we know for sure, and that is that there is ample evidence that hydroxychloroquine can help people. Conversely, little to no evidence shows that it is unsafe for people to use.

I. Hydroxychloroquine Has a Long, Safe History of Use

Hydroxychloroquine has long been used and even encouraged among people of different ages, health conditions, and other factors. Most are aware that hydroxychloroquine has been in use for quite some time. A research paper outlining the synthesis of hydroxychloroquine was first published in 1950,⁴ and the U.S. Food and Drug Administration approved its use on April 18, 1955.⁵ Since then, it has been used in countless cases to treat and prevent malaria, arthritis, and other chloroquine-based drugs have been used for over a decade to treat SARS coronavirus infections such as COVID-19.⁶ The Center for Disease Control describes hydroxychloroquine as a drug that can that “be prescribed to adults and children of all ages” and that it can be “safely taken by pregnant women and nursing mothers.”⁷ Of course, as with all medications, there are side effects and precautions that must be taken,⁸ but with the counsel of a physician, these problems can be addressed and avoided, or at the very least, mitigated.

² Emma Colton, *Yale Epidemiologist Says Hydroxychloroquine Could Save Up to 100K Lives if Used for Coronavirus*, WASH. EXAMINER (July 22, 2020), <https://www.washingtonexaminer.com/news/yale-epidemiologist-says-hydroxychloroquine-could-save-up-to-100k-lives-if-used-for-coronavirus>.

³ Mandeep R. Mehra et al., *RETRACTED: Hydroxychloroquine or Chloroquine With or Without a Macrolide for Treatment of COVID-19: A Multinational Registry Analysis*, THE LANCET (May 22, 2020), <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931180-6>.

⁴ *Molecule of the Week Archive: Hydroxychloroquine*, Am. Chem. Soc’y (Sept. 18, 2017), <https://www.acs.org/content/acs/en/molecule-of-the-week/archive/h/Hydroxychloroquine.html>.

⁵ *All Approvals and Tentative Approvals: April 1955*, U.S. FOOD & DRUG. ADMIN., <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process&rptName=1&reportSelectMonth=4&reportSelectYear=1955&nav>.

⁶ Martin J. Vincent et al., *Chloroquine Is a Potent Inhibitor of SARS Coronavirus Infection and Spread*, *Virology* 332, 69 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/>. (“Chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage.”) *Id.*

⁷ U.S. CTR. FOR DISEASE CONTROL, *MEDICINES FOR THE PREVENTION OF MALARIA WHILE TRAVELING – HYDROXY CHLOROQUINE (PLAQUENIL) 1* (2017), available at <https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf>.

⁸ *Id.* at 1.

Furthermore, overdoses from hydroxychloroquine seem to be so rare that they are not very much studied. The National Institutes of Health published a study showing that in the span of almost fifty years, only seven cases of anyone ever overdosing on hydroxychloroquine, and it is not even clear that those that overdosed died.⁹ The case study evaluated in their research depicts a 16-year-old girl who overdosed on hydroxychloroquine, but was successfully treated and recovered after a few days.¹⁰ We understand that there are still some unknowns with the drug. But other more common drugs we deal with every day, such as Tylenol, are far more deadly, and are available over the counter.¹¹ If we're willing to take that risk, why would we not take the even lower risk of encouraging the use of hydroxychloroquine—especially when we know the risk of doing nothing, at least with respect to COVID patients, could have potentially deadly outcomes?

II. Thousands of Lives Could be Saved

Lastly, we believe that if the legal use of hydroxychloroquine is clarified and encouraged, hundreds of thousands of lives may be saved. Yale epidemiologist Dr. Harvey Risch—the same physician we referenced earlier who opined on the politicizing of the drug—recently estimated, based on his research, that between 75,000 to 100,000 lives could be saved if we began using hydroxychloroquine immediately upon the outset of COVID symptoms, or, even better, as a prophylactic for those among vulnerable populations.¹² We have seen plenty of examples of the drug working in Texas as well. Dr. Robin Armstrong, for example, recently treated elderly patients who had contracted the virus using his regimen that includes hydroxychloroquine. Out of thirty-eight patients, only one died.¹³

Indeed, a recent study showed a significant drop in mortality among COVID patients taking hydroxychloroquine—even among those who start a late regimen.¹⁴ The study measured the effectiveness of the drug in 2,541 patients and found that 26% of those who did not take the drug died as compared to only 13% of those who were taking the drug.¹⁵ Even our very own Representative Tony Tinderholt, who tested positive for the virus last month and underwent a terrible few weeks of illness, swears by the drug's effectiveness, having undergone a turn in health immediately after starting a treatment including hydroxychloroquine well after his symptoms had become serious. If hydroxychloroquine has been used as

⁹ K. Marquardt & T. E. Albertson, *Treatment of Hydroxychloroquine Overdose*, AM. J. EMERG. MED. (abstract) (2001), available at <https://pubmed.ncbi.nlm.nih.gov/11555803/#:~:text=Although%20hydroxychloroquine%20overdoses%20are%20very,after%20experience%20with%20chloroquine%20overdoses.>

¹⁰ *Id.*

¹¹ Parivash Nourjah et al., *Estimates of Acetaminophen (Paracetamol) Associated Overdoses in the United States*, 15 PHARMACOEPIDEMIOLOGY & DRUG SAFETY, <https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.1191>.

¹² Colton, *supra* note 2.

¹³ Ben Billups, *Video: Dr. Robin Armstrong Explains Use of Hydroxychloroquine to Treat Coronavirus*, THE TEXAN (Apr. 22, 2020), <https://thetexan.news/hydroxychloroquine-coronavirus-treatment-robin-armstrong-video-podcast/>.

¹⁴ Samia Arshad et al., *Treatment with Hydroxychloroquine, Azithromycin, and Combination in Patients Hospitalized with COVID-19*, 97 INT'L J. OF INFECTIOUS DISEASES 396, available at [https://www.ijdonline.com/article/S1201-9712\(20\)30534-8/fulltext](https://www.ijdonline.com/article/S1201-9712(20)30534-8/fulltext). U.S. Ctr. for Disease Control

¹⁵ See also Mica Soellner, *Study Finds COVID-19 Patients Who Took Hydroxychloroquine Were Less Likely to Die*, WASH. EXAMINER (July 3, 2020), <https://www.washingtonexaminer.com/news/study-finds-covid-19-patients-who-took-hydroxychloroquine-were-less-likely-to-die>.

a prophylactic in malaria with people of all ages,¹⁶ why can it not be used similarly among our vulnerable population?¹⁷

In closing, we reiterate our request for you to further make clear to pharmacists that any real or imagined shortage of hydroxychloroquine has ended and that there is no ban on its use in Texas. If this drug can be safely used to prevent malaria over many decades, it can safely be used to prevent COVID-19 as well—which will not just help the vulnerable, but every Texan, as we slowly but surely get back to work.

Sincerely,

A handwritten signature in black ink, appearing to read "Mayes Middleton". The signature is fluid and cursive, with the first name "Mayes" being more prominent than the last name "Middleton".

Rep. Mayes Middleton
Chairman, Texas Freedom Caucus

¹⁶ U.S. CTR. FOR DISEASE CONTROL, *supra* note 8. (“Both adults and children should take one dose of hydroxychloroquine per week starting at least 1 week before traveling to the area where malaria transmission occurs. They should take one dose per week while there, and for 4 consecutive weeks after leaving.”) *Id.*

¹⁷ *Id.* (“Some people are already taking hydroxychloroquine regularly for other medical conditions such as arthritis. In those instances, they may not need to take an additional medicine to prevent malaria. Your doctor can advise you.”) *Id.*