Duty to Warn: Expanding Application of the Learned Intermediary Doctrine to Pharmacists

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The learned intermediary doctrine has been adopted in some form by courts in all fifty states. It is a defense tool in pharmaceutical litigation that provides an exception to the traditional rule in products liability law that manufacturers have a duty to warn the ultimate consumer, and it precludes manufacturer liability for failure to warn the consumer when an adequate warning has been given to a "learned intermediary."

Traditionally, the protection that the doctrine affords has been based on the premise that prescribing physicians act as learned intermediaries between manufacturers and consumers. Therefore, physicians stand in the best position to evaluate patients' needs, and assess risks and benefits of particular courses of treatment. And if the product is properly labeled with the appropriate warnings and instructions to fully inform the physician of the risks involved and the procedures for use, the manufacturer may reasonably assume that the physician will exercise his/her informed judgment in the patient's best interests. See e.g., Tracy v. Merrell Dow Pharmaceuticals, Inc., 58 Ohio St. 3d 147, 150, 569 N.E.2d 875 (1991).

The doctrine's reach has until recently been limited only to physicians, and not to pharmacists. Historically, pharmacists had a duty to fill prescriptions accurately, but they did not have a duty to inquire about prescriptions or to warn customers of potential risks or contraindications. But changes in industry practices and recent legislation have led courts in some states to expand the protection of the doctrine, treating pharmacists as learned intermediaries, as well.

Earlier courts shielded pharmacists from liability for the duty to warn by holding that (1) pharmacists lacked an understanding of, and access to, patients' medical history; (2) pharmacists had no duty to monitor and intervene with patients' ongoing treatment; and (3) requiring pharmacists to warn would interfere with the doctor-patient relationship. McKee v. American Home Prods. Corp., 113 Wn.2d 701, 782 P.2d 1045 (1989); see also, Adkins v. Mong, 168 Mich. App. 726, 425 N.W.2d 151 (1988).
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The reasoning behind those opinions became outdated in light of, among other developments, the passage of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), which contained provisions affecting how pharmacists handle prescription processing. OBRA 90's goal for pharmacists is to improve patient drug therapy and decrease the cost of caring for patients. OBRA 90 requires pharmacists to take a more active role in patient care by inquiring into patients' conditions, maintaining a medical history profile for each patient, and performing drug counseling prior to dispensing medications. Under OBRA 90, pharmacists arguably now have a legislatively mandated duty to warn.

In many ways, OBRA 90 simply codified practices that had grown increasingly common in the industry. Even before OBRA 90, pharmacists were already playing a more active role in the processing and monitoring of prescription drugs. Accordingly, courts had begun to consider the standard of care for the practice of pharmacy in local and similar communities when determining pharmacist liability.

In *Dooley v. Everett*, this standard of care was held to include (1) maintaining a patient profile system; (2) reviewing the profile to determine, among other things, if any drugs would interact with patients' current medications; (3) warning patients of any possible interactions; and (4) advising patients of symptoms of toxicity. 805 S.W.2d 380 (Tenn. Ct. App. 1990). The case involved a child who suffered neurological injuries after ingesting toxic levels of an asthma medication. The defendant pharmacy dispensed the asthma medication for three months, during which time it also filled an antibiotic prescription for the child. The package insert for the antibiotic warned of a possible drug interaction between the antibiotic and the asthma medication that could produce toxic levels of the asthma drug. The court reversed summary judgment, holding that the pharmacist could have breached its duty to warn of the potential interaction.

Similarly, in *Lasley v. Shrake's Country Club Pharmacy, Inc.*, the court reversed a grant of summary judgment in favor of a pharmacy on the ground that it was a jury question whether the pharmacy owed the customer a duty to warn about potential interactions as part of its duty of reasonable care. 179 Ariz. 583, 880 P.2d 1129 (Ariz. Ct. App. 1994). The customer argued that the pharmacy had a duty to warn either the customer or his physician that the prolonged use of two addictive drugs in combination could cause addiction or other adverse consequences. The court held that the pharmacy owed the customer a duty of reasonable care, and that it was a jury question whether the pharmacy's failure to warn the customer violated that duty of care.

Pharmacists have also been held potentially liable when they have taken duties upon themselves in their practice. The Illinois Supreme Court recently held that while physicians were generally the persons responsible for monitoring their patients' medications, the plaintiff-customer had raised a triable issue of fact because the pharmacy had a practice of maintaining patient-specific information about drug allergies, and knew that the drug in question was contraindicated for the patient. *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 766 N.E.2d 1118 (2002). Similarly, in *Baker v. Arbor Drugs, Inc.*, the court reversed a grant of summary judgment for a pharmacy and held that the pharmacy had a duty to warn a customer about potential drug interactions because the pharmacy had assumed that duty when it advertised that its computer system would detect the potential for
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These developments in the legislature and the courts provide the defense bar with another arrow in its quiver. It is important to consider the potential liability of not only the plaintiffs’ physicians but also of the pharmacies that filled their prescriptions. Consider what labeling and product inserts were provided to the pharmacies. Investigate whether your plaintiffs’ pharmacies provided warnings about dosage, contraindications, and other risks. And whenever possible, assert the learned intermediary defense as applied to both physicians and pharmacists. Though pharmacist liability is still not widely accepted in American courts, it is gaining acceptance. Given the advancements in technology and the increasingly automated monitoring systems available to pharmacies, combined with the legislative guidelines issued by Congress and state legislatures, it is only a matter of time before pharmacist liability becomes a majority rule.