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IN THIS ISSUE

Sara M. Turner and Julie Schiff re-examine the learned intermediary doctrine, a long-standing defense for drug and medical device manufacturers facing potential liability under a failure to warn theory, and address concerns that a growing number of recognized exceptions have effectively swallowed up the doctrine's rule.

Re-Examining the Learned Intermediary Doctrine: The Age-Old Theory Appears Alive and Well

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I. Introduction

Although product manufacturers generally have a duty to directly warn consumers of all material, foreseeable risks associated with the use of their products,[1] many courts have recognized an exception to this obligation in situations in which a learned intermediary, such as a physician, recommends or prescribes a drug or medical device to the consumer.[2]

The learned intermediary doctrine has proved a useful tool over the years for drug and medical device manufacturers facing potential liability under a failure to warn theory.[3] However, a growing number of recognized exceptions to the doctrine have raised concerns about the rule's continued vitality.

Despite these anxieties, several recent decisions provide reassurance that the doctrine continues to be widely accepted. Indeed, the learned intermediary doctrine appears alive and well.

II. What is the Learned Intermediary Doctrine?

Under the learned intermediary doctrine, the learned intermediary, often a prescribing physician, is ultimately responsible for informing the patient about the risks and benefits associated with usage of a manufacturer's drug or medical device.[4] This allows drug and medical device manufacturers to avoid liability for failure to warn by informing the learned intermediary of all the material risks associated with the drug or medical device's use.[5] Thus, under the learned intermediary doctrine, the drug or medical device manufacturer's duty to warn the consumer flows through the learned intermediary rather than directly to the consumer, and the relevant inquiry is whether the prescribing physician—not the consumer—was adequately warned.

III. What Rationales Underlie the Doctrine?

The rationale most commonly advanced to support the learned intermediary doctrine is that the actions of prescription drugs and

[1] Restatement (Third) of Torts: Prods. Liab. § 2(c) (1998).

[2] *See, e.g., Stanback v. Parke, Davis & Co*., 657 F.2d 642, 647 (4th Cir. 1981) (holding that the manufacturer had no duty to warn the plaintiff directly of the alleged risk of Guillain-Barre Syndrome associated with the vaccine); *Reyes v. Wyeth Lab., Inc*., 498 F.2d 1264, 1276 (5th Cir. 1974) (stating that pharmaceutical companies selling prescriptions usually need only warn the prescribing physician and not the consumer); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) ("Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient."); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (implying that a drug manufacturer is liable for failure to meet its duty to warn if it fails to notify the prescribing physician but not if it fails to warn the consumer).

[3] Restatement (Third) of Torts: Prods. Liab. § 6 cmt. d (1998*); see Sterling*, 370 F.2d at 85 (8th Cir. 1966). *Sterling* was the first case to use the term "learned intermediary."

[4] Restatement (Third) of Torts: Prods. Liab. § 6 cmt. b (1998).

[5] *Id.; see Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (1996).

medical devices are complex and that prescribing physicians are in the best position to determine a drug or medical device's potential risks and benefits for a particular patient.[6] This view hinges on the prescribing physician's education, expertise, and familiarity with the individual patient's needs.

Proponents of the learned intermediary doctrine also emphasize that it is the doctor, not the patient, who ultimately decides whether or not a prescription drug or medical device should be used.[7] Additionally, supporters point to the fact that physicians have a legal duty—under the doctrine of informed consent—to provide patients with the information they need to make decisions regarding their treatment.[8]

Those who support the learned intermediary doctrine also argue that drug and medical device manufacturers lack the means to provide warnings directly to patients and that warnings made directly to patients would interfere with the doctor-patient relationship.[9] They also argue it would be exceedingly difficult for drug or medical device manufacturers to fashion warnings that adequately convey the risks and benefits associated with particular drugs or medical devices in language in which patients can understand.[10]

IV. What Are the Doctrine's Recognized Exceptions?

The learned intermediary doctrine has been recognized in nearly every state, as well as

[6] Restatement (Third) of Torts: Prods. Liab. § 6(d)(1) cmt. b (1998) ("The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy"); *see, e.g., Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) ("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."); *Thomas v. Hoffmann-La Roche, Inc.*, 731 F. Supp. 224, 229 (N.D. Miss. 1989) ("The physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient."); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763 (Ky. 2004) (noting that prescribing physicians are "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.").

[7] *See, e.g., Davis v. Wyeth Lab. Inc*., 399 F.2d 121, 130 (9th Cir. 1968) (stating that the decision to prescribe a drug is "essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities.").

[8] *See, e.g., Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("The physician decides what facts should be told to the patient.").

[9] *See, e.g., Dunkin v. Syntex Lab., Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (arguing that "attempts to give detailed warnings to patients could mislead patients and might also tend to interfere with the physician/patient relationship."); *Larkin*, 153 S.W.3d at 763 (noting that manufacturers lack the means to provide warnings directly to patients and that direct warnings to patients would interfere with the doctor-patient relationship).

[10] *See, e.g., Brooks v. Medtronic, Inc.,* 750 F.2d 1227, 1232 (4th Cir. 1984) (arguing that direct warnings to the consumer of prescription drugs would be "almost inevitably involved and longwinded" and often not in the patient's "best interest"); *Davis*, 399 F.2d at 129 (arguing that the medical nature of the warning makes it difficult to adequately warn the lay consumer).

Puerto Rico and the District of Columbia.[11] In the vast majority of states, the doctrine applies solely as a matter of common law. However, a few states have codified the doctrine.[12]

Although an overwhelming majority of states have adopted or applied the learned intermediary doctrine, some states have carved out limited exceptions to the doctrine for certain prescribed products, including products that have been featured in direct-to-consumer advertising,[13] mass immunization vaccines,[14] oral contraceptives and contraceptive devices,[15] over-promoted drugs,[16] and drugs withdrawn from the market.[17] These exceptions relate to scenarios in which "there is a lack of communication between patients and their physicians or where patients essentially control the selection of the product."[18]

V. Where Does the Doctrine Stand Today?

A number of recent decisions have reaffirmed that the learned intermediary doctrine is indeed alive and well and that the growing number of recognized exceptions have by no means swallowed up the doctrine's rule.[19]

[11] *See, e.g., Porter v. Eli Lilly & Co.*, No. 06-1297, 2008 WL 544739, at *6 (N.D. Ga. Feb. 25, 2008) (noting that "[t]he doctrine is well established in state tort law, by some accounting applied in forty-four jurisdictions."), *aff'd*, 291 F. App'x 963 (11th Cir. 2008); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002) (providing a 50-state survey to support its position that "the doctrine either applies or is recognized, without an exception relevant to the *Norplant* cases, in 48 states, the District of Columbia, and Puerto Rico").

[12] *See* Miss. Code Ann. §11-1-63(c)(ii); N.J. Stat. Ann. §2A:58C-4; N.C. Gen. Stat. Ann. §99B-5(c); Ohio Rev. Code Ann. §2307.76(C).

[13] *See, e.g., Perez v. Wyeth,* 734 A.2d 1245 (N.J. 1999) (noting that "[c]onsumer-directed advertising of pharmaceuticals [] belies each of the premises on which the learned intermediary doctrine rests"); *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298, 301 (Okla. 1997) ("When direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists.").

[14] *See, e.g., Reyes v. Wyeth Lab., Inc.*, 498 F.2d 1264, 1277 (5th Cir. 1974) (concluding that the defendant manufacturer had a duty to directly warn individual vaccinees); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (same); *but see* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-14(a) (1994) (overturning the mass immunization exception in part and establishing a no fault system of recovery).

[15] *See, e.g., Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380 (E.D. Mich. 1985) (holding that the manufacturer of oral contraceptives has a duty to warn the patient); *Lukaszewicz v. Ortho Pharm. Corp*., 510 F. Supp. 961, 965 (E.D. Wis. 1981), *modified*, 532 F. Supp. 211 (E.D. Wis. 1981) (focusing on federal regulations and concluding that the manufacturer of oral contraceptives had a duty to warn the user).

[16] *See, e.g., Proctor v. Davis*, 682 N.E.2d 1203, 1214 (Ill. Ct. App. 1997)(holding that a "drug company cannot absolve itself from the duty to warn by pointing to the unauthorized use of its drug by physicians with whom it has not shared its knowledge of dangerous side effects and injury.")

[17] *See, e.g., Nichols v. McNeilab, Inc.*, 850 F. Supp. 562 (E.D. Mich. 1993) (denying summary judgment for a manufacturer whose medication had been withdrawn from the market and who argued that under the learned intermediary doctrine, it was sufficient that the manufacturer had advised physicians of the medication's withdrawal and had issued press releases).

[18] *Vitanza v. Upjohn Co*., 778 A.2d 829, 847 (Conn. 2001).

[19] *See, e.g., Smith v. Johnson & Johnson*, No. 3:08CV245, 2011 WL 3876997 (S.D. Miss. Aug. 31, 2011) (applying the learned intermediary doctrine and granting summary judgment on plaintiff's failure to

In *In re Avandia Mktg., Sales Practices & Products Liab. Litig.*,[20] for example, the U.S. District Court for the Eastern District of Pennsylvania dismissed all claims brought against a drug manufacturer on the basis that the Plaintiffs had failed to prove proximate cause because at no point did the prescribing physician testify that a different warning from the drug manufacturer would have altered his prescription to the patient.

The Plaintiffs, Mr. and Mrs. Schatz, filed suit against GlaxoSmithKline ("GSK"), alleging various claims, including, negligence, negligent misrepresentation, strict liability, breach of warranty, fraud, and unjust enrichment.[21] The Plaintiffs specifically alleged that Mrs. Schatz had suffered bone fractures in March 2007 due to her usage of GSK's diabetes medication, Avandia.[22] GSK moved for summary judgment on the basis that the Plaintiffs had failed to prove GSK's alleged failure to warn was the proximate cause of Mrs. Schatz's injuries, and the Court granted summary judgment in GSK's favor.[23]

In reaching its conclusion, the Court explained that a manufacturer's duty to warn is discharged under the learned intermediary doctrine when the manufacturer adequately warns the patient's doctor of the risks associated with usage of the drug.[24] To establish proximate cause, the Court continued, the prescribing doctor must testify that had he received a different warning, he would have altered his prescription to the patient.[25]

Prior to March 2007, the Avandia label had not included any warnings or precautions related to the risk of bone fractures from taking the drug.[26] However, after a long-term study related to the increased risk of bone fractures in female patients taking Avandia was published in the New England Journal of Medicine, GSK distributed a Dear Health Care Provider letter summarizing the study's results and subsequently revised the Avandia label to include a precaution regarding the increased incidence of bone fractures in female patients taking the drug.[27]

Notwithstanding the foregoing, the Plaintiff's prescribing physician testified he would ***still*** prescribe Avandia to a patient with the same medical history presented by the Plaintiff in 2002.[28] Additionally, "[a]t no point in his

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warn claims involving a medical device); *Schilf v. Eli Lilly & Co.*, No. 07-4015, 2010 WL 4024922 (D.S.D. Oct. 13, 2010) (denying the plaintiff's motion for summary judgment based on the learned intermediary doctrine); *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 70 (Tenn. 2011) (citing *Pittman v. Upjohn Co*., 890 S.W.2d 425, 429 (Tenn. 1994)) (holding that "[a] majority of jurisdictions, including Tennessee, recognize that a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks."); *Simineri v. LifeCell Corp.*, 2015 WL 3384588 (N.J.Super.) (denying plaintiffs' motion for partial summary judgment and upholding the learned intermediary doctrine).

[20] No. 07-MD-01871, 2015 WL 1383070 (E.D. Pa. Mar. 24, 2015).

[21] *In re Avandia*, 2015 WL 1383070 at *1.

[22] *Id.*

[23] *Id.*

[24] *Id.* at *3.

[25] *Id.*

[26] *Id.* at *2.

[27] *Id.*

[28] *Id.* at *3.

deposition [did] he testify that he would have made different medical decisions about Mrs. Schatz's treatment if GSK had provided different or more prominent warnings about the risk of fractures."[29]

Relying on the physician's testimony, the Court granted summary judgment in GSK's favor.

Similarly, in *O'Bryan v. Synthes, Inc.*,[30] the U.S. District Court for the Southern District of West Virginia held that the learned intermediary doctrine applied to a plaintiff's failure to warn claims related to the implantation of a medical device.

The Plaintiff alleged that Synthes was liable to her because it had failed to warn her that the metallic fixation plate implanted to repair her fractured fibula could fail if it were subjected to full weight-bearing before the bone had healed. Although the plate's package insert contained warnings exactly to this effect, the Plaintiff argued that her physician had not provided her with the package insert and that had she known the device could fracture in less than four weeks, she would not have undergone the implant surgery.[31]

Relying on *Tyree v. Boston Scientific Corp.*,[32] the Court held that "[t]he learned intermediary doctrine requires Synthes to warn only the plaintiff's treating physician about the Synthes plate."[33] Because Synthes had done just that, the Court granted summary judgment for Synthes on the Plaintiff's failure to warn claims.

VI. Conclusion

Despite the growing number of recognized exceptions to the learned intermediary doctrine, for now, the doctrine appears to be safe. As the discussion above makes clear, the vast majority of states have adopted or applied the learned intermediary doctrine, and several recent decisions, most notably, *In re Avandia* and *O'Brien*, both of which were decided in March of 2015, provide reassurance that the doctrine continues to be widely accepted.

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[29] *Id.*
[30] No. 5:13-CV-25981, 2015 WL 1220973 (S.D.W. Va. Mar. 17, 2015).
[31] *Id.* at *12.
[32] ___ F. Supp.3d ___, 2014 WL 5431993 (S.D.W. Va. Oct. 23, 2014). *Tyree* limited the application of *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 901-02, 914 (W. Va. 2007), which explicitly rejected the learned intermediary doctrine.
[33] *Id.* at *17.

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