The learned intermediary doctrine, which requires pharmaceutical companies to warn doctors but not patients of a drug's dangers and side-effects, is strong armor against liability for injury caused by drugs. But it's not without chinks.
Pharmaceutical companies develop new medications after years of research and development and subject to close FDA scrutiny. Prescription drug sales were estimated to be $251.8 billion during 2005, an increase of 5.4 percent from the prior year.¹

Inevitably, lawsuits challenge the efficacy and propriety of some of those medications. The lawsuits chiefly attack the pharmaceutical companies for failing to warn of the dangers and side-effects of the medications.

The learned intermediary doctrine helps shield pharmaceutical companies from liability for the sale of the drugs. That shield is not impenetrable, however. This article summarizes Illinois law regarding that doctrine, highlights some exceptions that are developing in Illinois and other states, and gives practical suggestions to defense counsel on how to take advantage of the doctrine in using physician testimony on behalf of a pharmaceutical company.

The learned intermediary doctrine in Illinois

Generally. In 1987, the Illinois Supreme Court adopted the learned intermediary doctrine in Kirk v Michael Reese Hospital & Medical Center.² Prior to Kirk, several Illinois appellate courts had applied the doctrine.³

The learned intermediary doctrine, as articulated by the supreme court in Kirk, absolves a prescription-drug manufacturer of the duty to directly warn the consumer of its prescription drugs.⁴ Instead, the pharmaceutical company has a duty to warn the learned intermediary (i.e., prescribing physician) of any dangers, which the manufacturer knows or should know about, associated with the use of the drug.⁵

If the prescribing physician is adequately warned by the drug manufacturer, the drug manufacturer is relieved of liability for allegedly failing to warn the patient. The responsibility of warning the user is placed solely on the physician.⁶

The Illinois Supreme Court articulated the policy behind the learned intermediary doctrine in Kirk:

“Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both the patient and palliative.”⁷

Prescription drugs are in a class of products deemed “unavoidably unsafe.”⁸ While there is no way to make prescription medications perfectly

1. IMS Health Reports 5.4 Percent Dollar Growth in 2005 U.S. Prescription Sales (Feb 22, 2006), online at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_77180090,00.html.
4. Kirk at 519, 513 NE2d at 392-93. Note that the learned intermediary doctrine is not limited to drugs only; it also protects manufacturers of medical devices and other products which can only be obtained by a consumer through a prescription from a healthcare provider.
5. Id at 522-23, 513 NE2d at 394. The drug manufacturer does not have a duty to warn of the relative effectiveness or safety of its drug as compared to a competitor’s drug. See Photo v Searle Laboratories, 294 Ill App 3d 393, 396-97, 690 NE2d 619, 620-21 (1st D 1997).
6. Kirk at 523, 513 NE2d at 394-95.
8. See Restatement (Second) of Torts §402A, comment k.

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The learned intermediary doctrine protects a pharmaceutical company under some circumstances even if its warnings are allegedly inadequate. Even if a pharmaceutical company fails to adequately warn a prescribing physician of a hazard associated with a medication, the manufacturer is relieved of liability if the physician has independent knowledge of the hazard.

Thus, the key question to address in failure to warn claims is whether the prescribing physician had knowledge, from any source, of the potential hazard that resulted in harm to the plaintiff. If the physician was aware of a risk prior to prescribing a drug which ultimately harms a patient, he or she is considered a “learned intermediary” and the manufacturer cannot be held liable for failure to warn. Conversely, if a physician does not have prior knowledge and the manufacturer’s warning is deemed inadequate, the physician is not a learned intermediary and the drug manufacturer is not shielded by the doctrine.

The adequacy of a warning given by a pharmaceutical company to a physician is a question of fact. While this question often serves to preclude summary judgment for defendants, it is not an absolute bar to summary judgment. The plaintiff must introduce evidence suggesting a genuine dispute as to whether the warnings given were inadequate.

Expert testimony is necessary to prove the inadequacy of a warning, unless the inadequacy would be obvious to a layperson. Thus, a plaintiff who fails to offer expert testimony on the inadequacy of a warning risks losing on summary judgment.

In Koncz v Burroughs Wellcome Co, the plaintiff failed both to offer expert testimony and to introduce any evidence suggesting a genuine dispute as to the inadequacy of the warnings, and therefore summary judgment was entered for the defendant.

The prescribing physician in Koncz had testified in his deposition that he was aware of certain potential side effects of a drug prior to prescribing the drug to plaintiff – the same side effects about which the plaintiff claimed he was not adequately warned.

A “heeding presumption”? Typically, the plaintiff has the burden of proving not only that the warning was inadequate but that the inadequate warning caused the injury. However, in one Illinois appellate learned-intermediary-doctrine case, Tongate v Wyeth Laboratories, the court applied a “heeding presumption” – a rebuttable presumption that a failure to warn was a proximate cause of the injury. In other words, the plaintiff under that theory need not prove that an inadequate warning caused the injury. Once he or she shows that a warning was inadequate, the burden shifts to the defendant to prove that the inadequate warning did not cause the plaintiff’s injury.

Two federal district court cases, applying Illinois law, have also applied a “heeding presumption” in learned intermediary cases.

In Erickson v Baxter Healthcare, Inc, the defendants argued that summary judgment was appropriate because the plaintiff had not shown that the treating physicians were not independently aware of an undisclosed risk or would have treated the patient any differently even had they known the risk. The federal district court judge denied summary judgment, stating that “the plaintiffs are entitled at this stage to a presumption that a learned intermediary would have heeded the warnings given.”

Likewise, in Woodbury v Janssen Pharmaceutica, Inc., a federal district court judge denied summary judgment based on the heeding presumption.

The Illinois Supreme Court has never discussed a heeding presumption in the context of the learned intermediary doctrine, and there is substantial persuasive authority in other jurisdictions holding that the heeding presumption is not applicable in learned intermediary cases. Even Tongate, which applied the “heeding presumption,” did not analyze or discuss the applicability of the presumption to learned intermediary cases, but simply applied it based on two cases from other jurisdictions.

Pharmacist liability

Illinois courts since 1987 have extended the learned intermediary doctrine to shield pharmacists from liability for failing to warn customers of the dangers of prescription drugs. However, a pharmacist who voluntarily

9. See Kirk at 517, 513 NE2d at 392.
10. See Ashman v SK & F Lab Co, 702 F Supp 1401, 1405 (ND Ill 1988).
13. See Hanson at 432, 764 NE2d at 43, relying on Proctor at 283, 682 NE2d at 1215.
15. See Koncz (cited in note 11) (granting summary judgment for defendant where plaintiff introduced no evidence suggesting that warnings given were inadequate).
20. See Kelley v Associated Anesthesiologists, Inc, 226 Ill App 3d 604, 608, 589 NE2d 1050, 1053 (3d D 1992) (plaintiff failed to prove defendant’s warning proximately caused his injury); Northern Trust at 401, 572 NE2d at 1037 (plaintiff required to show that inadequate warning was the proximate cause of injuries).
22. Erickson, 151 F Supp 2d at 970.
23. Id, citing Malv at 566, 390 NE2d at 1233.
25. See, for example, Thomas v Hoffman-LaRoche, Inc, 949 F2d 806 (3rd Cir 1992).
26. See Tongate at 967, 580 NE2d at 1230-31.
warns a customer of potential dangers of a drug may nevertheless be liable for negligence with respect to the warning given.28

The Illinois Supreme Court has greatly limited the “voluntary undertaking” theory of liability in the pharmacy context.29 A pharmacist’s duty is limited to the extent of the undertaking.30 Thus, indicated that “special circumstances” could exist in a particular case involving a pharmacist that would remove the case from the scope of the learned intermediary doctrine.31

In Happel v Wal-Mart Stores, Inc, a pharmacy had “special knowledge” of a customer’s medical history.32 In fact, the pharmacy knew from questions asked at prior visits that the customer had certain drug allergies.33 When the customer presented a prescription to the pharmacy for a drug that the pharmacy knew was contraindicated for persons such as the customer, the pharmacy had a duty to contact the prescribing physician or customer and inform them that the prescribed drug was contraindicated.34

**Strengthening the doctrine: Kennedy v Medtronic**

In Kennedy v Medtronic,35 the first district appellate court found that the learned intermediary doctrine applied in holding that a manufacturer of a pacemaker did not owe a duty to warn a patient receiving the pacemaker.36 Kennedy is the most recent Illinois case applying the learned intermediary doctrine and the first since the Illinois Supreme Court’s decision in Happel, which refused to apply the doctrine. The first district rejected the plaintiff’s reliance on Happel, and rather than finding an exception to the learned intermediary doctrine, actually strengthened the doctrine.

The plaintiff in Kennedy asserted that a manufacturer, which knew that a procedure involving its medical device would take place in inadequate facilities, had a duty to refrain from providing the medical device to the physician and a duty to warn the patient. The court declined to find such a duty, holding that to do so would be to place the manufacturer in the middle of the doctor-patient relationship. Summary judgment in favor of the manufacturer was affirmed.

The court also rejected the plaintiff’s claim that the manufacturer had voluntarily assumed a duty to assist in the surgery by providing a clinical specialist who was present during the

**Exceptions to the doctrine**

Several exceptions to the learned intermediary doctrine have arisen in Illinois and other states.

**Over-the-counter drugs.** The learned intermediary doctrine does not apply to over-the-counter drugs or other non-prescription medical products, even if a physician recommends the product to a patient.37

**Mass immunizations.** In the context of mass immunizations, the learned intermediary doctrine is often not applied, based on the rationale that the physician-patient relationship is lacking where a patient merely stands in line with other consumers to take a drug such as a polio vaccine, dispensed without individualized balancing of the risks by

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28. See Frye (cited in note 27) (recognizing voluntary undertaking theory of liability as a possible exception to the learned intermediary doctrine).
29. Id at 31-32, 605 NE2d at 560.
30. Id.
31. Id at 33-34, 605 NE2d at 561. See also Kasin (cited in note 27).
32. See McNichols v Johnson & Johnson, 461 F Supp 2d 736 (SD Ill); Rutherford v Merck & Co, Inc, 428 F Supp 2d 842 (SD Ill); Riddle v Merck & Co, Inc, 2006 WL 1046070 (SD Ill); Brooks v Merck & Co, Inc, 443 F Supp 2d 994 (SD Ill); Hardaway v Merck & Co, Inc, 2006 WL 2349965 (SD Ill); Nicol v Merck & Co, Inc, 2006 WL 3049887 (SD Ill).
34. See Happel v Wal-Mart Stores, Inc, 199 Ill 2d at 179, 197, 766 NE2d at 1129.
35. Id at 181-82, 766 NE2d at 1121.
36. Id at 196, 766 NE2d at 1129.
37. 366 Ill App 3d 298, 851 NE2d 778 (1st D 2006).
38. For a more in-depth discussion of this case, see Stephen R. Kaufmann and Jason D. Johnson, First District Refuses to Find Exception to Learned Intermediary Doctrine, 16 IDC Q 1 (2006).
a physician.40 Illinois courts have not adopted this exception.41

**Oral contraceptives.** Some courts in other states have carved out an exception in the context of oral contraceptives and contraceptive devices, although the Illinois Supreme Court rejected this exception.42 The states that have recognized the exception did so because typically the patient and not the doctor assumes the role of choosing a contraceptive, there is usually little initial or follow-up contact between the patient and the prescribing physician, and oral contraceptives are specifically subject to federal regulations intended to ensure an informed decision about their use.43

**Withdrawn drugs.** The learned intermediary doctrine has also been held inapplicable where a pharmaceutical manufacturer that previously marketed a product later withdraws it from the wholesale market.44 In that context, it is foreseeable that warnings to physicians regarding the withdrawal of the prescription drug will not reach all patients who used it.45 No Illinois cases address whether there is an exception to the learned intermediary doctrine for “withdrawn drugs.”

**“Over promotion.”** An “over promotion” exception has been recognized where the manufacturer’s warnings for the medication are “downplayed” and the drug is so “over promoted” that it causes the prescribing doctor to disregard the warnings given.46

**Direct-to-consumer marketing.** Both television advertising and the role of the Internet as direct lines to patients/consumers promise to be areas for an increasingly important potential exception. The New Jersey Supreme Court in Perez v Wyeth Laboratories47 decided a products liability action against the manufacturer-distributor of a contraceptive device alleging that the manufacturer failed to provide adequate warnings about the side-effects associated with the product. The plaintiffs argued that the learned intermediary doctrine should not be applied to their case because a contraceptive device was marketed directly to consumers.

The court agreed, relying primarily on a “changing times” rationale. The court offered three rationales for abrogation of the learned intermediary doctrine in extensive direct-to-consumer advertising: (1) the shift to patient-centered ethics centered on the doctrine of informed consent, the decline of paternalism, and the patient’s right to participate in healthcare decision-making; (2) the effects of managed care on the doctor-patient relationship which decreases the amount of time a doctor has to deliver an adequate warning to the patient; and (3) the development of communication from the drug manufacturers to patients and to potential patients through mass media.48

Other jurisdictions, including Illinois, have not adopted the Perez court’s direct-to-consumer marketing exception.49

**“Contract to avoid liability.”** One final exception of note is the “contract to avoid liability” exception. This has arisen when the government was involved in dispensing medications. In that exception, the pharmaceutical company has been held to satisfy its duty to warn consumers by contractually obligating the purchaser of the drug to provide a warning either to a learned intermediary or directly to the consumer.50

**The physician as witness: practice pointers for defense counsel**

Generally. Attorneys defending a pharmaceutical company against a failure to warn claim should realize that the testimony of the prescribing physician is often the key to defending the claim. Plaintiff’s evidence of an alleged inadequate warning will be ineffective if the prescribing physician testifies that he or she was independently aware of the risk or would have prescribed the drug even if he or she had known of the risk plaintiff claims was not contained in the warnings.

Similarly, a plaintiff’s evidence that a drug manufacturer allegedly distributed false advertising, impermissibly marketed its drug, or made false assertions of fact will not carry the day if the prescribing physician testifies he or she never saw or relied upon any of the alleged false statements.

Because of the importance of the prescribing physician’s testimony, counsel should seriously consider noticing his or her deposition a short time after the conclusion of the plaintiff’s deposition and before plaintiff’s counsel notices the deposition. In light of Illinois’ Petrillo doctrine, a deposition is the only way in which defense counsel can speak directly to the prescribing physician.

By setting the discovery deposition (and perhaps thereafter the evidence deposition as well) of the prescribing doctor prior to a notice by plaintiff’s counsel, defense counsel has the opportunity to “set the agenda” or “tone” in the deposition. Of course, this deposition would be set after all medical records of the plaintiff have been gathered from all medical providers.

**Topics to cover in physician’s dep.** There are several critical topics to cover in the prescribing physician’s deposition. First, the physician’s medical training and experience should be covered in detail, together with his or her experience in prescribing the medication at issue or similar medications.

Next, the physician’s knowledge about the medication in general from whatever source (including its risks, benefits and side-effects) should be ascertained. In particular, the physician’s knowledge about the medication’s package insert should be covered, as well as information obtained from drug representatives who visit the office.

It should be confirmed that the representatives did not provide information contrary to information...
contained in the package insert and/or that the physician’s decisions to prescribe were not based upon information provided by the representative. Unless the physician is of the opinion that he or she was defrauded by the pharmaceutical company or that the warnings in the package insert were patently inadequate, you should have the physician confirm that the medication was prescribed with the patient’s best interests at heart, based upon the physician’s best medical judgment and taking into account both the risks and the benefits of the medication.

Questions should be asked about the physician’s discussions with the patient regarding the prescription and obvious side-effects to expect. The physician’s testimony may contradict the testimony of the plaintiff.

While the doctor may not remember exactly what was told to the plaintiff or may not have documented his or her discussion with the plaintiff, the doctor will typically be able to testify to his or her “standard practice” in advising a patient about a particular medication. The physician’s reasons for discontinuing the medication, if applicable, should be discussed.

Finally, the physician’s opinions regarding whether the medication caused injury to the plaintiff must be explored. Worst case, if the medication indeed caused injury to the plaintiff, the prescribing physician should be able to testify that the unfortunate injury was one which was warned about in the package insert and that the medication was prescribed knowing of the possibility of that injury.

Summary judgment. Of course, the goal of the prescribing physician’s deposition is to elicit favorable testimony establishing the prescribing physician as a learned intermediary in order to prevail at the summary judgment stage.

A practitioner has two avenues to follow in order to obtain summary judgment on the failure to warn claim, and both should be fully explored.

First, in the process of fully exploring the physician’s medical training and experience the prescribing physician may testify that he or she was aware of the alleged unidentified risk. In so doing, the physician will be established as a learned intermediary. Defense counsel should then elicit testimony, if possible, from the prescribing doctor that he or she read and understood the warnings provided with the product by the medication’s FDA-approved package insert.

Ideally, the physician would testify that he or she felt the warnings in the package insert were adequate, although counsel should proceed with caution, since the response will be uncertain. Even though the adequacy of a warning is a question of fact that normally survives summary judgment, no genuine issue of fact remains as to the adequacy of the warning after the prescribing doctor testifies he or she was previously aware of the risk in dispute.

Second, the prescribing physician may testify that he or she would have treated the plaintiff in the same manner, as happened in Proctor v Davis.12

Finally, should summary judgment be unsuccessful and the matter proceeds to trial, defense counsel should tender Illinois Pattern Jury Instruction 400.07B, the learned intermediary instruction. It is an accurate statement of Illinois law. To date, there are no Illinois cases which mention that particular instruction.

Conclusion

The learned intermediary doctrine is an important defense available in Illinois to pharmaceutical companies. The viability of a failure to warn claim against a drug manufacturer often hinges on the applicability of the doctrine.

Thus, the primary focus of attorneys defending a failure to warn claim should be establishing the prescribing physician as a learned intermediary. Defense counsel need to be aware of the possible exceptions and limits to the doctrine so that they can adequately develop this important defense from the onset of the case.13


52. Proctor (cited in note 12).