

WASHOE COUNTY BOARD OF COUNTY COMMISSIONERS

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March 31, 2020

Nevada Governor Steve Sisolak c/o Kyle E. N. George, Interim General Counsel (via Communications Director rmcinerney@gov.nv.gov)

State Capitol Bldg. 101 N. Carson Street Carson City NV 89701

Nevada State Board of Pharmacy
Helen Park, President
c/o Brett Kandt, General Counsel (bkandt@pharmacy.nv.gov)
985 Damonte Ranch Pkwy., Ste. 206
Reno NV 89521

Re: March 23, 2020, Emergency Regulation on Prescribing and Dispensing Chloroquine and Hydroxychloroquine During COVID-19 Pandemic

Greetings:

Thank you again for taking my call to talk about the emergency regulation. As we discussed, I am writing individually to request a modification that would allow prescriptions of these drugs for an actual COVID-19 diagnosis, regardless of hospitalization. As you know, the Board of Pharmacy (Board) sought and received endorsement by you in order to adopt this regulation on an emergency basis under NRS 233B.0613. Importantly, the primary basis articulated by the Board for invocation of the special expedited emergency enactment was as follows: "the hoarding and stockpiling of chloroquine and hydroxychloroquine during the COVID-19 pandemic and the resulting shortage of supplies of these drugs for legitimate medical purposes." It also appears that the regulation was premised on the lack of official FDA action on the drugs to approve their use in treating COVID-19.

The FDA has now jumped into action. Over the weekend, the FDA issued an Emergency Use Authorization (EUA) approving the treatment of COVID-19 with these drugs from the national stockpile, and it has facilitated the acquisition of large quantities of them for distribution to the states to be used by hospitals in treating their COVID-19 patients

(https://www.fda.gov/media/136534/download). I appreciate the initiative you took on this issue, and it appears your action has gotten results. The FDA's EUA appears to specifically coincide with the twin

aims of the temporary emergency regulation: FDA approval and supply protection.

Specifically, the FDA's emergency use authorization is based on its conclusion that the totality of the scientific information available shows that these drugs may be effective in treating COVID-19. The EUA is also based on the conclusion that the available scientific evidence shows them to be reasonably safe for the purposes specified. These conclusions have been reached under the emergency authorization provisions of the FDCA, given the direness of the threat posed by the national COVID-19 outbreak and the lack of time to complete the ordinary FDA approval process for new indications of already-approved drugs. It goes without saying that time is of the essence.

Now that the FDA has acted, it would be appropriate to roll back at least one restriction in the Board's regulation: specifically, the requirement that COVID-19 prescriptions for these drugs only be allowed for hospitalized patients. I am concerned that the hospitalization requirement will prevent doctors from treating COVID-19 patients early in the course of an infection, which could eliminate the need for hospitalizations in the first place. This would allow patients to treat their infections while isolated at home, reducing their contact with and possible infection of other patients in the hospital, reducing the consumption of PPE, and reducing the possibilities for infecting hospital staff.

At the same time, this rollback would still ban the prescription of these drugs on a "prophylactic" or "just in case" basis. When coupled with the existing 30 day supply limitation and the introduction of large quantities of these drugs from the national stockpile for use by hospitals, restricting prescriptions to actual COVID-19 diagnoses regardless of hospitalization will still reasonably protect supply. It will also be useful in reducing hospitalizations and further spread of the disease.

For these reasons, I am requesting that you act immediately to work with the Board and roll back this one small aspect of the emergency regulation by allowing licensed healthcare practitioners in the state to prescribe these drugs for treatment of COVID-19 upon diagnosis, regardless of hospitalization.

Sincerely,

Bob Lucey

Chairman Washoe County Commission