

WASHOE COUNTY

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STAFF REPORT BOARD MEETING DATE: May 7, 2020

CM/ACM	
Finance	
DA	
Risk Mgt	
HR	
Other	

- DATE: May 7, 2020
 - TO: Board of County Commissioners
- **FROM:** Robert Lucey, Chair, Washoe County Board of Commissioners, 775-328-2005, <u>blucey@washoecounty.us</u>
- **THROUGH:** Washoe County District Attorney Christopher Hicks, by Chief Deputy Washoe County District Attorney Nathan J. Edwards, Civil Division, 337-5700, <u>nedwards@da.washoecounty.us</u>, and Assistant Washoe County District Attorney Dave Watts-Vial, Civil Division, 337-5700, <u>dwatts@da.washoecounty.us</u>
 - Discussion and possible reconsideration, based on new SUBJECT: developments in available medications for the treatment of COVID-19, of April 18, 2020, direction to the Washoe County District Attorney's Office to file an amicus (or similar) legal brief on behalf of the county in support of the Nevada Osteopathic Medical Association's (NOMA) and Dr. Bruce Fong's legal challenge to the Nevada State Board of Pharmacy's (BOP) March 23, 2020, emergency regulation banning chloroquine and hydroxychloroquine prescriptions for the treatment of COVID-19 except in cases of hospitalization. An amicus brief is a document submitted by a non-party to a lawsuit that is intended to outline legal arguments and authorities for the benefit of the Court in ruling on the legal issues involved. NOMA presented its challenge by letter to the BOP on April 9, 2020, asking it to pass upon the validity of the regulation pursuant to NRS 233B.110 and asserting its invalidity on various statutory and constitutional grounds. NOMA's challenge seeks to allow licensed healthcare providers to prescribe these medications to treat people with COVID-19 regardless of hospitalization. (All Commission Districts)

SUMMARY

This item involves a lawsuit that has been filed against the Nevada State Board of Pharmacy (BOP) by the Nevada Osteopathic Medical Association (NOMA) and its president, Dr. Bruce Fong, challenging the BOP's March 23, 2020, emergency regulation banning prescriptions of chloroquine or hydroxychloroquine to treat COVID-19 infections, except in cases of hospitalization. If approved, this item would result in reconsidering and withdrawing direction to the District Attorney's Office to file an amicus brief in support of NOMA's lawsuit. An amicus brief is a document filed in a lawsuit by a non-party that analyzes legal issues involved in the case in order to assist the court in resolving the dispute.

Washoe County Strategic Objective supported by this item: Stewardship of our

Community, Public Safety

PREVIOUS ACTION

• On April 18, 2020, the Board directed the District Attorney's Office to file an amicus brief in support of NOMA's lawsuit.

BACKGROUND

A lawsuit by NOMA has been filed against the BOP challenging the BOP's March 23, 2020, emergency regulation banning prescriptions of chloroquine or hydroxychloroquine to treat COVID-19 infections, except in cases of hospitalization. According to a statement of the BOP released the day after passage of the rule, it was necessary to prevent hoarding and stockpiling of the drugs, in order to ensure their availability for "legitimate" purposes such as the treatment of lupus or rheumatoid arthritis. The rule bars primary care doctors outside of the hospital setting from treating their COVID-19 patients with these medications.

On April 9, 2020, NOMA and Dr. Fong challenged the regulation by letter. In it, they asked that the BOP modify the rule to allow prescriptions for COVID-19 patients regardless of hospitalizations, in order to allow primary care doctors to use their own judgment, in consultation with their established patients, in deciding whether and when to treat a COVID-19 infection with chloroquine or hydroxychloroquine. Among other things, NOMA's challenge argues that the BOP regulation is invalid for the following reasons: (1) there was no actual supply emergency demonstrated to support its passage in the first place, only a single sentence by the BOP to that effect; (2) the regulation is preempted by federal law, specifically the FDA regulations, the FDCA, and case law that recognizes the right of doctors to prescribe medications "off-label" after they have already received original approval by the FDA; (3) the regulation constitutes the practice of medicine by the BOP, which does not practice medicine; and (4) the regulation interferes with the constitutional and statutory rights of doctors and patients to make intimate decisions about how to treat a dangerous disease.

On April 13, 2020, after receiving both Chair Lucey's and NOMA's letters, the BOP issued a "waiver" that has been interpreted to allow hospital ER doctors to use these medications on an outpatient basis, using their medical judgment. But as of April 18, 2020, the date of this Board's decision to file an amicus brief in support of NOMA's lawsuit, there had been no further modifications of the rule. Moreover, also as of that time, there was no other available medication for the possible treatment of COVID-19 infections. However, there is now new information bearing on the urgency and significance of this issue. On Monday, April 29, 2020, reports were released that an experimental antiviral drug known as Remdesivir has proven effective at blocking the coronavirus and improving patient outcomes. Further reports indicated that the FDA is in the process of expediting the drug's availability to COVID-19 patients, which might include an emergency use authorization to officially allow the drug's use for this purpose. This represents a landscape change in the medical field. See https://www.nbcnews.com/health/health-news/coronavirus-drug-remdesivir-shows-promise-large-trial-n1195171.

While NOMA's dispute over its rights and its patients' rights in the face of the BOP's regulation is an ongoing matter and is yet to be resolved, the county's interest in this matter rests on broader principles and public health concerns. Those include the county's empowerment to serve the needs of its local citizens "diligently, decisively, and effectively" (NRS 244.137(5)), to protect the "[p]ublic health, safety, and welfare in the county" on matters of local concern (NRS 244.137(2)(a)), and to enact so-called "police and sanitary" ordinances that are not in conflict with the general laws and regulations of the state (NRS 244.357), to create a program providing for prescription medications to its residents at reduced prices (NRS 244.3685), to abate dangerous conditions in the county (NRS 244.3605), to establish medical facilities in outlying areas of the county to provide outpatient and emergency care to the sick or injured there (NRS 244.1605), and "to take care of and provide for the indigent sick" within its jurisdiction (NRS 244.160). The county is also currently a party to an agreement with the cities of Reno and Sparks and the Washoe County Health District establishing an Incident Management Team to respond to and marshal the resources of these entities in fighting the COVID-19 outbreak. Potential earlier treatment of infections could lessen the impact on hospital and public health resources such as consumption of personal protective equipment (PPE), use of ventilators, occupation of ICU beds, infection of first responders and healthcare providers, and the need for additional surge capacity facilities for the treatment of infected residents.

Given the availability or expected imminent availability of an alternative medication for the treatment of COVID-19, it is possible that the county's broader interests in the public health issues here are adequately addressed. For this reason, an issue has arisen over the need for the county to file an amicus brief in support of NOMA's lawsuit. Accordingly, this item represents an opportunity for this Board to re-consider its decision to direct the filing of an amicus brief.

FISCAL IMPACT

N/A

RECOMMENDATION

If the Board of County Commissioners desires to re-consider its support of NOMA's legal challenge, based on new developments in available medications for the treatment of COVID-19, then it should withdraw its direction to the Washoe County District Attorney's Office to file an amicus (or similar) legal brief on behalf of the county in support of NOMA's and Dr. Bruce Fong's legal challenge to the Nevada State Board of Pharmacy's

March 23, 2020, emergency regulation banning chloroquine and hydroxychloroquine prescriptions for the treatment of COVID-19 except in cases of hospitalization.

POSSIBLE MOTION

The following motion is offered for consideration:

I move to re-consider and withdraw, based on new developments in available medications for the treatment of COVID-19, the direction to the Washoe County District Attorney's Office to file an amicus (or similar) legal brief on behalf of the county in support of the NOMA's and Dr. Bruce Fong's legal challenge to the Nevada State Board of Pharmacy's March 23, 2020, emergency regulation banning chloroquine and hydroxychloroquine prescriptions for the treatment of COVID-19 except in cases of hospitalization.