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Mr. Carl W. Aron
President
Louisiana Board of Pharmacy
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Baton Rouge, LA 70809
caron@pharmacy.la.gov

Dear Mr. Aron:

It has come to my attention that in August the Louisiana Board of Pharmacy (“Board”) circulated a memo titled, “Do Not Use Ivermectin to Treat or Prevent COVID-19,” which raised the question among practitioners as to whether the Board of Pharmacy can instruct pharmacists to refuse to dispense drugs prescribed by licensed healthcare providers for off-label use. Subsequently, the Board issued a notice dated August 27, 2021, clarifying that the Board has no laws, rules, policies, or guidelines stopping the use of Ivermectin. I applaud this clarification as it will leave open the possibility for physicians to prescribe and pharmacists to dispense FDA approved drugs for off-label use in situations where a physician believes it is the best treatment option available for a patient suffering from COVID-19. This interpretation is consistent with existing law as discussed below.

A review of the U.S. Food and Drug Administration’s website found the agency acknowledges a physician may prescribe an FDA approved drug for off-label use for any number or reasons, including that there may not be an approved drug to treat the disease or medical condition or that other treatments were not successful. *See* <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>. The FDA guidance to patients on this matter is clear regarding off-label use: once the FDA approves a drug, healthcare providers generally may prescribe that drug for an unapproved use when they judge it medically appropriate for their patient.

As you should be aware, the Louisiana Medical Practice Act provides that the “practice of medicine” includes – among other things– treating, curing, or relieving any bodily or mental disease, condition, infirmity, deformity, defect, ailment, or injury in any human being, other than himself, by the use of any drug. La. R.S. 37:1262. And pursuant to La. R.S. 37:1164 “drug” means:

- (a) Any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or other animals.
- (b) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

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Reading both the FDA's own statements and the Louisiana Medical Practice Act together, nothing prohibits a licensed physician from prescribing to a patient an FDA approved drug for an off-label use.

If a physician is allowed to prescribe off-label drugs for the treatment of his or her patients, then how could the Louisiana Board of Pharmacy prohibit pharmacists from dispensing these prescriptions?

Louisiana Revised Statutes Title 37, Chapter 14, is commonly known as the Louisiana Pharmacy Practice Act, and it governs the practice of pharmacy in Louisiana. This Act begins with a "statement of purpose" that provides that the purpose of this Chapter is to promote, preserve, and protect public health, safety, and welfare. The Act then establishes a Board of Pharmacy with the authority and responsibility of regulating the profession and practice of *pharmacy* in Louisiana, not the practice of medicine. The Board's own website states the ways in which it carries out this mission. See <http://www.pharmacy.la.gov/index.cfm?md=pagebuilder&tmp=home&pid=44>.

Upon reviewing this Act, I find nothing that would allow the Board to second guess the sound medical judgment of a physician when it comes to prescribing legal drugs to their patients, nor do I see anything that allows pharmacists generally to object to off-label use of FDA approved drugs.

Therefore, I feel compelled to caution both the Board and pharmacists from impeding a licensed physician's ability to use FDA approved legal drugs for off-label use to treat a patient – as I find that it is within the professional discretion of a physician, not the pharmacist, to choose the treatment that best meets the individual medical needs of each of their patients.

The Board historically has not, to my knowledge through research, taken a position on the off-label prescription of an FDA approved drug when a physician has determined that it meets the criteria spelled out in the off-label use of prescriptive drugs by a physician.

It is important for the Board to encourage healthcare professionals to use their knowledge and all obtainable resources to treat their patients. I thank the Board for clarifying that nothing under existing law limits the pharmacists from dispensing FDA approved medications such as Ivermectin for off-label use.

For Louisiana,



Jeff Landry
Attorney General

cc: Louisiana State Board of Medical Examiners (vculotta@lsbme.la.gov)