



Dec 19, 2018

Categories:
[Publications](#)

Authors:
[Elise N. McQuain](#)

The Learned Intermediary Doctrine: An Update

The term “learned intermediary” was coined when a federal appellate court reasoned that, in situations involving prescription drugs, “the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer.”¹ [In May of 2012, Frost Brown Todd \(FBT\) released guidance regarding the status of the learned intermediary doctrine.](#) Since that time, the status of the doctrine in the eight states in which FBT has offices has, in some cases, undergone a complete overhaul, even as other states have maintained the status quo.

What is the Learned Intermediary Doctrine?

The concept is deceptively simple: a manufacturer of prescription medications or medical devices has a duty to advise the prescribing medical professional of the proper use and potential risks of its products, rather than a duty to advise the patient or the public.²

Three of the most basic rationales in support of this rule are: (1) the prescribing physician is in a superior position to give the warning and provide an independent medical decision as to whether use of the drug is appropriate for treatment; (2) manufacturers lack effective means to communicate directly with the patient; and (3) imposing a duty to warn upon the manufacturer would unduly interfere with the physician–patient relationship.³ Despite its apparent simplicity, no consensus exists among states as to the source or the scope of the learned intermediary doctrine as a defense; however, every state now acknowledges the defense in some form.

The FBT Footprint

FBT maintains twelve offices in eight states: Indiana, Kentucky, Ohio, Pennsylvania, Tennessee, Texas, Virginia, and West Virginia. What follows is an overview of the learned intermediary doctrine’s current status in each of these states.

Indiana

Indiana’s adoption of the learned intermediary doctrine in 1979 remains strong.⁴ Furthermore, Indiana extended the doctrine to

pharmacists.⁵ In so holding, the Indiana Court of Appeals explained that much of the reasoning supporting the learned intermediary doctrine similarly applied to pharmacists, and as such, pharmacists should only be required to provide those warnings specifically found in the prescription.⁶

Indiana has also acknowledged a similar doctrine called the sophisticated intermediary doctrine.⁷ The sophisticated intermediary doctrine is applicable if: “(1) the product is sold to an intermediary with knowledge or sophistication equal to that of the manufacturer; (2) the manufacturer adequately warns this intermediary; and (3) the manufacturer can reasonably rely on the intermediary to warn the ultimate consumer.”⁸ This extends the application of the principals behind the learned intermediary doctrine far beyond the medical field.

Kentucky

Kentucky’s adoption of the learned intermediary doctrine came in the form of adopting the Restatement (Third) of Torts.⁹ Kentucky also sets forth that in order for a warning to a physician to be adequate, it must “apprise the general practitioner...of the dangerous propensities of the drug.”¹⁰ Kentucky points to other jurisdictions that held that a package insert may be sufficient and that a warning posted in the Physician’s Desk Reference may also be adequate.¹¹ However, caselaw further elaborating on the requirements of an adequate warning is limited.

Ohio

Of the states in FBT’s footprint, Ohio has one of the broadest applications of the principals expressed by the learned intermediary doctrine. Ohio’s codified law unequivocally upholds the learned intermediary doctrine’s application to manufacturers of prescriptions drugs and medical devices.¹² Provisions in the law also limit a manufacturer’s duty to warn to exclude open and obvious risks or risks that are matters of common knowledge.¹³

Ohio also recognizes the sophisticated or knowledgeable purchaser doctrine in which “a manufacturer’s duty to warn may be discharged by providing the information about the dangers of the product to a third person upon whom it can reasonably rely to communicate the warning to the ultimate users of the product.”¹⁴

This doctrine has been extended to manufacturers that provide chemicals to employers whose employees were injured by the chemicals¹⁵ and manufacturers of welding consumables.¹⁶ Clearly, the learned intermediary doctrine can be extended to a variety of situations in Ohio.

Pennsylvania

Pennsylvania was the earliest within the FBT footprint to adopt the learned intermediary doctrine when it held in 1971 that the warning required for a prescription drug extended to the prescribing doctor, not the public or the patient.¹⁷ The Superior Court of Pennsylvania explained that the warning for a prescription drug must be directed at the prescribing doctors because it is the duty of the physician to be aware of “(1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking.”¹⁸ The court further held that a manufacturer must exercise reasonable care to inform physicians of the facts that make the prescription drug likely to be dangerous.¹⁹

Tennessee

In Tennessee, the learned intermediary doctrine is applicable when a physician is an intermediary between the patient and the manufacturer of a prescription drug or medical product.²⁰ In order to be successful in a claim against a manufacturer of a prescription drug or medical product, a plaintiff must establish the following: “(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.”²¹

Unlike other states, Tennessee has consistently refused to expand the doctrine beyond the pharmaceutical or medical fields.²²

Texas

Prior to adopting the learned intermediary doctrine with regard to prescription drugs, Texas recognized generally that some manufacturers or suppliers utilized an intermediary to communicate warnings to the users of a product.²³ The Supreme Court of Texas adopted the learned intermediary doctrine with regard to pharmaceutical drugs in 2012.²⁴ In that same case, the Court

rejected the opportunity to adopt an exception to the learned intermediary doctrine that would hold manufacturers that advertise directly to consumers to a different standard.²⁵ Shortly thereafter, an intermediary court extended the doctrine to resistance bands utilized by patients at a hospital's physical therapy unit.²⁶

Virginia

While the Supreme Court of Virginia has not explicitly adopted the learned intermediary doctrine, the Court has seemed to apply the doctrine as far back as 1980.²⁷ Despite the Court's lack of official adoption, it is unlikely that the Court would go against the weight of legal authority and its previous decision and reject the learned intermediary doctrine if provided the opportunity.

West Virginia

Historically, West Virginia's Supreme Court of Appeals rejected the learned intermediary doctrine.²⁸ However, in 2016, the West Virginia Legislature enacted West Virginia Code § 55-7-30, explicitly adopting the learned intermediary doctrine.²⁹ Pursuant to the provision, "[a] manufacturer or seller of a prescription drug or medical device may not be held liable in a product liability action for a claim based upon inadequate warning or instruction...."³⁰ The section does go on to permit claims against a manufacturer or seller of a prescription drug or medical device for inadequate warning or instruction if the manufacturer or seller "acted unreasonably in failing to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings," and such a failure was the proximate cause of harm.³¹ While not adopting the identical language of the Restatement (Third) of Torts like Kentucky, the concepts and language are similar.³² It is still too early to see how West Virginia's highest court will interpret this new provision;³³ however, the clarity of the new code section creates a clear defense for manufacturers and sellers of prescriptions drugs or medical devices.

Challenges and Exceptions

Certain exceptions have been carved into the learned intermediary doctrine. One such exception is for vaccines administered in public,

mass clinics where a physician is not involved.³⁴ Additionally, some courts apply an exception for contraceptive medications and devices, because the patient is typically the individual making the decision regarding what medication or device to use with limited physician involvement or subsequent monitoring.³⁵

Despite New Jersey's adoption in 1999 of an exception when the manufacturer advertises directly to consumers no other state currently upholds the exception, and many states have in fact specifically rejected it.³⁶

It is now widely accepted that every state recognizes the learned intermediary doctrine in some form. Despite the U.S. District Court of New Mexico's prediction that the Supreme Court of New Mexico would not adopt the learned intermediary doctrine, New Mexico's appellate courts have historically followed the doctrine, with the most recent being after the District Court's prediction.³⁷ Further, while the Wisconsin Supreme Court has yet to address the issue of the learned intermediary doctrine, numerous federal districts have predicted that the Court would adopt the doctrine if given the opportunity.³⁸ While the exact scope of the doctrine remains unclear in some jurisdictions, the argument remains a valuable defense available in some form to defendants in every state.

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

[2] See Restatement (Third) of Torts: Prod. Liab. § 6(d) & cmt. b (1998).

[3] *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763–64 (Ky. 2004).

[4] *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548–49 (Ind. Ct. App. 1979).

[5] *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 885–87 (Ind. Ct. App. 1985).

[6] *Id.*

[7] See generally *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155 (Ind. Ct. App. 1997).

[8] *First Nat. Bank & Tr. Corp. v. Am. Eurocopter Corp.*, 378 F.3d 682, 691 (7th Cir. 2004) (applying Indiana law); see also *Hatter v. Pierce Mfg., Inc.*, 934 N.E.2d 1160 (Ind. Ct. App. 2010).

[9] *Larkin v. Pfizer Inc.*, 153 S.W.3d at 762; see also *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 109–10 (Ky. 2008).

[10] *Gunderson*, 279 S.W.3d at 109–10.

[11] *Id.*

[12] Ohio Revised Code §§ 2307.75 & 2307.76(C); *Boyd v. Lincoln Electric*, 902 N.E.2d 1023, 1035 (Oh. Ct. App. 2008); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Oh. 2002).

[13] Ohio Revised Code § 2307.76(B).

[14] *Doane v. Givaudan Flavors Corp.*, 919 N.E.2d 290, 297 (Oh. Ct. App. 2009).

[15] See generally *id.*

[16] *Boyd*, 902 N.E.2d at 1035.

[17] *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971); *Baldino v. Castagna*, 478 A.2d 807, 812 (Pa. 1984).

[18] *Hahn v. Richter*, 628 A.2d 860, 866 (Pa. 1993), *aff'd*, 673 A.2d 888 (Pa. Supr. Ct. 1996).

[19] *Id.*

[20] *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994).

[21] *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

[22] *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011); *Whitehead v. Dycho Co.*, 775 S.W.2d 593, 598 (Tenn. 1989); *Laws v. Johnson*, 799 S.W.2d 249 (Tenn. Ct. App. 1990).

[23] *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986).

[24] *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157–58 (Tex. 2012).

[25] *Id.* at 162–64.

[26] See generally *Seifried v. Hygenic Corp.*, 410 S.W.3d 427 (Tex. Ct. App. 2013).

[27] *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980); see also *Hart v. Savage*, Civ. Act. No. L-04-1663, 2006 WL 3021110, *2 (Va. Cir. Ct. Norfolk, Oct. 19, 2006); *Hamlett v. Virginia Vascular Assocs.*, Civ. Act. No. 02-1560, 2003 WL 22382792 (Va. Cir. Ct. Norfolk, April 21, 2003).

[28] *Johnson & Johnson v. Karl*, 647 S.E.2d 899 (W. Va. 2007).

[29] “It is the intention of the Legislature in enacting this section to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices.” W. Va. Code § 55-7-30(b).

[30] W. Va. Code § 55-7-30(a).

[31] *Id.*

[32] See Restatement (Third) of Torts: Prod. Liab. § 6(d).

[33] The Supreme Court of Appeals held that the newly enacted statute does not impact cases filed before its effective date. *J.C. by & through Michelle C. v. Pfizer, Inc.*, 240 W. Va. 571, 575 n.9, 814 S.E.2d 234, 238 n.9 (W. Va. 2018)

[34] *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (4th Cir. 1974); *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir.1968).

[35] *Hill v. Searle Labs., a Div. of Searle Pharm., Inc.*, 884 F.2d 1064, 1070-71 (8th Cir. 1989); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878-79 (E.D. Mich. 1985); but see *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991) (applying learned intermediary doctrine to oral contraceptives).

[36] *Hamilton*, 372 S.W.3d at 161; *Larkin*, 153 S.W.3d at 766; *Mendez Montes De Oca v. Aventis Pharma*, 579 F. Supp.2d 222, 228-29 (D.P.R. 2008); *Beale v. Biomet, Inc.*, 492 F. Supp.2d 1360, 1376 (S.D. Fla. 2007).

[37] *Silva v. SmithKlineBeecham Corp.*, Civ. Act. No. 31,276, 2013 WL 4516160, at *2-3 (N.M. Ct. App. Feb. 7, 2013); *Serna v. Roche Laboratories, Division of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189

(N.M. Ct. App. 1984); *Jones v. Minnesota Mining & Manufacturing Co.*, 669 P.2d 744, 748 (N.M. Ct. App. 1983); *Perfetti v. McGahn Medical*, 662 P.2d 646, 650 (N.M. Ct. App. 1983); *Richards v. Upjohn Co.*, 625 P.2d 1192, 1195 (N.M. Ct. App. 1980); *Hines v. St. Joseph's Hospital*, 527 P.2d 1075, 1077 (N.M. Ct. App. 1974).

[38] *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, 218 F. Supp. 3d 700, 727 (N.D. Ill. 2016) (applying Wisconsin law and predicting that the Wisconsin Supreme Court would adopt the learned intermediary doctrine); *but see Forst v. SmithKlineBeecham Corp.*, 602 F.Supp.2d 960, 968 (E.D. Wis. 2009) (predicting that the Wisconsin Supreme Court would not adopt the learned intermediary doctrine.)

© 2026 FBT Gibbons LLP. May be considered attorney advertising in some jurisdictions.