

Learned Intermediary Doctrine Protects Pharmacy from Liability for Failure to Warn of Prescription Drug Side Effects

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On March 25, 2019, in [Urbaniak v. American Drug Stores, LLC](#), 2019 IL App (1st) 180248, the Illinois First District Appellate Court held that pursuant to the learned intermediary doctrine a pharmacy has no duty to warn customers of prescription drug side effects that may occur in anyone who takes the drug.

Facts

In 2008, the Urbaniak patient's gastroenterologist prescribed a drug called Reglan to treat gastroparesis. Beginning in 2010, the patient's primary care physician took over writing the Reglan prescription. The patient took the drug continuously from May 2008 to August 2014, when he was diagnosed with tardive dyskinesia, an incurable disabling neurological condition that is a known side effect of prolonged use of Reglan.

For the six years that patient took Reglan, he had all of his prescriptions filled at Osco Drug, a local retailer of defendant American Drug Stores, LLC. During this time period, Osco received Reglan in containers of 500 pills from the manufacturer and divided them for distribution to consumers. The 500-pill containers from the manufacturer contained a package insert that included a black-box warning from the FDA about the risk of developing tardive dyskinesia if Reglan were consumed for longer than 12 weeks. When dispensing Reglan, Osco distributed a medication guide to consumers that provided warnings and other information about the drug, including the FDA's black-box warning about tardive dyskinesia.

The patient's internist did not know about the tardive dyskinesia risk associated with the long-term use of Reglan and thus never informed the patient of this risk. Osco's pharmacists had frequent contact with the internist during the period that the patient was taking Reglan and never informed him or his doctor of the tardive dyskinesia risk. Osco's pharmacists also never spoke to the patient about the risks associated with taking Reglan for longer than 12 weeks. The patient did not read the medication guides that he received from Osco with each prescription refill.

The patient filed suit, asserting claims of medical malpractice against his internist and negligence against the pharmacy. The internist settled the case, and the trial court granted summary judgment to the pharmacy on the ground that it did not owe the patient a duty to verbally warn him or the internist

about the risks of taking Reglan for longer than 12 weeks.

Holding

On appeal, the First District Appellate Court affirmed on the basis of the learned intermediary doctrine. “In its most basic form, the learned intermediary doctrine obligates drug manufacturers to warn only physicians about the potential risks of a drug, and then physicians are required to use medical judgment to determine which warnings to provide to patients to whom the drug is prescribed. The doctor acts as an intermediary of the information for the benefit of and on behalf of the patient. The learned intermediary doctrine applies to pharmacists in the same way that it does drug manufacturers ? the duty to warn of side effects is not placed on the pharmacist, it is placed on the prescribing physician.”

In rejecting the plaintiff’s argument that Osco should have spoken to the patient about the side effects of Reglan because it knew that he had taken the drug for years, the appellate court observed that “were we to rule in his favor, we would be extending any duty our courts have previously recognized for pharmacists in Illinois.”

The appellate court reasoned that the duty the plaintiff advocated would require pharmacies to inquire into a doctor’s medical judgment concerning the regimen for administering a drug, and this is impermissible under the learned intermediary doctrine:

Osco also *did* warn plaintiff about the dangers of taking Reglan for longer than 12 weeks. It just did so in writing and plaintiff argues that it should have been done verbally. That is not a theory of liability the court can accept. Osco passed along the warning from the FDA. Plaintiff admits that he never read the medication guide given to him with his prescription. Plaintiff posits that Osco should have waded further into the situation. But the learned intermediary doctrine dictates that pharmacists stay out of the physician-patient relationship. And when it comes to prescription drugs, the extent of the warnings to be given to patients is within the discretion of the physician. The legal framework, through application of the learned intermediary doctrine, places the responsibility for providing medical advice on the doctor, not the pharmacist. (*Italics in original.*)

The appellate court explained further that Illinois courts “have already made clear that pharmacies do not have a duty to determine whether a prescription is ‘excessive,’ and there is no basis to make a legal distinction between an excessive dose for regular duration and a regular dose for an excessive duration. The rationale for not imposing a duty on the pharmacists in such cases is that the pharmacists did nothing more than fill prescriptions as ordered by physicians. To impose a duty to verbally warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship.”

Finally, the appellate court distinguished *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179 (2002), in which case the Illinois Supreme Court held that the learned intermediary doctrine does not apply where the pharmacy had actual knowledge of the customer’s allergies, actual knowledge of the fact that the prescribed drug was contraindicated for a person with the customer’s allergies, and actual knowledge that the contraindication could lead to injury or death.

The appellate court reasoned that “contraindications refer to specific treatments that might be harmful to a specific patient ? like where a specific drug should not be used for a specific person at a specific time” and the plaintiff here “is really trying to make the case that Reglan should be considered contraindicated for *anyone* after 12 weeks of use. Contraindications speak in terms of

specific patients and specific treatments. Reglan was not specifically contraindicated for the plaintiff for any articulable reason.” (Italics in original.)

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