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The Learned Intermediary Doctrine

The term “learned intermediary” was coined in a 1966 decision by the Eighth Circuit when the court reasoned that, in situations involving prescription drugs, “the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer.”¹ Forty-nine years and thousands of cases later, the learned intermediary doctrine is recognized in a majority of states. However, despite its progression and general acceptance, a line of cases presents challenges to the sustainability of this important defense in products liability litigation.

[For the most recent information on the Learned Intermediary Doctrine, read the 2018 article The Learned Intermediary Doctrine: An Update.](#)

What is the Learned Intermediary Doctrine?

The concept is simple: a manufacturer of prescription medications and devices discharges its duty to warn users of the risks associated with its products by warning the prescribing physician of the proper use and risks of the manufacturer’s product. That is, the prescription drug manufacturer’s duty to warn runs to the doctor, not the patient or public.²

The three basic rationales articulated in support of the rule are: 1) the prescribing physician is in a superior position to give the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient; 2) manufacturers lack effective means to communicate directly with each patient; and, 3) imposing a duty to warn upon the manufacturer would unduly interfere with the physician–patient relationship.³ So, it sounds simple, right? Not quite.

No consensus exists between and among the states as to the source, the scope, or, in a few jurisdictions, even the availability of the learned intermediary doctrine as a defense. A review of case law in the seven states in Frost Brown Todd’s footprint shows just how disparately the learned intermediary doctrine is treated.

The FBT Footprint

Frost Brown Todd maintains 11 offices in seven states: Indiana,

Kentucky, Ohio, Tennessee, Texas, Virginia and West Virginia.

Indiana Indiana adopted the learned intermediary doctrine into law in 1979, establishing it as a defense in cases involving prescription drugs and medical devices.⁴ Indiana was one of the first states to extend the protection afforded by the learned intermediary doctrine to pharmacists.⁵ Separate and apart from specific statutes that define the role and duties of pharmacists, the Indiana law provides that physicians, not pharmacists, are in the better position to weigh the potential risks and rewards of particular medications for specific patients. Thus, pharmacists in Indiana have no duty to warn customers about the potential side effects of medication *unless such warnings were included in the prescription received from the physician*.⁶ Despite repeated attempts to impose liability on pharmacists in failure to warn cases, Indiana courts refuse to budge.⁷

In addition, at least one Indiana Court of Appeals is willing to expand the potential reach of the learned intermediary doctrine to cases outside of the medical field. In *Hatter v. Pierce Mfg., Inc.*, 934 N.E.2d 1160 (Ind. Ct. App. 2010), the court discussed the applicability of the *sophisticated* intermediary doctrine in a case brought by a firefighter against the manufacturer of a fire truck. In *Hatter*, a firefighter was injured when a cap on the truck's rear intake pipe was propelled off the pipe into the firefighter's face.

At issue was the knowledge or sophistication of the fire department and whether it, instead of the manufacturer, had a duty to warn the firefighter. The *Hatter* court's discussion of the sophisticated intermediary doctrine mirrored discussions on the learned intermediary doctrine. "[T]he sophisticated intermediary doctrine provides a defense to a manufacturer's duty to warn and is applicable only if the intermediary—in this case, [The fire department] as the intermediary between Pierce and Hatter—knew or should have known of the product's dangers."⁹ The *Hatter* jury was so instructed and the jury returned a verdict for the manufacturer.

Kentucky Twenty-five years after the doctrine was recognized in Indiana, a sharply divided Kentucky Supreme Court adopted the learned intermediary doctrine as set forth in Section 6(d) of the

Restatement (Third) of Torts: Product Liability (1998).¹⁰ Pursuant to Section 6(d) of the Restatement (Third) a manufacturer has a duty to warn prescribing physicians and “other health care providers.” In addition, a manufacturer has a duty to warn a patient if the prescribing physician or other health care provider is not in a position to properly warn the patient of the harm associated with the product. Kentucky is the only state within the FBT footprint to have formally adopted Section 6 of the Restatement (Third), the confines of which have not yet been tested. Kentucky courts have yet to test the scope and strength of Kentucky’s version of the learned intermediary doctrine.

Ohio The Ohio Supreme Court adopted the learned intermediary doctrine and later codified the doctrine with respect to prescription drugs in Revised Code 2307.75(D)¹¹ and 2307.76 (C).¹² Several Ohio courts have found that the learned intermediary doctrine only applies to drug manufacturers because of the unique relationship between physician and patient.¹³ However, some recent decisions have discussed the learned intermediary doctrine in applications outside the prescription drug field: to chemical suppliers¹⁴ and manufacturers¹⁵ of welding consumables. So while the **basic** law in Ohio is clear,¹⁶ the **precise** scope of the application of the law in Ohio is still foggy.

Tennessee The learned intermediary doctrine is applicable under Tennessee law where a physician is an intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient.¹⁷ In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff’s injury.¹⁸ Derived from Section 388, Restatement (Second) of Torts (1965), the defense is based on the pivotal role that physicians play in the distribution of prescription products and because “[p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.”¹⁹

Tennessee courts have repeatedly and consistently refused to expand its application beyond the pharmaceutical or medical

arenas.²⁰ Compared to the other states discussed thus far, the scope of the application of the learned intermediary doctrine in Tennessee appears fixed.

West Virginia West Virginia courts have not adopted the learned intermediary doctrine. Both the northern and southern federal district courts predicted that the West Virginia Supreme Court of Appeals, when presented with the issue, would choose to adopt the learned intermediary doctrine.²¹ The southern district court described the doctrine as an “‘understandable exception’ to the general rule that manufacturers must warn foreseeable end-users about the dangers inherent in their products.”²² In addition to acknowledging that “the determination of whether certain medications and medical devices should be utilized in any given case requires an individualized medical judgment which can be made only by the patient’s physician with knowledge of the patient’s characteristics,” the northern district court looked to the fact that “West Virginia generally follows the Restatement of Law in appropriate cases.”²³

However, contrary to the predictions made by West Virginia’s federal courts, the West Virginia Supreme Court flatly refused to adopt the learned intermediary doctrine in *Johnson & Johnson v. Karl*, 647 S.E.2d 899 (W.Va. 2007). The court concluded that physicians and manufacturers each have a duty to warn, and held West Virginia’s law of comparative contribution among joint tortfeasors is adequate to address issues of liability between physicians and drug companies. *Id.*

While the *Karl* court gutted the availability of the defense in West Virginia, the West Virginia legislature provided some relief by enacting a statute declaring the applicability of the learned intermediary doctrine is to be governed by the product liability law of the place of the injury (*lex loci delicti*). W.Va. Code 55–8–16(a). But, the statute only applies to cases filed on or after July 1, 2011.

At least we are no longer left wondering. The learned intermediary doctrine is not available as a defense in West Virginia.

Challenges and Exceptions

Certain exceptions have been carved into the “learned intermediary

doctrine.” The first exception is for vaccines administered in public, mass clinics, where a physician is not generally involved.²⁴ Another exception is for contraceptive medications and devices, where the patient is actively involved in the decision and the products are used for extended periods of time without medical assessment.²⁵

In addition to the generally accepted exceptions, continuing challenges to the learned intermediary doctrine abound. For example, a 1999 New Jersey decision adopted an exception to the learned intermediary doctrine for cases in which the manufacturer engaged in direct-to-consumer advertising.²⁶ And, more states are chiming in. New Mexico was the second court to reject the doctrine *in toto*.²⁷ In 2009, a federal court in Wisconsin declined to apply the learned intermediary doctrine because “[t]he Wisconsin Supreme Court has never determined whether the doctrine applies to drug manufacturers in Wisconsin and no lower Wisconsin Court has adopted it.”²⁸ Most recently, a Texas court carved out a new exception by determining the learned intermediary doctrine did not apply where the drug manufacturer prepared an informational video for doctors to provide to their patients which video did not discuss the side effect experienced by the plaintiff.²⁹ “The changes in the delivery of healthcare brought about by direct marketing and managed care demonstrate that the theoretical underpinnings of the ‘learned intermediary’ doctrine do not apply when a drug manufacturer directly markets to its consumers, the patients.”³⁰

In short, what started as a simple doctrine is no longer so simple and cannot be taken for granted – *especially in the age of direct-to-consumer marketing*. Although the majority of state and federal court opinions continue to enforce the learned intermediary doctrine, continuing challenges and a growing number of exceptions impact the manner by which the courts will consider the doctrine in the future.

¹ *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir., 1966).

² *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984).

³ *Larkin v. Pfizer, Inc.* 153 S.W.3d 758, 763–764 (Ky. 2004).

4 See *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 162–63 n. 10 (Ind.Ct.App.1997), trans. denied; *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 549 (1979).

5 *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 885 (Ind.Ct.App. 1985), reh'g denied.

6 *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 886–7 (Ind.Ct.App. 1985).

7 “[I]f the legislature wanted to require pharmacists to warn customers of the side effects associated with prescription drugs, it would have done so by statute. We will not impose such a duty absent clear legislative intent.” *Allberry v. Parkmor Drug, Inc.*, 834 N.E.2d 199 at ftnt. 5 (Ind.App. 2005).

8 *Id.*, at ftnt.7.

9 *Id.*, at 1170 (citations omitted).

10 *Larkin v. Pfizer Inc.*, 153 S.W.3d 758 (Ky. 2004).

11 An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect. R.C. 2307.75(D).

12 An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it. R.C. 2307.76(C).

13 *Layne v. GAF Corp.*, 537 N.E.2d 252 (Oh. 1988); *Roberts v. George V. Hamilton, Inc.*, not reported in N.E.2d, 2000 WL 875324 at 3 (Oh.App. 7 Dist. 2000)

14 *Doane v. Givaudan Flavors Corp.*, 919 N.E.2d 290 (Oh. 2009).

15 *Boyd v. Lincoln Electric*, 902 N.E.2d 1023 (Oh. App. 2008).

16 A manufacturer's duty is discharged upon providing a learned intermediary with an adequate warning. *Boyd v. Lincoln Electric*, 902 N.E.2d 1023 (Oh. App. 2008).

17 *Pittman v. Upjohn*, 890 S.W.2d 425 (Tenn. 1994); *King v. Danek Med., Inc.* 985 S.W.2d 499 (Tenn.Ct.App. 1998).

18 *Harden v. Danek Medical, Inc.*, 985 S.W.2d 449 (Tenn.Ct.App. 1998).

19 *Laws v. Johnson*, 799 S.W.2d 249 (Tenn.App. 1990).

20 *Id.*, at 700–704.

21 See *Ashworth v. Albers Medical, Inc.*, 395 F.Supp.2d 395 (S.D. W.Va. 2005); *Pumphrey v. C.R. Bard, Inc.*, 906 F.Supp. 334 (N.D. W.Va. 1995).

22 *Ashworth*, 395 F.Supp.2d at 407 (quoting *Walls v. Alparma USPD, Inc.*, 887 So.2d 881, 883–84 (Ala. 2004.))

23 *Pumphrey*, 906 F.Supp. at 338 (citing draft provision of *Restatement of the Law Third: Torts, Product Liability*).

24 See *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2d Cir.1987), cert. denied, 484 U.S. 898, 108 S.Ct. 232, 98 L.Ed.2d 191 (1987); and *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.1974).

25 See *Hill v. Searle Labs*, 884 F.2d 1064 (8th Cir.1989); and *Odgers v. Ortho Pharmaceutical Corp.*, 609 F.Supp. 867 (E.D.Mich.1985).

26 *Perez v. Wyeth Lab.*, 734 A.2d 1245 (N.J. 1999).

27 *Rimbert v. Eli Lilly*, 577 F.Supp. 2d 1174, 1214 (D.N.M. 2008)(The Court believes that the Supreme Court of New Mexico, given the opportunity in 2008, would not adopt the learned-intermediary doctrine, because of the erosion of the justifications for adoption of the doctrine, given the changing dynamics between doctors and patients, patients' self-diagnosis, and DTC advertising by drug manufacturers.)

28 *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D.Wis. 2009).

29 *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476 (Tex.App. – Corpus Christi 2010).

30 *Id.*, at 507–508.

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