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PRODUCT LIABILITY

PHARMACEUTICALS

A latent pitfall in pharmaceutical and medical device litigation is the learned intermediary doctrine, which is typically not broached until much of discovery is completed and can “completely destroy” an expensive, complex case, says attorney Kate E. Gillespie in this BNA Insight.

The author traces the history of the doctrine and offers a 52-jurisdiction survey that examines how the rule is treated.

Acquiring Immunity to the Learned Intermediary Defense

By KATE E. GILLESPIE

Kate E. Gillespie is an associate attorney in the Los Angeles drug product liability department of Baum, Hedlund, Aristei & Goldman, which has been at the forefront of the antidepressant product liability litigation for 19 years. Gillespie focuses her practice on injury and wrongful death Paxil suicide and anti-depressant birth defect cases, as well as pharmaceutical class action and mass tort litigation. The author can be reached at KGillespie@BaumHedlundLaw.com.

When “un-learned” doctors are deemed “learned” intermediaries, they can kill their patients’ cases. Physicians who think they are charged with the responsibility of knowing-it-all may be unwilling to admit they were under-informed by deceptive manufacturers, thus undermining all of the hard-earned evidence showing what the manufacturers hid. An “un-learned,” but defensive physician can become a “learned” shield to an otherwise powerful case. To inoculate your cases from this potentially deadly threat, it is important to understand the learned intermediary doctrine’s genesis, development and uses. Presented in this article is the history of the learned intermediary doctrine and a 52 jurisdictional survey (50 United States, District of Columbia and Puerto Rico) of the

adoption, rejection or silence regarding this potentially fatal defense.

Introduction

Litigation involving pharmaceutical drugs or medical devices involves many moving parts with some key potential pitfalls that can lie undetected in a plaintiff's case. While initially one must focus on discovering and proving what led to the product's hidden harmful defects, one also needs to keep in mind those latent pitfalls which have the potential to destroy your case. Such pitfalls can be the most damaging because they sweep the rug out from under you *after* you have invested a great deal of time and money establishing the defendants' wrongful conduct. One latent pitfall in pharmaceutical and medical device litigation is the learned intermediary doctrine. This defense is typically not broached until much of the discovery is completed, when the parties get to the prescribing doctor's deposition. Depending on how defensive the treating physician gets about his "unlearnedness," that deposition can be devastating to your case. To prevent succumbing to it, one must understand the learned intermediary doctrine's origins and the different jurisdictions' treatment of it.

Learned Intermediary Defined

Product manufacturers have a duty to make and sell things that are reasonably safe and not defective. If the type of product at issue is one that is inherently dangerous, then the manufacturer has a duty to warn the consumer about the defects or danger. However, the learned intermediary doctrine holds that drug manufacturers owe no duty to warn *consumers* about the risks of consuming prescription drugs because the manufacturers are allowed to rely on the prescribing physician to do so. In jurisdictions that have adopted the learned intermediary doctrine, the medical treater is accepted as, and expected to be, a *learned intermediary* between the manufacturer and the end user of the product (the patient). The medical treater is considered to be an expert who takes into account a prescription drug's varied effects, including the potential adverse reactions of the drug. It is the treater's task, based on the information obtained from the drug manufacturer, to weigh the risks of the drug against the benefits for a particular patient, and to give individualized warnings to the patient based on the prescriber's specialized knowledge.¹

In jurisdictions that have adopted the learned intermediary doctrine, a plaintiff asserting a failure to warn cause of action against a pharmaceutical or medical device manufacturer must prove that the manufacturer failed to provide an adequate warning to the medical treater *and* that an adequate warning of the risks of the product would have changed the prescriber's actions. Thus, the learned intermediary doctrine is a defense that, if successful, allows drug manufacturers to be relieved of their duty to warn of their drug's risks to the end-user (with the exception of certain products, such as vaccines and contraceptives) provided they adequately advise the *learned intermediary* of said risks.²

Drug manufacturers use this doctrine to shield themselves from responsibility even when they have clearly

failed to warn of a danger they knew or should have known. Predictably, pharmaceutical and device manufacturers use this doctrine as an ultimate defense in failure to warn cases in order to pass the buck (and liability) to the medical treaters and to destroy the plaintiff's cause of action against the manufacturer.

Birth of the Learned Intermediary Doctrine

From the development of strict product liability law and the establishment of a cause of action for failure to warn, the concept of the learned intermediary doctrine was born. In 1948, the doctrine first came into focus when the New York Supreme Court ruled that, because warnings accompanying medicines are directed at physicians, a manufacturer should not be held liable for failing to warn the end-user (patient) about risks associated with the product. In short, because the warnings are purposely not issued to patients directly, there is no basis for liability against a manufacturer for allegedly failing to warn the patient.³

The term "learned intermediary doctrine" was devised approximately 20 years later when the Eighth Circuit held that a physician was acting as a "learned intermediary" between the manufacturer and the patient because a prescription drug was involved rather than a normal consumer item.⁴ With prescription drugs, the doctor is expected to be a knowledgeable liaison between the manufacturer and the patient, one who is able to comprehend the instructions and warnings from the manufacturer and apply them to the specific patient. Thus, if the doctor is properly warned by the manufacturer of the risks of the pharmaceutical product, then there is no liability as to the manufacturer.

Survey of Learned Intermediary Doctrine

As the learned intermediary doctrine has evolved, various jurisdictions have taken different positions on the defense. Thus, the jurisdiction in which you are practicing could make a considerable difference as to whether your case glides into trial or reaches a settlement, or is at risk of dismissal. Below is a survey of the current view of the learned intermediary doctrine in the 50 United States, District of Columbia, and Puerto Rico.

Not all States have adopted the learned intermediary doctrine and, for those states that have, some may not have been adopted by the highest court. Based on this survey, the highest courts in 29 jurisdictions have adopted the learned intermediary doctrine⁵; the legislatures of four jurisdictions have adopted the learned intermediary doctrine into law⁶; the intermediate state appellate courts in six jurisdictions have adopted the learned intermediary doctrine⁷; 10 jurisdictions have not adopted the learned intermediary doctrine, but district courts in those jurisdictions have predicted the state's adoption or rejection of the learned intermediary

³ *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948)

⁴ *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966)

⁵ AL; AK; AR; CA; CT; DE; DC; FL; GA; HI; IL; KS; KY; MD; MA; MI; MN; MO; MT; NE; NV; NY; OK; OR; PA; TN; UT; VI; and WA

⁶ MS; NJ; NC; and OH

⁷ AZ; CO; IN; LA; TX; and WY

¹ *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1031-32 (D.N.J. 1988)

² See e.g., *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989).

doctrine⁸; two jurisdictions are silent as to the learned intermediary doctrine⁹; and one jurisdiction has rejected the doctrine outright.¹⁰ Thus, the total number of jurisdictions having adopted the learned intermediary doctrine is 33. As such, in the remaining 19 jurisdictions, application of the learned intermediary doctrine is more tenuous and will be easier to attack, thereby protecting your case from precariously hanging on the deposition of the prescriber and possibly being dismissed on summary judgment.

Alabama

The Supreme Court of Alabama adopted the learned intermediary doctrine in *Stone v. Smith, Kline & French Lab.*, 447 So.2d 1301 (Ala. 1984), holding that “[p]rescription 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 knowledge of both patient and palliative” (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). The court more recently applied the doctrine in *Springhill Hospitals Inc. v. Larrimore*, 5 So.3d 513 (Ala. 2008); *Walls v. Alpharma USPD*, 887 So.2d 881, 883 (Ala. 2004); and *Morguson v. 3M Corp.*, 857 So.2d 796, 801-02 (Ala. 2003).

Alaska

The Supreme Court of Alaska adopted the doctrine in *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 & n.17 (Alaska 1992) holding that, in the case of prescription drugs, the warnings should be sufficient to put the physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug, referencing *Polley v. Ciba-Geigy Corp.*, 658 F. Supp. 420 (D. Alaska 1987).

Arizona

Arizona Court of Appeals adopted the learned intermediary doctrine in *Piper v. Bear Medical Systems, Inc.*, 883 P.2d 407, 415 (Ariz. App. 1993); *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. App. 1978); and *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1087 (Ariz. App. 1978) holding that, in the case of prescription drugs (and especially for investigational drugs, which can be prescribed only by selected physician investigators), the manufacturer’s duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician. A drug manufacturer has discharged his duty to the public if he has properly warned the administering physician of the contraindications and possible side effects of the drug.

⁸ Adoption predicted: ID; IA; ME; NH; ND; PR; SC; SD. Rejection predicted: NM and WI (Note: the most recent federal court decisions have predicted rejection of the learned intermediary doctrine)

⁹ RI and VT

¹⁰ WV

Arkansas

The Supreme Court of Arkansas adopted the learned intermediary doctrine in *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) holding that a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug. The physician acts as the “learned intermediary” between the manufacturer and the ultimate consumer. The Court noted there are a number of arguments supporting the application of this exception to prescription drug products, which may be summarized as: First, a physician must prescribe the drug, the patient relies upon the physician’s judgment in selecting the drug, and the patient relies upon the physician’s advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient (citing *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989)).

California

The Supreme Court of California adopted the learned intermediary doctrine in *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996); *Brown v. Superior Court*, 751 P.2d 470, 477 n.9 (Cal. 1988); and *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 660 (Cal. 1973) holding that, in the case of prescription drugs, the duty to warn runs to the physician, not to the patient — a drug manufacturer need only warn the prescriber regarding the risks associated with its drugs and the manufacturer need not provide warnings to patients directly.

Colorado

Colorado Court of Appeals adopted the learned intermediary doctrine in *Hamilton v. Hardy*, 549 P.2d 1099, 1110 (Colo. App. 1976) (overruled on other grounds), holding that the drug manufacturer’s duty to the public is to warn the medical profession. However, the appellate court also held that, where a prescription drug manufacturer puts a drug on the market without adequate warning, the prescribing doctor’s conduct may not insulate the manufacturer from liability where the inadequacy of the warning may have contributed to a plaintiff’s injury.

Connecticut

The Supreme Court of Connecticut adopted the learned intermediary doctrine in *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 783-84 (Conn. 2006) (regarding medical devices) and *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836-38 (Conn. 2001) (regarding prescription drugs). In *Vitanza*, the court explained that “a product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions” (citing *Hill v. Searle Laboratories*, 884 F.2d 1064, 1067 (8th Cir. 1989)) (“defect need not be a matter of errors in manufacture . . . a product is defective when it is . . . not accompanied by adequate instructions and warnings of the dangers attending its use”). The court held, however, that the learned intermediary

doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly.

Delaware

The Supreme Court of Delaware adopted the learned intermediary doctrine in *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400-01 (Del. 1989) holding that adoption of the learned intermediary doctrine is appropriate in medical device and prescription drug cases. “A patient obviously is unable to obtain a prescription drug or a device unless his physician orders it. When a patient consults with a physician seeking a prescription drug or restricted device, the patient also expects the physician to use his informed independent judgment to advise the patient and to prescribe the most appropriate use of the drug or device, based on his professional judgment. In the final analysis it is the physician who ultimately prescribes the drug or device. Thus, if the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn.”

District of Columbia

The District of Columbia Court of Appeals (the highest court in this jurisdiction) acknowledged the learned intermediary doctrine in *Mampe v. Ayerst Laboratories*, 548 A.2d 798, 801 & n.6 (D.C. 1988), which also recognized a rebuttable presumption that the prescribing physician would have read an adequate warning and that, in the absence of evidence rebutting the presumption, a jury may find that the defendant’s product was the producing cause of the plaintiff’s injury. The United States District Court of the District of Columbia examined the doctrine in *Dyson v. Pharmacia & Upjohn, Inc.*, 129 F. Supp.2d 19, 21 (D.D.C. Jan 19, 2001).

Florida

The Supreme Court of Florida adopted the learned intermediary doctrine in *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989) and affirmed in *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So.2d 825, 827 (Fla. 1997); and *Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) holding that prescription or ethical drugs can be administered only under the direction of a physician, and Florida law requires that the manufacturer provide an adequate warning only to the physician, or learned intermediary. Whether the physician in fact reads the warning or passes its contents along to the recipient of the drug is irrelevant to the liability of the manufacturer. *Id.*

Georgia

The Supreme Court of Georgia adopted the learned intermediary doctrine in *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003) holding that, under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient’s doctor who acts as a learned intermediary between the

patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer in that the “decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician’s knowledge of a patient’s particular need and susceptibilities” (citing *Lance v. American Edwards Laboratories*, 452 S.E.2d 185 (Ga. Ct. App. 1994)).

Hawaii

The Supreme Court of Hawaii adopted the learned intermediary doctrine in *Craft v. Peebles*, 893 P.2d 138, 155 (Hawaii 1995). The court agreed with the holdings in *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89 (D.Md.1989) and *Toole v. McClintock*, 999 F.2d 1430 (Ala. 1993) wherein the courts held that the learned intermediary rule had its genesis in the prescription drug arena, but its application had been expanded to medical devices by analogy and that, in both circumstances, physicians are in a better position to assess risks and determine when a particular patient reasonably should be informed about a risk. Further, the courts held that the adequacy of a manufacturer’s warning is measured by the effect on the physician to whom it owed a duty to warn, and not by its effect on the patient.

Idaho

Idaho has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Adams v. U.S.*, 622 F. Supp.2d 996 (D. Idaho 2009) holding that, under Idaho law, a supplier positioned on the commercial chain remote from the ultimate consumer may, under certain circumstances, fulfill its duty to warn by adequately warning an intermediary (citing *Silman v. Aluminum Co. of America*, 731 P.2d 1267 (Idaho 1986)). A doctor may stand as a learned intermediary between a drug maker and the patient because a doctor understands the risks of the drug and is better-positioned to warn the patient. However, under *Silman*, the burden is shifted to the manufacturer to prove that (1) its reliance on the intermediary to pass on the warning to end-users was reasonable, and (2) it adequately warned the intermediary.

Illinois

The Supreme Court of Illinois adopted the learned intermediary doctrine in *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1127 (Ill. 2002); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002); *Martin v. Ortho Pharmaceutical Corp.*, 661 N.E.2d 352, 354 (Ill. 1996); and *Kirk v. Michael Reese Hospital & Medical Center*, 513 N.E.2d 387, 393 (Ill. 1987) holding that the rationale underlying the learned intermediary doctrine is that the prescribing physician has knowledge of the drugs he is prescribing and, more importantly, knowledge of his patient’s medical history. It is the physician who is in the best position to prescribe drugs and monitor their use, thus, manufacturers should not be required to warn individual patients of the dangers inherent in their use. That is the proper province of the prescribing physician, not the drug manufacturer, who has a duty only to warn the physician.

Indiana

The Indiana Court of Appeals adopted the learned intermediary doctrine in *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-59 (Ind. App. 1979) holding that, where a product is available only on prescription or through the services of a physician, the physician acts as a “learned intermediary” between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products he prescribes or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts to relay to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.

Iowa

Iowa has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) and *Madsen v. American Home Products Corp.*, 477 F. Supp.2d 1025, 1033-34 (E.D. Mo. 2007). In *Petty*, the district court held that, under Iowa law, the drug manufacturer’s duty to warn extends to the ultimate consumer in a mass immunization context, where there is no learned intermediary. In *Madsen*, the district court reasoned that Iowa’s adoption of the Restatement (Third) of Torts’ analytical framework for product defect cases and the overwhelming precedent adopting the learned intermediary doctrine convinces the Court that the Iowa Supreme Court would recognize that the doctrine governs failure-to-warn claims.

Kansas

The Supreme Court of Kansas adopted the learned intermediary doctrine in *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 928 (Kan. 1990); *Humes v. Clinton*, 792 P.2d 1032, 1039-40 (Kan. 1990); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1227-28 (Kan. 1987); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986); and *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1052 (Kan. 1984), ultimately holding in *Wooderson* that the manufacturer of an ethical drug has a duty to warn the medical profession of dangerous side effects of its products of which it knows, has reason to know, or should know, based upon its position as an expert in the field, upon its research, upon cases reported to it, and upon scientific development, research, and publications in the field.

Kentucky

The Supreme Court of Kentucky adopted the learned intermediary doctrine in *Larkin v. Pfizer, Inc.*, 153

S.W.3d 758, 761 (Ky. 2004) holding that the best rationale [for adopting the learned intermediary doctrine] is that the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy. However, if the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer (citing *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 529 (1974)). Further, the court held that the learned intermediary rule is consistent with [the] informed consent statute, KRS 304.40-320, which anticipates that doctors will inform their patients of any risks or dangers inherent in proposed treatment.

Louisiana

Louisiana Court of Appeals adopted the learned intermediary doctrine in *Kampmann v. Mason*, 921 So.2d 1093, 1094 (La. App. 2006); *David v. Our Lady of Lake Hospital, Inc.*, 857 So. 2d 529, 532 (La. App. 2003); *Brown v. Glaxo, Inc.*, 790 So.2d 35, 38 (La. App. 2000); *Calhoun v. Hoffman-LaRoche, Inc.*, 768 So.2d 57, 61 (La. App. 2000); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So.2d 75, 79-80 (La. App. 1994); *Rhoto v. Ribando*, 504 So.2d 1119, 1123 (La. App. 1987); *Kinney v. Hutchinson*, 468 So.2d 714, 717 (La. App. 1985); and *Cobb v. Syntex Laboratories, Inc.*, 444 So.2d 203, 205-06 (La. App. 1983), generally holding that the drug manufacturer’s duty to the “user” as defined in La. R.S. 9:2800.57 is assumed by the doctor. Under La. R.S. 9:2800.57 A, the drug manufacturer’s duty is to “provide reasonable care to provide an adequate warning” to the doctor.

Maine

Maine has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995) and *Doe v. Solvay Pharmaceuticals, Inc.*, 350 F. Supp.2d 257, 270-71 (D. Me. 2004), *aff’d*, 153 Fed. Appx. 1 (1st Cir. 2005).

Maryland

The Court of Appeals of Maryland (the highest court in this jurisdiction) adopted the learned intermediary doctrine in *Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 577 (Md. 2006) and *Nolan v. Dillon*, 276 A.2d 36, 40 (Md. 1971) holding that the court adopted a form of the “learned intermediary” doctrine in *People’s Serv. Drug Stores, Inc. v. Somerville*, 161 Md. 662, 158 A. 12 (Md. 1932).

Massachusetts

The Supreme Judicial Court of Massachusetts adopted the learned intermediary doctrine in *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 820 (Mass. 2002) holding that “a prescription drug manufacturer’s duty to warn of dangers associated with its product runs only to the physician; it is the physician’s duty to warn the ulti-

mate consumer (citing *McKee v. American Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989)). In *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 68 (Mass. 1985), the court rejected the learned intermediary doctrine in the context of oral contraceptives, but indicated in dicta that it would adopt it in the general prescription drug context.

Michigan

The Supreme Court of Michigan adopted the learned intermediary doctrine in *Smith v. E.R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979) holding that a manufacturer of a prescription drug has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the drug which the manufacturer knows or should know to exist.

Minnesota

The Supreme Court of Minnesota adopted the learned intermediary doctrine in *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 n.1 (Minn. 1970) holding that, "manufacturer has no duty to warn the lay public regarding prescription drugs."

Mississippi

The Mississippi legislature adopted the learned intermediary doctrine. See, Miss. Code § 11-1-63(c)(ii). See also, *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31, 57 (Miss. 2004); *Moore v. Memorial Hospital*, 825 So.2d 658, 664 (Miss. 2002); *Bennett v. Madakasira*, 821 So.2d 794, 804 (Miss. 2002); and *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688, 691-92 (Miss. 1988).

Missouri

The Supreme Court of Missouri adopted the learned intermediary doctrine in *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146-47 (Mo. 1967) holding that a prescription drug manufacturer has a duty to properly warn the doctor of the dangers involved. It is incumbent upon the manufacturer to bring the warning home to the doctor.

Montana

The Supreme Court of Montana adopted the learned intermediary doctrine in *Hill v. Squibb & Sons*, 592 P.2d 1383, 1387-88 (Mont. 1979) holding that, as a general rule, the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it.

Nebraska

The Supreme Court of Nebraska adopted the learned intermediary doctrine in *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000) holding that pharmaceutical products have historically been treated differently in regard to a duty to warn. Although, in ordinary product cases, a manufacturer's duty to warn runs directly to the consumer of the product, in cases involving prescription drugs, it is widely

held that the duty to warn extends only to members of the medical profession and not to the consumer.

Nevada

The Supreme Court of Nevada adopted the learned intermediary doctrine in *Allison v. Merck & Co.*, 878 P.2d 948, 958 n.16 (Nev. 1994) (plurality op.), 969 (dissent also following learned intermediary rule) holding the medical treater must provide individualized medical judgment regarding pharmaceutical product use for the doctrine to apply.

New Hampshire

New Hampshire has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972) holding that, although the court found no case directly on point, the court believes that, having embraced strict liability, the New Hampshire court would follow others in imposing upon a drug manufacturer an affirmative duty to warn the medical profession of the dangerous side effects that might result from the longterm use of its product. See also, *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981).

New Jersey

The New Jersey legislature adopted the learned intermediary doctrine. See, N.J. Stat. § 2A:58C-4 (1987). See also, *Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989); *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1257 (N.J. 1999).

New Mexico

New Mexico Court of Appeals adopted the learned intermediary doctrine in *Serna v. Roche Laboratories, Division of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189 (N.M. App. 1984) holding that [w]here the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient. However, the Court of Appeals also held that the adequacy of a warning to a physician is determined by the following criteria: 1) the warning must adequately indicate the scope of the danger; 2) the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3) the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4) a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, most importantly, in the context of the present case; and 5) the means to convey the warning must be adequate. See also, *Jones v. Minnesota Mining & Manufacturing Co.*, 669 P.2d 744, 748 (N.M. App. 1983); *Perfetti v. McGahn Medical*, 662 P.2d 646, 650 (N.M. App. 1983); *Richards v. Upjohn Co.*, 625 P.2d 1192, 1195 (N.M. App. 1980); and *Hines v. St. Joseph's Hospital*, 527 P.2d 1075, 1077 (N.M. App. 1974). However, in *Rimbert v. Eli Lilly & Co.*, 577 F. Supp.2d 1174 (D.N.M., 2008), the federal court rejected the learned intermediary doctrine predicting that New Mexico would not adopt the learned intermediary doctrine due to the prevalence of direct to consumer marketing:

[T]he changed landscape makes the justifications other courts have used for the learned-intermediary doctrine outdated and unpersuasive. With the advent of [direct-to-consumer] advertising and the trend of people self-diagnosing and, based on that diagnosis, requesting particular prescription drugs, the reliance on physicians is not the same as it was in the 1970s and 1980s. While the Court does not in any way minimize the importance of doctors in the prescription-drug claim, neither the drug manufacturers nor the patient totally relies on the intermediary. The manufacturer and the patient are communicating directly and the consumer is relying on that direct communication.

Rimbert, 577 F. Supp.2d at 1218.

New York

The New York Court of Appeals (the highest court in this jurisdiction) adopted the learned intermediary doctrine in *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999) and *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993), holding that the learned intermediary doctrine focuses on the scope of a drug manufacturer's duty to warn of the dangers of the drug in question. That duty is fulfilled by giving adequate warning to the prescribing physician. The physician must then balance the risks and benefits of various drugs and treatments and act as an "informed intermediary" between manufacturer and patient.

North Carolina

The North Carolina legislature adopted the learned intermediary doctrine. See, N.C. Gen. Stat. § 99B-5(c) (1996). See also, *Holley v. Burroughs Wellcome Co.*, 330 S.E.2d at 233 (N.C. App. 1985).

North Dakota

North Dakota has not adopted the learned intermediary doctrine, however the federal court in *Ehls v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004) predicted adoption of the doctrine, holding that [the court] believe[s] the district court correctly determined North Dakota would adopt the learned intermediary doctrine for two reasons. First, North Dakota adopted section 402A of the Restatement (Second) of Torts, from which the learned intermediary doctrine evolves. The district court reasoned that, because North Dakota has adopted other comments from section 402A 'North Dakota would recognize the learned intermediary doctrine as the rule of law in cases where the adequacy of the warning as to a prescription drug is at issue.'

Ohio

The Ohio legislature adopted the learned intermediary doctrine. See, Ohio Rev. Code § 2307.76(c). See also, *Howland v. Purdue Pharma, L.P.*, 821 N.E.2d 141, 146 (Ohio 2004); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002); *Wagner v. Roche Laboratories*, 671 N.E.2d 252, 256 (Ohio 1996); *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 569 N.E.2d 875, 876, 878 (Ohio 1991); *White v. Wyeth Laboratories*,

Inc., 533 N.E.2d 748, 755 (Ohio 1988); and *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 834, 836-37 (Ohio 1981).

Oklahoma

The Supreme Court of Oklahoma has adopted the learned intermediary doctrine in *McKee v. Moore*, 648 P.2d 21, 24 (Okla.1982) (prescription drug case) and *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (prosthetic implant cases). The doctrine operates as an exception to the manufacturer's duty to warn the ultimate consumer, and shields manufacturers of prescription drugs from liability if the manufacturer adequately warns the prescribing physicians of the dangers of the drug. *McKee*, at 24. The reasoning behind this rule is that the doctor acts as a learned intermediary between the patient and the prescription drug manufacturer by assessing the medical risks in light of the patient's needs. *Cunningham v. Pfizer & Co., Inc.*, 532 P.2d 1377, 1381 (Okla. 1975).

Oregon

The Supreme Court of Oregon adopted the learned intermediary doctrine with respect to negligence claims in *Oksenholt v. Lederle Laboratories*, 656 P.2d 293, 296-97 (Or. 1982); *Vaughn v. G.D. Searle & Co.*, 536 P.2d 1247, 1247-48 (Or. 1975); and *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974) holding that it is well settled that the manufacturer of ethical drugs bears the additional duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know. Importantly, the court also held that the duty of the ethical drug manufacturer to warn extends, then, to all members of the medical profession who come into contact with the patient in a decision-making capacity. To satisfy this duty, the manufacturer must utilize methods of warning which will be reasonably effective, taking into account both the seriousness of the drug's adverse effects and the difficulties inherent in bringing such information to the attention of a group as large and diverse as the medical profession. The Oregon Legislature rejected application of the learned intermediary doctrine in the context of strict liability. See, *Griffith v. Blatt*, 334 Or. 456, 467, 51 P.3d 1256, 1262 (2002) ("Neither the text nor the context of those statutes indicates that the legislature intended to relieve a seller from potential strict product liability on the basis of the adequacy of a manufacturer's product warnings to another intermediary (here the physician)."

Pennsylvania

The Supreme Court of Pennsylvania adopted the learned intermediary doctrine in *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991) and *Baldino v. Castagna*, 478 A.2d 807, 812 (Pa. 1984) holding that the warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as "[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to

prescribe a given drug” (citing *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987)). See also, *Incollingo v. Ewing*, 282 A.2d 206, 220 & n.8 (Pa. 1971).

Puerto Rico

Puerto Rico has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Guevara v. Dorsey Laboratories, Division of Sandoz, Inc.*, 845 F.2d 364, 366 (1st Cir. 1988) and *Pierluisi v. E.R. Squibb & Sons, Inc.*, 440 F. Supp. 691, 694-95 (D.P.R. 1977) holding there is an abundant source of common law precedent regarding the learned intermediary doctrine. “The duty of the ethical drug manufacturer (a prescription drug as distinguished from a proprietary or patent drug sold over the counter) to warn extends, then, to all members of the medical profession who come into contact with the patient in a decision-making capacity. To satisfy this duty, the manufacturer must utilize methods of warning which will be reasonably effective, taking into account both the seriousness of the drug’s adverse effects and the difficulties inherent in bringing such information to the attention of a group as large and diverse as the medical profession” (citing *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969)).

Rhode Island

The Rhode Island courts and legislature are silent as to the learned intermediary doctrine.

South Carolina

South Carolina has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Brooks v. Medtronic Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984), holding that, although the South Carolina Supreme Court has not addressed the issue, [the court] conclude[s] it would adopt the [learned intermediary doctrine], generally accepted and supported by sound policy, restricting the manufacturer’s duty to warn to the prescribing physician. In *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1004 (4th Cir. 1992) the court held that, under this doctrine, the manufacturer’s duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device.

South Dakota

South Dakota has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 162 (D.S.D. 1967), *aff’d*, 408 F.2d 978 (8th Cir. 1969) and *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 231 (D.S.D. 1983), *aff’d*, 739 F.2d 340 (8th Cir. 1984) holding that [the federal] court believes the South Dakota Supreme Court would apply comments j and k of Restatement Section 402A and that the South Dakota Supreme Court has cautioned that Section 402A “does not make the manufacturer an absolute insurer against any injuries caused by his product” (citing *Engberg v. Ford Motor Co.*, 205 N.W.2d 104 (S.D. 1973)).

Tennessee

The Supreme Court of Tennessee adopted the learned intermediary doctrine in *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) holding that, under the learned intermediary doctrine, makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions. See, Restatement (Second) of Torts, § 388 comment n, (1965). However, physicians can be learned intermediaries only when they have received adequate warnings (citing *Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 850 (S.D.Fla.1990)).

Texas

Texas Courts of Appeals adopted the learned intermediary doctrine in *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 461-62 (Tex. App. 2000) holding that the application of the learned intermediary doctrine typically acts as an exception to a manufacturer’s duty to warn customers in products liability cases. According to this doctrine, the manufacturer of a prescription drug has a duty to adequately warn the prescribing physician of the drug’s dangers. The physician, relying on his medical training, experience, and knowledge of the individual patient, then chooses the type and quantity of drug to be prescribed. See, *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex.App. 1993, writ denied). Further, the physician assumes the duty to warn the patient of dangers associated with a particular prescribed drug. See also, *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App. 2000); *Guzman v. Synthes (USA)*, 20 S.W.3d 717, 720 n.2 (Tex. App. 1999); and *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App. 1998).

Utah

The Supreme Court of Utah adopted the learned intermediary doctrine in *Schaerrer v. Stewart’s Plaza Pharmacy, Inc.*, 79 P.3d 922, 928-29 (Utah 2003) and *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984) holding that manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient. However, the manufacturer will be held directly liable to the patient for breach of the duty to make timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know (citing *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 528 P.2d 522 (1974)).

Vermont

The Vermont courts and legislature are silent as to the learned intermediary doctrine.

Virginia

The Supreme Court of Virginia adopted the learned intermediary doctrine in *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980) holding that [the court] starts with elementary principles of law. In 2 R. Hursh & H. Bailey, *American Law of Products Liability* s 8:11, 173 (2d ed. 1974), it is stated that “. . . in the case of prescription

drugs, it is the general rule that the duty of the drug manufacturer is to warn the physician who prescribes the drug in question. . . .’

Washington

The Supreme Court of Washington adopted the learned intermediary doctrine in *Washington State Physicians Insurance Exchange & Ass’n v. Fisons Corp.*, 858 P.2d 1054, 1061 (Wash. 1993); *Rogers v. Miles Laboratories, Inc.*, 802 P.2d 1346, 1353 (Wash. 1991); *McKee v. American Home Products Corp.*, 782 P.2d 1045, 1149-50 (Wash. 1989); and *Terhune v. A.H. Robbins Co.*, 577 P.2d 975, 978 (Wash. 1978) holding that the learned intermediary doctrine provides that a prescription drug manufacturer’s duty to warn of dangers associated with its product runs only to the physician; it is the physician’s duty to warn the ultimate consumer.

West Virginia

The Supreme Court of Appeals of West Virginia (the highest court in this jurisdiction) rejected the learned intermediary doctrine as to prescription product cases in *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007) holding that “justifications for the learned intermediary doctrine [are] largely outdated and unpersuasive” *id.* at 914. The Court noted that “[s]ignificant changes in the drug industry have postdated the adoption of the learned intermediary doctrine in the majority of states in which it is followed. We refer specifically to the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information.” The Supreme Court ruled that, “[u]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule.”

Wisconsin

Wisconsin has not adopted the learned intermediary doctrine. See, *Forst v. SmithKline Beecham*, 602

F. Supp.2d 960, 968 (E.D. Wis. 2009) (“[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.”). Multiple Wisconsin courts have held that the learned intermediary doctrine does not apply under Wisconsin law. See e.g., *Forst*, 602 F. Supp.2d at 968 (“The court need not and will not apply the ‘learned intermediary’ doctrine in this case”); *Peters v. Astrazeneca, LP*, 417 F. Supp.2d 1051, 1054 (W.D.Wis. 2006) (same). An Indiana federal court (applying Wisconsin law) applied the doctrine in *Menges v. Deputy Motech, Inc.*, 61 F. Supp.2d 817, 830 (N.D. Ind. 1999). In applying the doctrine, however, *Menges* did not cite to any Wisconsin authority and instead relied upon cases from Georgia and Virginia.

Wyoming

Wyoming has not adopted the learned intermediary doctrine, however federal courts have predicted adoption of the doctrine in *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851-53 (10th Cir. 2003); *Haste v. American Home Products Corp.*, 577 F.2d 1122, 1124-25 (10th Cir. 1978) (animal drug); and *Jacobs v. Dista Products Co.*, 693 F. Supp. 1029, 1036 (D. Wyo. 1988). The courts held that, generally, ultimate consumers are made aware of the side effects through their physicians, and through the process of informed consent decide that the benefits of a particular drug outweigh chances of an adverse reaction. In view of the general trend across the country, as well as Wyoming’s adoption of § 402A and its comments and similar case law, it is the opinion of the court that if the Wyoming Supreme Court had before it the precise issue upon which this Court now rules, its decision would essentially mirror this holding.

Conclusion

Not all cases are vulnerable to an “unlearned” physician’s injection as a learned intermediary. For those jurisdictions where the defense thrives, per the above, early detection and education may prevent a fatal outcome. Consider yourself vaccinated and proceed accordingly.