



AND THE LAW

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THE LEARNED INTERMEDIARY DOCTRINE

It is almost impossible to attend a pharmacy law conference and not have a discussion about the Learned Intermediary Doctrine. The Doctrine was first expressed in a lawsuit against a drug manufacturer in 1966.¹ The Doctrine states that a drug manufacturer has no duty to warn a patient about the risks of a drug. The manufacturer's duty is fulfilled by informing the prescriber (the "Learned Intermediary") of the drug's risks and benefits. The prescriber then has the responsibility of choosing the appropriate therapy because the prescriber has knowledge of the patient's medical condition.

Through the years, the Learned Intermediary Doctrine was expanded to include pharmacists. This was done through court decisions, by statute, or other procedural means. Specifically, courts held that pharmacists had no duty to warn patients of the risks of a particular drug. The Learned Intermediary Doctrine put that responsibility on the physician. There

was fear that the pharmacist would somehow interfere in the physician-patient relationship. Under the Doctrine, the pharmacist discharged their duty by correctly filling the physician's prescription for the patient.

As the different states have looked at the Learned Intermediary Doctrine, they have taken different approaches to it; some adopted it, some rejected it, and some created exceptions to it. And as things usually go in the law, the different states didn't agree on the exceptions. So what is a practicing pharmacist supposed to do?

This is where I give you a different answer depending on whether I'm wearing my lawyer hat or my pharmacist hat. A common exception to the Learned Intermediary Doctrine in states that have adopted it is situations where the pharmacist has specific information about the patient's condition (e.g., she is pregnant or he is allergic to penicillin). My advice as a lawyer in these situations would be to advise my pharmacist clients to know as little about their patients as possible. That way you

¹ Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir., 1966)

can fall under the protection of the Learned Intermediary Doctrine. As a pharmacist, this advice is contrary to the direction that the pharmacy profession is headed. We are trying to become more involved in patient care, not less.

At these same conferences, there are also many discussions about gaining provider status. How can pharmacists make a case to be considered health care providers and hide behind the Learned Intermediary Doctrine at the same time? Cases rejecting the Learned Intermediary Doctrine state that pharmacists are not merely order-fillers and want to discourage robotic compliance with the physician's order.

So what is the pharmacist to do? Relying on the Learned Intermediary Doctrine is not necessarily a good strategy. The courts have not consistently applied the Learned Intermediary Doctrine. My review of cases leads me to conclude that courts really don't understand what pharmacists can and are supposed to do. For example, one case reached the right answer for the wrong reason.² There are exceptions to it and you don't want your case to be the one in which the court creates another exception. Many of the cases were decided before OBRA '90³ and its resulting regulations were implemented. Few discussions today talk about OBRA's impact on the Learned Intermediary Doctrine, but I believe that it is underestimated. It is beyond the scope of this article to recite a detailed history of these decisions. Suffice it to say that relying on the Doctrine is a risky strategy because it is

too difficult to predict the court's outcome.

The better option is for the pharmacists to use their training, experience, and expertise for the benefit of the patient. Protecting patients from harm is a strategy within the pharmacist's control. Intervene when you see something that raises a red flag. Protecting your patients ultimately protects you. Additionally, utilizing our expertise and making a positive impact on patient outcomes is a more persuasive way of convincing payers, patients, and regulators that pharmacists are a vital part of the health care team. Let's move into the 21st Century.

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This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

² Morgan v. Wal-Mart Stores, Inc., 30 S.W. 3d 455 (Tex. App.-Austin, Aug. 10, 2000)

³ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388.