

## Department of Commerce, Community, & Economic Development

Corporations, Business, & Professional Licensing Board of Pharmacy

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September 29, 2021

Representatives Kurka, McCarty, and McCabe Re: Board of Pharmacy meeting – COVID 19 discussion

Dear Representatives,

Thank you for taking the time to comment during the Board of Pharmacy's September 23-24<sup>th</sup> meeting. We appreciate the thoughtful questions and statements you posed to us regarding the role of pharmacists and the use of ivermeetin to treat COVID-19. Below are answers to the questions asked.

Representative McCarty: There is concerning news around prescribers not being able to get ivermectin in the hands of patients. Is there a supply shortage of ivermectin? Is there a supply shortage of monoclonal antibodies?

Medication supply continues to be an issue that is of upmost concern to those at the State and Federal level. Currently, monoclonal antibodies are being allocated to Alaska based on usage which can lead to supply restrictions in some cases. Thus far, supply constraints have been limited. However, as demand for these products grow supply issues may develop. In the case of ivermectin, supply is an issue being reported. Since ivermectin is not a medication prescribed in large amounts in the United States demand is currently far surpassing available supply.

Representative Kurka: There seems to be a large number of pharmacists who are not filling prescriptions of ivermectin for treatment. Are there pharmacies not filling?

Pharmacies/pharmacists may or may not fill prescriptions for ivermectin for prophylaxis/treatment of COVID-19 based on professional judgement.

Representative Kurka: I'm hearing from doctors and the community that pharmacists are feeling threatened that if they dispense ivermectin, they may be risking their license. Who is doing the threatening? Who is liable?

Liability is a question the courts have taken up many times in the past decades. As pharmacists roles have expanded to meet growing healthcare demands, the responsibility for those roles has expanded as well. A case in the Indiana Supreme Court from 1994 (Hooks SuperX vs McLaughlin) took the stance that the duty of the pharmacist is independent of the physician/prescriber and therefore they have an obligation to monitor drug use and intervene when necessary. In the case of ivermectin, pharmacists across the country are faced with difficult decisions. There has not been clear evidence for the use of ivermectin for COVID-19 prophylaxis/treatment and there are currently multiple options available that have shown great benefit (vaccines and monoclonal antibodies). In addition, many times the doses of ivermectin being prescribed are double or triple the standard dosing and are prescribed for multiple days (instead of the usual one dose). This creates the proverbial "rock and a hard place" for many pharmacists. As always, pharmacists are encouraged to have discussions, educate, and make the best clinical judgement for the patient's safety as well as any potential liability. At this writing, there have been multiple deaths/hospitalizations associated with ivermectin used to treat COVID-19. This should give most

prescribers and pharmacists reason to pause before using this treatment. Lastly, under no circumstances have there been any threats against licensure coming from the Board of Pharmacy in regards to ivermectin. Our licensing standards are set in statue and regulation and we hold tightly to those clearly defined standards.

Representative Kurka: Does the PREP Act include changes to the ability to dispense ivermectin?

No it does not at this time.

Representative McCabe: Several pharmacists claim they are being threatened by this board or possibly by federal agencies because ivermectin is claimed to be contraindicated for COVID-19, even though the NIH states it is a better therapeutic option than remdesivir. I did read the board's draft statement, though I would suggest there be a link to the NIH website. I know pharmacists are last line of defense for mistakes with codeine and heroin and those sorts of drugs, but since the FDA has approved it for other diseases, pharmacists should be part of the solution by getting of the way and letting prescribers do their jobs. Ivermectin is effective in India and Scotland, so I would appreciate this to be considered in the board's draft.

See answer above regarding liability. In addition, the following is the direct recommendation from NIH regarding ivermectin:

There is insufficient evidence for the Panel to recommend either for or against the use of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19.

Furthermore, they add:

Ivermectin has been shown to inhibit the replication of SARS-CoV-2 in cell cultures. However, pharmacokinetic and pharmacodynamic studies suggest that achieving the plasma concentrations necessary for the antiviral efficacy detected in vitro would require administration of doses up to 100-fold higher than those approved for use in humans.

Thus, it would be my recommendation that should ivermectin be used in the course of treatment or prophylaxis for COVID-19 it be done on a limited basis in conjunction with multiple on-going clinical trials. This does put an additional burden on the prescriber for follow up and guidelines for care. However, the corresponding data could be used to determine clearly whether or not ivermectin has benefit for COVID-19 treatment/prophylaxis. This is especially important when choosing treatment now more than ever since there are two well defined options for both (vaccines and monoclonal antibodies).

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