

Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists' Duty to Warn

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I. INTRODUCTION

On August 4, 1993, Heidi Happel, a woman with an allergy to aspirin, called her doctor complaining of severe menstrual cramps.¹ Heidi sought a more effective pain reliever and her doctor, who had been treating her for almost a year and knew of her allergies, prescribed Toradol, a medication known in the medical community for its similarities to aspirin.² Heidi's doctor telephoned the prescription to a Wal-Mart pharmacy where Heidi previously filled six prescriptions.³ Wal-Mart routinely asked their patients of "their known allergies prior to dispensing medication."⁴ In addition, Wal-Mart maintained a database of the patient's information.⁵ After Heidi learned that the prescription had been phoned in, Heidi called her husband and asked him to

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1. *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1121 (Ill. 2002) [hereinafter *Happel II*]; see also, Amanda York, *Supreme Court: Pharmacists Should Warn of Allergic Reactions*, ASSOCIATED PRESS NEWSWIRE, Mar. 21, 2002, available at <http://www.walmart survivor.com/032102.html> (last visited Oct. 10, 2003).

2. *Happel II*, 766 N.E. 2d at 1121.

3. *Id.*

4. *Id.*

5. *Id.*

pick up the medication after he finished work.⁶ When Heidi's husband arrived at Wal-Mart, the Wal-Mart employee asked Heidi's husband whether the recipient of the medication had any allergies.⁷ Heidi's husband told the Wal-Mart employee that his wife had allergies "to aspirin, ibuprofen, and acetaminophen."⁸ Neither the Wal-Mart employee nor the labels on the bottle warned Heidi's husband of any contraindications.⁹ After Heidi took the first dose of Toradol, she began to experience respiratory problems including tightness in her chest.¹⁰ Within an hour, Heidi went into anaphylactic shock and was rushed to the emergency room.¹¹

On September 30, 1994, Heidi sued her doctor and Wal-Mart for negligence.¹² Employing the logic of the "learned intermediary standard," the trial court granted summary judgment in favor of Wal-Mart, holding that pharmacies owed no general duty to warn of either the drug's side effects or the drug's possible contraindications.¹³ The appellate court reversed, holding that Wal-Mart might owe Heidi a duty to warn of the dangerous side effects of Toradol "and decided that an issue of fact remained to be decided that precluded the granting of summary judgment."¹⁴ However, the appellate court made it clear that the duty pharmacists owed to warn customers of dangerous side effects was a narrow one.¹⁵ According to the Illinois Appellate Court, an affirmative duty to warn the patient of dangerous side effects applied only "where defendant knew of Heidi's allergies . . . and where defendant knew that injury or death was substantially certain to result."¹⁶ The Illinois Supreme Court affirmed the appellate court's decision because Wal-Mart was aware not only of Heidi's drug allergies, but also of the fact that Toradol was contraindicated for persons such as Heidi with allergies to aspirin.¹⁷

On a related point in 2002, the Massachusetts Supreme Court, in *Cottam v. CVS Pharmacy*, addressed the liability exposure of a pharmacist who voluntarily assumed the duty to warn of the adverse side effects of drugs sold.¹⁸ In *Cottam*, a customer sued CVS for their failure to warn about the negative side effects of a prescription

6. *Id.*

7. *Happel II*, 766 N.E.2d at 1122.

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. *Happel II*, 766 N.E.2d at 1122.

13. *Id.* The learned intermediary doctrine even applies to cases where manufacturers allegedly market directly to consumers because the prescribing physician is still seen to play a vital role. See *In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 378-79 (5th Cir. 1999); *Hackett v. G.D. Searle & Co.*, 246 F.2d 591, 594 (W.D. Tex. 2002).

14. *Happel v. Wal-Mart*, 737 N.E.2d 650, 656 (Ill. App. Ct. 2000) [hereinafter *Happel I*].

15. *Id.* at 656-57.

16. *Id.* at 657.

17. *Happel II*, 743 N.E.2d at 1129.

18. 764 N.E.2d 814, 822 (Mass. 2002).

drug.¹⁹ The Massachusetts Supreme Court held that a pharmacist voluntarily assumed the duty to warn by advertising a service to customers that purported to list all of the negative side effects of drugs.²⁰ The Massachusetts Supreme Court held that pharmacists could not be shielded from liability because the preparation and advertising of the list infers to the customer that the information provided by the pharmacist is both complete and correct.²¹

Fifteen years have passed since the Washington Supreme Court, in *McKee v. American Home Products*, held that pharmacists had the duty to take corrective measures only when filling a prescription that contained an obvious or known error.²² Additionally, *McKee* held that the pharmacist had no "duty to question a judgment made by the physician as to the propriety of the prescription or to warn customers of the hazardous side effects associated with the drug."²³ In the intervening years, although *McKee* has not been overturned, both federal²⁴ and state²⁵ legislation has

19. *Id.* at 817.

20. *Id.* at 823.

21. *Id.*

22. 113 Wash. 2d 701, 715-20, 782 P.2d 1045, 1053-55 (1989). *Cf.* *Riff v. Morgan Pharm.*, 508 A.2d 1247, 1252 (Pa. Super. Ct. 1986) (holding that a pharmacist had a duty to warn a patient or notify a prescriber if the problems with prescription, on its face, created a substantial risk of serious harm to the patient. Duty is notification only, not a duty to assume complete control of patient's drug therapy). *See generally* David B. Brushwood, *The Pharmacist's Drug Information Responsibility after McKee v. Am. Home Prod.*, 48 FOOD & DRUG L. J. 377 (1993); Bryan Christopher Moody, *Prescription Medication and Consumer Protection: A Time for Reform*, 5 J. PHARMACY & L. 19 (1996); Elizabeth D. Smith, Note, *Are Pharmacists Responsible for Physicians' Prescription Errors?* *McKee v. Am. Home Prod.*, 113 WASH. 2d 701, 782 P.2d 1045 (1989), 65 WASH. L. REV. 959 (1990).

23. 113 Wash. 2d. at 720, 782 P.2d at 1056-57. Although the Washington Supreme Court has not addressed the issue in the intervening years since the decision, the high courts of other states have rejected the strict learned intermediary standard of *McKee*. *See* *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1133 (Ariz. App., 1994). *Cf.* *Silves v. King*, 93 Wash. App. 873, 970 P.2d 790 (1999).

24. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990).

25. WASH. ADMIN. CODE § 246-863-095 (1996). WASH. ADMIN. CODE § 246-863-095 provides, in pertinent part, that a:

(1) pharmacist shall not delegate the following professional responsibilities:

(a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not preclude a pharmacy assistant from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Extemporaneous compounding of the prescription provided that bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a level A pharmacy assistant when supervised by a pharmacist.

rendered *McKee* no longer “good law,” as new duties to warn of both negative side effects and contraindications have been statutorily imposed on pharmacists.²⁶ Therefore, the recent court cases in Illinois—*Happel v. Wal-Mart Stores, Inc.*²⁷—and Massachusetts—*Cottam v. CVS Pharmacy*²⁸—along with other cases,²⁹ reflect a growing trend in products liability law that seems to move away from the learned intermediary standard embodied in *McKee*³⁰ and towards the imposition of a new duty to warn on pharmacists. Under this recent trend in case law, a pharmacist would be charged with a duty to warn their customers of the possible negative interactions or contraindications of the drugs in the prescriptions that they filled.³¹ Therefore, the *Happel* and *Cottam* decisions provide Washington with a renewed opportunity to reflect and reassess its view of the pharmacist’s duties to warn.

Despite having good intentions, the extension of this trend and the corresponding erosion of the learned intermediary standard is neither sound economics nor effective medicine.³² The expansion of the standard embodied in recent cases might further

(e) Interpretation of data in a patient medication record system.

(f) Ultimate responsibility for all aspects of the completed prescription and assumption of responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(g) Dispense prescriptions to patient with proper patient information as required by WAC 246-846-220.

(h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 69.38.030 and WAC 246-887-030 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

(i) Professional communications with physicians, dentists, nurses, and other health care practitioners.

Id.

26. See generally Frank M. McClellan, *Reading the RX Right is not Enough*, TRIAL, May 2002, at 26 (2002) (discussing that the expanding duties of a pharmacists).

27. 766 N.E.2d 1118, 1129 (Ill. 2002).

28. 764 N.E.2d 814, 823 (Mass. 2002).

29. See *Griffith v. Blatt*, 51 P.3d 1256, 1262 (Or. 2002) (holding that the learned intermediary standard did not apply because Oregon adopted a strict liability standard based on section 402A of the Restatement (Second) of Torts and a seller of products owed a duty to warn if they knew of the side effects of the product); *Homer v. Spalitto*, 1 S.W.3d 519, 522-24 (Mo. Ct. App. 1999) (holding that pharmacists had a duty to both review and warn customers of the dangerous side-effects); *Lasley v. Shrake’s Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1132-34 (Ariz. Ct. App. 1994) (holding that the pharmacists had a duty to monitor and warn patients of the addictive side effects of prescriptions).

30. 113 Wash. 2d 701, 782 P.2d 1045 (1989). Under the learned intermediary doctrine, a drug manufacturer need not warn each patient of a product’s potential danger as long as it properly warns the patient’s prescribing physician, who is the “learned intermediary” between the patient and the manufacturer. See *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591-92 (Tex. 1986).

31. Lauren Fleischer, Note, *From Pill-Counting to Patient Care: Pharmacists’ Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 179-81 (1999).

32. The learned intermediary standard generally imposed no duty to warn on a pharmacist and held that the law’s attempt to disclose the hazards of prescription drugs to patients operated

escalate the explosion of medical malpractice litigation. Such a result will only have negative consequences on the very individuals that the proponents of imposing a new duty seek to protect—customers and patients.

This paper will explore developments in the learned intermediary standard, as reflected by the recent cases that tend to suggest a trend towards the imposition of a duty to warn when pharmacists are aware of potential contraindications. Part II examines the historical background of the learned intermediary doctrine and charts the slow transition from no duty to warn to a modified duty to warn when a pharmacist has knowledge of patients' potential side effects, as illustrated by several recent cases. Part III argues that the trend towards the imposition of a new duty to warn and the increased potential for liability among pharmacists that ensues might result in a number of unforeseen consequences that would harm the customer. These problems include increased cost of prescriptions due to higher medical malpractice insurance, which would be required to protect against plaintiff lawsuits.

As a result, Part IV asserts that a new amendment should be added to the Restatement of Torts (Third) to specifically address the role of the pharmacist. Alternatively and more ambitiously, Congress should intervene in what has traditionally been the purview of state tort law to pass legislation in order to protect pharmacists from tort liability³³ by solidifying the learned intermediary standard. Although such proposals increase the likelihood of even higher doctors' malpractice premiums than exist currently, raised premiums might result in much-needed systemic medical malpractice tort reform. Finally, Part V concludes by highlighting the need to fortify the learned intermediary doctrine in order to quell the potential avalanche of litigation that might be released if the new duty to warn is imposed on pharmacists.

II. THE LEARNED INTERMEDIARY STANDARD AND ITS CRITICS

The question of who among the various participants in the drug industry (manufacturers, doctors, or pharmacists) is charged with the duty to warn customers and patients of the possible adverse side effects of a particular prescription drug or harmful drug interactions is a complicated matter.³⁴ The issue is further obscured by

through a two-pronged duty. First, manufacturers had a duty to inform the physician about the uses and hazards of the drug and its side effects and, second, doctors had to warn patients of the potential side effects or hazards of the medication. The learned intermediary standard is based, in part, on the notion that the prescribing doctor is in the best position to evaluate the potential pitfalls of the prescription drugs. See Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 842-45 (1996).

33. Congress can regulate economic intrastate activities if the activities affect interstate commerce. See *United States v. Darby*, 312 U.S. 100, 118 (1941).

34. See generally Roseann B. Termini, *The Pharmacist Duty to Warn Revisited: The Changing Role of Pharmacy in Health Care and the Resultant Impact of the Obligation of a Pharmacist to Warn*, 24 OHIO N.U. L. REV. 551 (1998).

the conflicting guidance provided by the various Restatements of Torts provisions³⁵ and the states' conflicting interpretations of who, among the various participants in the drug industry, has a duty to warn.³⁶

Generally, drug manufacturers, like other producers of products with dangerous side effects or latent defects, have a duty to warn customers of scientifically known side effects as well as possible adverse interactions.³⁷ However, product liability case law developed the "learned intermediary" standard as an exception to the general rule, thereby providing the benchmark for warnings related to standard prescription drugs.³⁸ The learned intermediary standard provides that manufacturers of prescription drugs and medical devices³⁹ can discharge their duty of care to patients by providing warnings to the prescribing physicians.⁴⁰ The development of the "learned intermediary standard" exception can be partly explained by the assumption that physicians always select prescription drugs for a patient.⁴¹ Therefore, drug manufacturers can satisfy the warning requirement by providing prescribing

35. "The question of liability for prescription drugs has engendered a three-way debate among (1) the proponents of a pure negligence or risk-utility standard; (2) Those who agree with new formulation of section 6 of the 1966 Restatement (Third) of Torts: Products Liability (the Restatement (Third)); and (3) the adherents of section 402A, comment R, of the Restatement (Second) of Torts." Hon. William A. Dreier, *Manufacturers' Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Product Liability*, 30 SETON HALL L. REV. 258, 258 (1999). RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (d) (1998) provides:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Id.

36. See Patricia G. Barnes, *Prescription for Liability: Some Courts Say Pharmacists Have a Duty to Warn Patient of Drug Hazards*, 85 A.B.A. J. 40 (1999).

37. See *Carlin v. Super. Ct. of Sutter County*, 56 Cal. Rptr. 2d 162, 163-64 (1996).

38. See Diane Schmauder Kane, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1 (1998).

39. A manufacturer's showing of compliance with a preemptive FDA requirement that warnings be given directly to the patient takes the case out of the reach of state law. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1998).

40. *Id.* § 6 cmt. b, d, e.

41. In the current situation, it would be a more accurate statement to say that the health care providers or insurance plans have a significant influence on drug choice made by physicians. Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1026 (1996).

physicians with adequate warnings of prescription drugs' potential, adverse effects. Prescribing physicians, in turn, are expected to warn patients.⁴²

The underlying current of the rationale is that, other than trusting the doctor, the patient is not exercising an individual judgment, thus it is the doctor who makes the decision and the patient cannot be said to be exercising "choice."⁴³ Although, under the common law, a pharmacist was held to the standard of "the average practitioner" when filling a prescription,⁴⁴ the liability scheme provided by the learned intermediary standard generally immunized pharmacists from liability resulting from adverse reactions or side effects of drugs based on the rationale that the patient or customer received such warning from the prescribing physicians.⁴⁵

However, due to a combination of factors, the traditional rationale for the "learned intermediary" standard has been eroded.⁴⁶ Recently, courts have tended to impose a new duty to warn of potential contraindications or side effects on pharmacists who either advertise a service that purports to warn individuals of the side effects of drugs or who knew about the contradictions or side effects.⁴⁷ Critics of the learned intermediary standard argue that the concept has become obsolete in an environment featuring both mass advertising of drugs by drug manufacturers and

42. See Jennifer L. Smith, Comment and Note, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2 HOUS. J. HEALTH L. & POL'Y 187 (2002).

43. See Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101, 1104 (2000).

44. *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387 (Mich. App. 1987).

45. See Smith, *supra* note 42. According to the rationale of the learned intermediary standard, the patient is not exercising a judgment, other than the judgment to trust the doctor who makes the decision and makes the patient irrelevant. *Id.*

46. There has been a tremendous amount of literature on the subject either predicting or advocating the demise of the learned intermediary standard. See generally Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?* 37 WAKE FOREST L. REV. 97 (2002); James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning it Entirely*, 36 TORT & INS. L. J. 119 (2000); Jack B. Harrison & Mina J. Jerrerson, "[S]ome [A]ccurate [I]nformation is [B]etter than [N]o [I]nformation [a]t [a]ll": Arguments Against an Exception to the Learned Intermediary Doctrine based on Direct-to-Consumer Advertising, 78 OR. L. REV. 605 (1999); Justin Lee Heather, *Liability for Direct-to-Consumer Advertising and Drug Information on the Internet: While the Learned Intermediary Doctrine Still Lives, Drug Manufacturers can Take some Precautionary Measures if it is Ruled Inapplicable*, 68 DEF. COUNS. J. 412 (2001); Lear, *supra* note 43; Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931 (1993); Laurie K. Marshall, Comment, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With their Physicians*, 26 U. DAYTON L. REV. 95 (2000).

47. See *In re N.Y. County Diet Drug Litig.*, 691 N.Y.S.2d 501, 502 (N.Y. App. Div. 1 1999) (holding that pharmacists generally have no duty to warn absent knowledge of a customer's condition that makes the prescription drug contraindicated).

self-initiated prescriptions by patients.⁴⁸ These critics further argue that, since the traditional rationales for the learned intermediary standard have ceased to exist, a new duty to warn should be imposed on pharmacists.⁴⁹ According to the logic of advocates for the imposition of a new duty to warn, this duty would be imposed on pharmacists who are either aware of a drug's side effects or of the contraindication of the drug with other prescriptions that the patient is taking.⁵⁰

Many critics of the learned intermediary standard state that the traditional rationale for the theory has outlived its usefulness because the reality of patients' role in selecting prescription drugs is far greater than the learned intermediary standard would tend to suggest.⁵¹ Commentators⁵² and several recent cases⁵³ question the outright utility of the learned intermediary standard's treatment of over-the-counter drugs that were once only available via a prescription⁵⁴ as well as prescriptions that are often initiated by customers due to direct advertising, such as birth control pills, allergy pills, and pain relievers.⁵⁵ Additionally, direct marketing of prescription drugs to customers through the mass media⁵⁶ has raised questions about whether such actions by the manufacturers circumvent the doctor's warnings.⁵⁷ To further

48. See *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999); see also *Lear*, *supra* note 43; Paul F. Strain & Christina L. Gaarder, *Direct-to-Consumer Advertising and the Learned Intermediary Doctrine: Unsettling a Settled Question*, 30 U. BALT. L. REV. 377 (2001); Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, The Physician-Patient Relationship, and Direct-To-Consumer Marketing*, 52 S.C. L. REV. 993 (2001).

49. See generally Edward Casmere, *RX for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule*, 33 J. MARSHALL L. REV. 425 (2000).

50. *Id.* at 461; Dora A. Gonzalez, *A Prescription for Litigation: In Pursuit of the Pharmacists' "Duty to Warn" of the Adverse Side Effects of Prescription Drugs*, 1 J. LEGAL ADVOC. & PRAC. 53, 76 (1999); cf. Smith, *supra* note 42.

51. Marshall, *supra* note 46, at 102.

52. See generally Marshall, *supra* note 46, at 102.

53. See *Happel v. Wal-mart Stores, Inc.*, 766 N.E.2d 1118, 1130 (Ill. 2002); *Griffith v. Blatt*, 51 P.3d 1256, 1262 (Or. 2002).

54. For nonprescription drugs the learned intermediary doctrine does not apply and the drug manufacturer must warn the customer directly. See *Torseillo v. Whitehall Laboratories, Div. of Home Prod. Corp.*, 398 A.2d 132, 138 (N.J. Super. Ct. App. Div. 1979).

55. See Note, *The Mass Marketing of Prescription Drugs and Its Effect on the Learned Intermediary Doctrine*, 25 OKLA. CITY U. L. REV. 745, 766 (2000); see also Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525, 572-73 (2000).

56. For example, magazines for young women advertise drugs that aid in relieving teenage acne. Note, *supra* note 55, at 747.

57. See *Lear*, *supra* note 43, at 1115 (arguing that, by engaging in direct-to-consumer advertising, drug companies are implicitly admitting that consumers can understand how a prescription drug will benefit them). Correspondingly, if consumers are able to understand the benefits of a prescription drug, then, certainly, they are capable of understanding the associated risks. *Id.* at 1115-16.

complicate the situation, various commentators note that drug manufacturers engage in both solicitation and advertising directed towards physicians, suggesting that such action might bias the physician's opinion of the risks inherent in a particular medication.⁵⁸

With the erosion of the rationale justifying the learned intermediary standard, some commentators have suggested that pharmacists are last in the chain of distribution and should therefore have an affirmative duty to warn customers of adverse side effects and the contraindications of the prescriptions being filled.⁵⁹ Commentators argue that, in the computer era, pharmacists can easily keep track of a medication's side effects as well as patient records and, as a consequence, the imposition of a duty to warn on the pharmacist can be achieved with little cost to the pharmacist.⁶⁰ Additionally, some commentators argue that pharmacists provide the final safeguard for protecting the customer.⁶¹

However, the starting point of any inquiry into the case law surrounding pharmacists' duty to warn must be the recognition that courts have drawn a distinction between a pharmacist's duty to warn of potentially negative side effects and the duty to warn of potentially adverse drug interactions.⁶² As a result of this distinction, courts have consequently displayed a tendency to treat the two warnings in a different way.⁶³

A. Failure to Warn of Potentially Dangerous Side Effects

The failure to warn of the adverse side effects of drug prescriptions filled by a pharmacist is generally not recognized by courts.⁶⁴ Recently, the Texas Appellate Court, in *Morgan v. Wal-Mart Stores, Inc.*, held that a pharmacist who accurately fills a prescription is not liable for harm caused by failure to warn of the risks of the

58. See Patrick Cohoon, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S.TEX. L. REV. 1333, 1357 (2001); Wiseman, *supra* note 48, at 1012-13.

59. See generally Karina Fox, *A Weighty Issue: Will Pharmacists Survive the Fen-Phen Feeding Frenzy?* Kohl v. American Home Prod. Corp. and a Pharmacist's Duty to Warn of the Dangers of Prescription Drugs, 2001 BYU L. REV. 1349.

60. See Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine*, 23 J. LEGAL MED. 449, 453 (2002).

61. Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 767 (1976).

62. Richard McCormick, *Pharmaceutical Manufacturer's Duty to Warn of Adverse Drug Interactions: Drug Products Liability Law is Unprepared to Meet the Multitude of ADI Claims That are Likely to be the Next Wave of Litigation*, 66 DEF. COUNS. J. 59, 61 (1999).

63. *Id.* at 61.

64. See *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 466 (Tex. App. 2000); *Jones v. Irvin*, 602 F.Supp. 399, 402 (S.D. Ill 1985); *Pysz v. Henry's Drug Store*, 457 So.2d 561, 562 (Fla. Dist. Ct. App. 1984).

medication.⁶⁵ The court reasoned that, because Wal-Mart did not possess any special knowledge of its customers, the imposition of an additional duty to warn of the danger of the particular drug in question was unwarranted.⁶⁶ Additionally, the plaintiffs did not contend that Wal-Mart was or should have been aware of any contraindications.⁶⁷

Furthermore, the Kansas Appellate Court, in *Nichols v. Central Merchandise, Inc.*, ruled that requiring a pharmacist to warn of potentially adverse side effects would intrude on the doctor-patient relationship and place a higher burden on the pharmacist than on the manufacturer, who has a duty to warn the doctor.⁶⁸ The *Nichols* court held that the underlying rationale for not imposing a duty to warn about side effects of drugs on pharmacists is that drug manufacturers, whose duty it is to warn their customers, have already warned.⁶⁹ According to *Moore ex rel. Moore v. Memorial Hosp. of Gulfport*,⁷⁰ an imposition of a new duty to warn would be an intrusion by the pharmacist into the doctor's legally-mandated role. This line of reason contends that an intrusion into the doctor-patient relationship would be confusing to the patient because the decision to prescribe a specific drug involves an analysis of the patient's unique condition as well as a balancing of the risks and benefits of a given drug that may call for information and expertise beyond the scope of a pharmacist's training.⁷¹

B. Failure to Warn of Potentially Adverse Drug Interactions

Similarly, until recently, most courts have been reluctant to extend to pharmacists a duty to warn of potential contraindications.⁷² Some courts, including those in New York, have addressed the issue of whether pharmacists have a duty to

65. 30 S.W.3d at 466; see also Bernard J. Garbutt III & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Others Issues in the New Millennium*, 58 FOOD & DRUG L. J. 269, 271 (2003); see also Dabney J. Carr IV & Bryony H. Bowers, *Recent Developments in Learned Intermediary Doctrine*, 31-WTR BRIEF 20, 24 (2002).

66. *Morgan*, 30 S.W.3d at 466.

67. *Id.*

68. 817 P.2d 1131, 1133 (Kan. App. 1991); see also David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?* 44 DRAKE L. REV. 439, 442-43 (1996).

69. 817 P.2d at 1134 (citing *McKee v. Am. Home Prod.*, 113 Wash.2d 701, 720, 782 P.2d 1045, 1045 (1989)).

70. 825 So. 2d 658, 662 n.6 (Miss. 2002) (citing to *Wyeth Labs., Inc. v. Fontenberry*, 530 So.2d 688, 691 (Miss. 1988) (holding that pharmaceutical companies are only required to warn the prescribing physician of the side effects and contraindications of the drugs prescribed)).

71. *Id.* at 664.

72. See *Ramirez v. Richardson-Merrell, Inc.*, 628 F.Supp. 85, 88 (E.D. Pa. 1986); *Jones v. Irvin*, 602 F. Supp. 399, 402-03 (S.D. Ill. 1985); *Silves v. King*, 93 Wash. App. 873, 883, 970 P.2d 790, 794, (1999); *Johnson v. Walgreen Co.* 675 So.2d 1036, 1038 (Fla. Dist. Ct. App. 1996).

warn.⁷³ In general, the rule in New York is that pharmacists do not have an affirmative duty to warn customers of known contraindications absent knowledge of the customer's condition and the drug's contraindications.⁷⁴ For example, in *Hand v. Krakowski*, the court refused to grant the defendant pharmacists' motion for summary judgment.⁷⁵ In *Hand*, the court held that the pharmacist possessed knowledge of the customer's history of alcoholism and therefore knew or should have known about the contraindications posed by the medications prescribed.⁷⁶ However, the *Hand* court reasoned that pharmacists should not second-guess the decisions made by doctors unless pharmacists had specific knowledge of the possible contraindications.⁷⁷ As a general rule, courts in Washington have followed the lead of the *Hand* decision.⁷⁸

More recently, a few state courts have rejected the learned intermediary doctrine in the area of contraindications and have held that pharmacists do have a general duty to warn of known contraindications because the traditional rationales for the learned intermediary standard have eroded.⁷⁹ Commentators have suggested, and some states have begun, widening the umbrella of strict liability to include pharmacists.⁸⁰ For example, according to the Oregon Supreme Court, the framers of Oregon's strict liability statute—Oregon Revised Statute section 30.920(3),⁸¹ which was modeled

73. *Ullman v. Grant*, 450 N.Y.S.2d 955, 956 (1982) (holding that "a pharmacist is not negligent unless he knowingly dispenses a drug that is inferior or defective" and further stating that it is the duty of the manufacturer, not the pharmacist, to warn the plaintiff of possible side effects in the use of a prescription drug); *Bichler v. Willing*, 397 N.Y.S.2d 57, 59 (1977) (holding that there was no basis in law for liability under theories of negligence or breach of warranty where there were no allegations that the pharmacist altered the product in any way or had proffered any oral or written warranty as to its safety or side effects).

74. *Hand v. Krakowski*, 453 N.Y.S.2d 121, 123 (1982) (denying summary judgment to a defendant pharmacist on a negligence claim where the pharmacist who had dispensed prescribed, psychotropic drugs knew that the plaintiff was an alcoholic and knew, or should have known, that such drugs were contraindicated with alcohol use and therefore should never have been prescribed or dispensed); see also *Negrin v. Alza Corp.*, No. 98 CIV. 4772 DAB, 1999 WL 144507 at *5 (S.D.N.Y.).

75. 453 N.Y.S.2d at 123.

76. *Id.*

77. *Id.* at 123.

78. See *McKee v. Am. Home Prod.*, 113 Wash. 2d 701, 715, 782 P.2d 1045, 1045-53 (1989).

79. *Id.* at 714-15, 782 P.2d at 1052-53 (citing additional cases therein).

80. R. PAUL ASBURY, *Pharmacist Liability: The Doors of Litigation are Opening*, 40 SANTA CLARA L. REV. 907, 919, 930 (2000); George Pitcher, *The End of Oregon's Reasonable Seller Test: A Real Change in Law or a Mere Change in Terminology*, 32 WILLAMETTE L. REV. 851, 856 (1996).

81. Oregon Revised Statute section 30.920 provides:

(1) One who sells or leases any product in a defective condition unreasonably dangerous to the user or consumer or to the property of the user or consumer is subject to liability for physical harm or damage to property caused by that condition, if:

(a) The seller or lessor is engaged in the business of selling or leasing such a product; and

after Restatement (Second) of Torts section 402A comment h⁸²—did not intend for the pharmacist to receive the protection of the learned intermediary standard.⁸³ In *Griffith v. Blatt*, the Oregon Supreme Court, while not addressing the exact extent of a pharmacist's liability for failure to warn, rejected the application of the learned intermediary standard as a viable defense.⁸⁴ This can be partly explained by the fact that strict liability looks not towards the negligence of the purported tortfeasor, but to the damages caused by the defective product.⁸⁵ In strict product liability jurisprudence, typically anyone who is engaged in the stream of commerce of a product (from the manufacturer to the wholesaler and then to the retailer, or all of them) can be held responsible if the product is defective and someone is injured.⁸⁶ Thus, there is no need to prove negligence, but the injured party must prove that the product was defective.⁸⁷

(b) The product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold or leased.

(2) The rule stated in subsection (1) of this section shall apply, even though:

(a) The seller or lessor has exercised all possible care in the preparation and sale or lease of the product; and

(b) The user, consumer or injured party has not purchased or leased the product from or entered into any contractual relations with the seller or lessor.

(3) It is the intent of the Legislative Assembly that the rule stated in subsections (1) and (2) of this section shall be construed in accordance with the Restatement (Second) of Torts sec. 402A, Comments a to m (1965). All references in these comments to sale sell, selling or seller shall be construed to include lease, leases, leasing and lessor.

(4) Nothing in this section shall be construed to limit the rights and liabilities of sellers and lessors under principles of common law negligence or under ORS chapter 72.

OR. REV. STAT. § 30.920 (2002).

82. Comment h to section 402A of the Restatement (Second) of Torts provides:

A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger, and a product sold without such warning is in a defective condition.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (1965).

83. *Griffith v. Blatt*, 51 P.3d 1256, 1262 (Or. 2002).

84. *Id.*

85. See generally John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns A "New Cloth" for Section 402A Products Liability Design Defects—A Survey of the States Reveals a Different Weave*, 26 U. MEM. L. REV. 493, 508 (1996).

86. James R. MacAyeal, *The Comprehensive Environmental Response, Compensation, and Liability Act: The Correct Paradigm of Strict Liability and the Problem of Individual Causation*, 18 UCLA J. ENVTL. L. & POL'Y 217, 219 (2000-2001).

87. See *id.* (referencing ultra-hazardous material).

While Oregon's interpretation represents the exception rather than the general rule, a number of courts have recently held that pharmacists have a duty to warn in certain limited circumstances. In *Baker v. Arbor Drugs*, the court recognized a duty to warn of drug interactions when the pharmacy voluntarily assumed the duty by advertising a computer system that could detect the potential for adverse drug interactions.⁸⁸ Additionally, in *Lasley v. Shrake's Country Club Pharmacy, Inc.*, the court denied a summary judgment motion and determined that whether the failure to warn of drug interactions involved in the prolonged use of two addictive drugs violated the pharmacist's standard of care was a jury question.⁸⁹

The movement to establish a pharmacist's duty to warn quite possibly began with the passage of the Omnibus Budget Reconciliation Act of 1990.⁹⁰ This Act required all states to enact statutes no later than January 1, 1993, requiring pharmacists to offer counseling to Medicaid patients regarding proper usage of prescription drugs.⁹¹ Some commentators have suggested that, as a condition for a license to dispense controlled substances, states should impose a requirement that pharmacists play a more active role in preventing adverse drug interactions.⁹² Most recently, the Illinois Supreme Court, in *Happel v. Walmart Stores*, imposed a duty to warn about known contraindications.⁹³ The Illinois Supreme Court disagreed with the pharmacist's argument that imposing such a duty to warn would have a "chilling effect" by exposing the pharmacies to a great deal of liability and might result in pharmacies ending the practice of asking patients medical questions in situations where the pharmacists are not required by regulation to do so.⁹⁴ The Illinois Supreme Court held that:

88. 544 N.W.2d 727, 731 (Mich. Ct. App. 1996).

89. 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994), *review denied* CV 94-0229-PR (Oct. 4, 1994) (responding to this denial, the parties subsequently settled the matter by an undisclosed stipulation).

90. Pub. L. No. 101-508 § 4401, 104 Stat. 1388-141, 151-53 (1990).

91. Section 4401 also requires states to establish standards governing patient counseling. 104 Stat. at 151-53. In particular, dispensing pharmacists must offer to discuss the unique drug therapy regimen of each Medicaid recipient when filling prescriptions for them. *Id.* Furthermore, the statute mandates that pharmacists discuss special directions and precautions for preparation of drugs, administration, and use by the patient; common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered; techniques for self-monitoring drug therapy; proper storage; refill information; and appropriate action in case of missed dose. *Id.* Additionally, Medicaid pharmacy providers also must make reasonable efforts to obtain, record, and maintain at least the following Medicaid patient information: Name; address; telephone; age and gender; individual history, including disease state or states, known allergies and/or drug reactions, and a comprehensive list of medications and relevant medical devices as well as the pharmacist's comments about the drug history. *Id.*

92. See generally David W. Hepplewhite, *A Traditional Legal Analysis of the Roles and Duties of Pharmacists*, 44 *DRAKE L. REV.* 519, 547 (1996).

93. 743 N.E.2d 1118, 1125 (Ill. 2002).

94. *Id.* at 1124-25.

by asking customers about their drug allergies, the pharmacy is engendering reliance in the customer that the pharmacy will take steps to ensure that the customer does not receive a drug to which the customer is allergic. There can be no other reason for a pharmacy's seeking this information regarding drug allergies. Where the pharmacy fails to warn the customer, then the customer is placed at risk of serious injury or death.⁹⁵

Therefore, the Illinois Supreme Court recognized that the pharmacy in question, by voluntarily requesting patient information, assumed the duty to warn.⁹⁶ The Court, unfortunately, left unanswered the question as to whether the pharmacy had an affirmative duty to warn of known contraindications. However, the Court inferred that asking the question garners the patient's trust and might result in the customer letting his or her guard down because the patient would assume that the pharmacist would not sell them a drug that would adversely interact with other drugs.⁹⁷ However, the *Happel* ruling states that, if pharmacists voluntarily ask customers vital information, pharmacists should ensure that their technology systems and personnel provide the proper safeguards to insure that errors do not occur.⁹⁸

The Washington state courts have adopted an approach similar to the reasoning in *Happel*, *Baker*, *Lasley*, and *Cottam*.⁹⁹ While not imposing a general duty to warn on pharmacists, Washington courts tend to require a duty to warn when pharmacists are aware of a specific contraindication.¹⁰⁰ For example, in *Silves v. King*, the Washington Court of Appeals held that pharmacists had a duty to warn customers only when the pharmacist possessed knowledge of an absolute contraindication of two prescription drugs.¹⁰¹ Relying on *McKee v. American Home Products*, *Silves v. King* involved a patient with a blood clotting problem.¹⁰² In *Silves*, a patient who was taking heparin brought a medical malpractice action against the emergency room physician who prescribed an anti-inflammatory drug for the patient's arthritis.¹⁰³ The patient sued the doctor, hospital, and pharmacist after the patient suffered the adverse

95. *Id.*

96. *Id.* at 1125.

97. *Id.* at 1124-25.

98. *Happel II*, 766 N.E.2d at 1124.

99. Compare *McKee v. Am. Home Prod.*, 113 Wash. 2d 701, 715, 782 P.2d 1045, 1053 (1989), with *Happel II*, 766 N.E.2d at 1129; *Baker v. Arbor Drugs, Inc.*, 544 N.W.2d 727, 730 (Mich. Ct. App. 1996); *Lasley v. Shrakes Country Club Pharmacy*, 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994); *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 823 (Mass. 2002).

100. See, e.g., *McKee*, 113 Wash. 2d at 715, 782 P.2d at 1053; *Silves v. King*, 93 Wash. App. 873, 879-80, 970 P.2d 790, 794 (1999).

101. 970 P.2d at 794.

102. *Id.*

103. *Id.* at 793.

effects of drug interactions.¹⁰⁴ The trial court granted summary judgment in favor of the hospital and a jury trial verdict resulted in a victory for the doctor.¹⁰⁵ On appeal, the court held that the pharmacist who filled the prescription did not have a duty to consult with a physician regarding the dangers of possible contraindications unless the pharmacist was aware of them.¹⁰⁶

III. POTENTIAL PITFALLS

An expansion of the pharmacist's duties beyond the mandates of the Omnibus Budget Reconciliation Act of 1990 ("OBRA")¹⁰⁷ and Washington Administrative Code ("WAC") section 246-863-095¹⁰⁸ will further undermine the learned intermediary standard. Moreover, the proponents of such a new duty may be disappointed by a myriad of unintended consequences that might spring from this new obligation. Some of the problems arise from the possibility that imposition of a new duty to warn of either drugs' side effects or negative contraindications might result in higher costs for prescriptions. Another consequence might be that pharmacists will be discouraged from providing the viable service of maintaining customer records and issuing warnings to customers in fear of being exposed to liability.

The trend towards the creation of a duty to warn of known contraindications, as reflected in the decisions in *Happel* and other cases,¹⁰⁹ will result in a number of negative consequences and is an example of a cure that addresses the wrong disease. First, the imposition of a new duty would further undermine the foundations of the learned intermediary standard by shifting the liability from prescribing physicians and drug manufactures to pharmacists. At the same time, the erosion of the learned intermediary standard will likely undermine the credibility and accountability given to doctors. Second, the imposition of a duty on pharmacists to warn of either the contraindications or side effects of prescription drugs will create inappropriate, new gatekeepers. Finally, such a new duty will cause an increase in the costs of prescription drugs because the costs for malpractice insurance and litigation are likely to be passed onto the consumer.

104. *Id.*

105. *Id.*

106. *Silves*, 93 Wash. App. at 880, 970 P.2d at 794.

107. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (codified in scattered sections of 42 U.S.C.).

108. WASH. ADMIN. CODE §§ 246-863-095, 246-869-220 (2003).

109. See cases cited *supra* note 99.

A. *Undermining the Foundations of the Learned Intermediary Standard Leads to Decentralized Accountability*

First, the trend towards the imposition of a duty to warn of known drug interactions undermines the foundations of the learned intermediary standard, which is based on the centralized accountability of the prescribing doctor's judgment.¹¹⁰ The underlying rationale for the learned intermediary standard posits that a prescribing doctor possesses medical training and extensive knowledge of a patient's medical history.¹¹¹ According to the learned intermediary standard, the combination of the doctor's training and knowledge of the patient's history places the prescribing doctor in a superior position to determine whether a particular medication will have adverse interactions with the patient's other medications.¹¹²

The proponents of the imposition of the new duty argue that, in the current situation, patients visit so many different medical specialists that their pharmacist might be the only individual actor who has accurate knowledge of all the different prescriptions and that the pharmacist, as seller of dangerous goods, should be held accountable for the adverse effects of any defective goods sold.¹¹³ However, such an argument assumes, perhaps falsely, that patients only use one pharmacist. Many times, patients shop around for the best price among competing pharmacies because prices vary for the same drugs.¹¹⁴

The learned intermediary standard provides a centralized focus of accountability and potential liability on the prescribing doctor.¹¹⁵ By potentially widening the net of liability to include pharmacies, the erosion of the learned intermediary standard disperses liability away from negligent prescribing doctors toward pharmacists. Commentators arguing for the imposition of a pharmacist's duty to warn note that the

110. See generally Wiseman, *supra* note 48, at 1003.

111. *Id.* Some commentators have suggested that "consumers commonly look to a pharmacist's expertise in drugs when a prescription is filled. Additionally, . . . pharmacists and physicians will not become adversaries if pharmacists have a duty to warn, but instead, such a duty actually may encourage pharmacists and physicians to work together." Edward Casmere, *RX for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule*, 33 J. MARSHALL L. REV. 425, 444 (2002) (citing *Hooks Super X, Inc. v. McLaughlin*, 642 N.E.2d 514, 517 (Ind. 1994)).

112. Wiseman, *supra* note 48, at 1003.

113. See generally David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 *DRAKE L. R.* 439 (1996).

114. See *Prescription Drugs: Shop Around for the Best Prices*, CONSUMERS' RES. MAG., July 1, 2003, at 34, available at 2003 WL 15443538 (stating that, increasingly, the customer would be wise to shop around for the best prices because of price disparity); see also Nikki Davis Maute, *Consumers Compare Drug Prices*, HATTIESBURG AM., July 9, 2002, at A1, available at 2002 WL 20703599.

115. Cf. Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 *FOOD DRUG COSM. L.J.* 829, 830 (1991); Student Article, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Customer Prescription Drug Advertising*, 2 *CORNELL J. L. & PUB. POL'Y* 449, 460-61 (1993).

health care profession has moved away from the general physician of the past towards increased specialization in doctors' practices.¹¹⁶ The argument follows that these specialists rely on information provided by patients that is sometimes incomplete or wrong, while the pharmacists who disperse the drugs have easy access to more complete information on each customer via computer.¹¹⁷ Such an approach might unintentionally reward both doctors who fail to collect the necessary information and the patient who did not provide the correct vital data by shifting the liability on to the merchant who maintains correct records of prior purchases or prescriptions filled.

Furthermore, the duty to warn of possible drug interactions seems only to be imposed on those companies that voluntarily collect vital and medical information about their customers, such as Wal-Mart in *Happel*.¹¹⁸ The trend toward the imposition of a duty to warn of possible contraindications and exposure of pharmacists to liability for "breaches of a standard of care" might simply result in such pharmacists halting the collection of such information, if pharmacists assess that the risk-reward ratio favors non-collection.¹¹⁹ An argument can be made that pharmacists offering the warning service benefit by having a competitive edge in attracting customers over those pharmacists who do not offer such a service.¹²⁰ The argument follows that those who voluntarily assume or undertake to perform a service that might have life and death consequences have a duty not to perform those services negligently. However, a scheme that imposes liability on pharmacists could result in pharmacists weighing the risks and rewards and choosing not to collect the information.

B. *The Creation of Inappropriate Gatekeepers*

While pharmacists receive extensive training,¹²¹ creating a duty to warn of adverse negative contraindications might result in pharmacists "second guessing" the medical expertise of the prescribing physician. Even assuming that pharmacists are

116. See David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439, 441-42 (1996).

117. DAVID B. BRUSHWOOD, PHARMACY MALPRACTICE LAW & REGULATION § 8.11, at 259 (2d ed. 1998).

118. *Happel v. Wal-Mart*, 766 N.E.2d 1118, 1125 (Ill. 2002).

119. This argument is based on current case developments. If a general duty were imposed, this issue would be irrelevant.

120. *E.g.*, *Baker v. Arbor Drugs, Inc.*, 544 N.W.2d 727, 731 (Mich. Ct. App. 1996).

121. For example, students at the Washington State University: College of Pharmacy take 2 years of pre-pharmacy training that includes science classes followed by 4 years of pharmacy training that includes various clinical experiences. The six year educational experience is followed by an intense "bar" examination. See Washington State University: College of Pharmacy, *Future Students-Academics*, at <http://www.pharmacy.wsu.edu/futurestudents/academics.html> (last visited Oct. 18, 2003).

qualified to make determinations on contraindications, the patient/customer might be confused by the conflicting opinions of the prescribing doctor, on one hand, and pharmacist, on the other. It is true that doctors can err by accidentally prescribing drugs contraindicated with the patient's other drugs. Sometimes, the pharmacist can discover plain errors and alert the customer of the doctor's written error or clear errors in the drug prescribed.¹²² However, the proposition of the pharmacist acting as a voluntary safety valve is rather different than charging the pharmacist with an affirmative duty to monitor all of their customers' prescriptions for possible contraindications.

It is arguable that the whole pharmacist versus doctor debate could be rendered moot by the adoption of legislation requiring drug manufactures to insert patient package inserts ("PPIs") in the prescription boxes or as a printout when a prescription is filled.¹²³ Although, at first glance, the PPIs stored with prescription containers might appear to be a simple as well as a seductive solution to the duty-to-warn problem, there are a number of potential weaknesses to such an approach. In 1979, Congress adopted a plan to insert PPI warnings in the boxes of the prescription drugs that patients received, which included a list of the common hazards associated with the use of a certain drug.¹²⁴ The PPI experiment, however, proved to be short-lived and a failure due to the various short comings of such a regulatory regime.¹²⁵

Under such a PPI system, customer/patients might take the insert warnings as superior to the advice of their doctors, resulting in inadvertently undermining the prescribing doctor's authority.¹²⁶ Furthermore, the information contained in the inserts might differ or conflict with the counsel provided by the prescribing physician.¹²⁷ Additionally, the insert warnings simply might go unread and, as a result, the customer might not follow the advice or warnings contained within the

122. "A 2000 study found that more than half of retail and hospital pharmacists 'often' correct medication directions and more than 40% 'often' take measures to prevent drug interactions. Results such as these clearly reveal that pharmacists have the ability to intercept prescribing errors and interactions before the patient is harmed." Jennifer L. Smith, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2 HOUS. J. HEALTH L. & POL'Y 187, 200 (2002) (citing Michael F. Conlan, *The Watchful Eye*, DRUG TOPICS, Sept. 4, 2000, at 28-29).

123. 25 AM. JUR. 2d. *Drugs and Controlled Substances* § 241 (2002).

124. Prescription Drug Products, 44 Fed. Reg. 40,016 (July 6, 1979).

125. Prescription Drug Products, 47 Fed. Reg. 7200 (Feb. 17, 1982).

126. See generally Howard M. Rowe, *Patient Package Inserts: The Proper Prescription?*, 50 FOOD & DRUG L. J. 95 (1995).

127. See Catherine A. Paytash, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach To Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343 (1999); cf. Alan R. Styles, Note, *Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts*, 39 CLEV. ST. L. REV. 111 (1991).

pamphlets.¹²⁸ Moreover, not all patients are literate in English or possess the education necessary to understand the written warnings.¹²⁹

C. Higher Costs of Medication

The creation of a new duty to warn would also result in higher costs of prescriptions for the customer.¹³⁰ Confronted with potential liability for failure to warn of the negative interactions and the possibility that courts could impose a duty on pharmacists to collect customers' vital information, those pharmacists will have to insure themselves against potential malpractice suits for breaches of a standard of care.¹³¹ The need for such insurance will result in higher startup and maintenance costs for individuals involved in conducting a pharmacy business.¹³² The higher costs will be passed on to the customer in the price of drugs.¹³³

Additionally, a non-chain pharmacist might not have the financial resources or the computer technology to collect the material needed to monitor possible contraindications.¹³⁴ Under the current trend, those pharmacists that opt not to collect the data would not be required to do so. Although, at first glance, such a situation might appear to present those pharmacists who do not collect information with a competitive advantage by saving them the costs of installing monitoring procedures, which in turn would result in lower drug prices, such differing standards of information collection and price disparity might adversely affect the patient/consumer

128. The question of whether patients read the information contained in package inserts was confronted in Europe. D.K. Raynor & P. Knapp, *Do Patients See, Read and Retain the New Mandatory Medicines Information Leaflets?*, 264 PHARM. J. 268 (2000), available at http://www.pharmj.com/Editorial/20000212/papers/info_leaflets.html (last visited Oct. 3, 2003) (suggesting that fifty percent of the patients did not read the package inserts).

129. See *Technology and Prescription Drug Safety: Hearing on S.R. 79 Before the Spec. Comm. on Aging*, 107th Cong. 16-24 (2002) (statement of Peter A. Klein, R. Ph., Business Development for Envisioning America), available at <http://aging.senate.gov/events/hr65pk.pdf> (last visited Oct. 3, 2003).

130. See generally *Leesley v. West*, 518 N.E.2d 758 (Ill. App. Ct. 1988). "The *Leesley* opinion is typical. The court assumes that imposing a duty to warn would be burdensome to pharmacists because they would bear the additional costs of reproducing the material they receive from the manufacturer." David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, n.276 (1990-1991).

131. John C. West & David E. Smith, *A Prescription for Liability: The Pharmacy Mandate of the Omnibus Budget Reconciliation Act of 1990 and Its Impact upon Pharmacists' Common Law Duties*, 2 J. PHARMACY & L. 127 (1994).

132. Cf. Bernard Mehl, *Pharmacy and the Complexity of Health Care*, 58 AM. J. HEALTH-SYS. PHARMACY 1507, 1511 (2001).

133. See Castagnera & Gerner, *supra* note 46, at 124 (discussing the possible costs imposed by a duty to warn).

134. See generally Gary G. Cacciatore, *Computers, OBRA 90 and the Pharmacist's Duty to Warn*, 5 J. PHARMACY & L. 103, 118 (1996).

because some communities might not be serviced by the larger pharmacy chains.¹³⁵ Consequently, the demise of the learned intermediary standard would have a potentially adverse effect on the quality of service that the customer receives.

IV. PROPOSING A UNIFIED SOLUTION

In order to curb the erosion of the learned intermediary standard, Congress should take the step of adopting section 6(d) of the Restatement (Third) of Torts: Products Liability as a nationwide standard. The implementation of a consistent standard would protect pharmacists from potential liability arising from the failure to warn of possible negative effects of known contraindications.

Much of the confusion stemming from the pharmacist's duty to warn is the result of conflicting interpretations provided by various Restatement provisions as well as a variety of approaches by state courts. As a general rule, pharmacists do not have a duty to warn of the side effects of drugs prescribed.¹³⁶ Some states, however, have moved in the direction of imposing a duty to warn of known contraindications, employing the logic of a pure negligence scheme¹³⁷ or strict liability of Restatement (Second) of Torts section 402A comment k, which has resulted in confusion due to the lack of a universal standard.¹³⁸ Unfortunately, both of these approaches have had negative consequences.¹³⁹ Strict liability seems to needlessly punish innocent sellers

135. See generally DEPT. OF HEALTH & HUMAN SERV., REPORT TO CONGRESS: THE PHARMACIST WORKFORCE: A STUDY OF THE SUPPLY & DEMAND FOR PHARMACISTS, (2000), available at http://www.unr.edu/med/dept/pharmacology/PDF_DocFiles/Pharmacy%20Workforce%20Study.pdf (last visited Oct. 10, 2003) (discussing problems with pharmacists in rural areas).

136. 25 AM. JUR. 2d *Drugs and Controlled Substances* § 241 (2003).

137. Tim S. Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449, 455 (1993).

138. M. Stuart Madden, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals*, 21 PACE L. REV. 313, 320 (2001). Section 402A of the Restatement (Second) of Torts provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

139. See generally Mark E. Roszkowski & Robert A. Prentice, *Reconciling Comparative Negligence and Strict Liability: A Public Policy Analysis*, 33 ST. LOUIS U. L.J. 19 (1988).

of defective products, while a pure liability scheme only seems to disperse liability to pharmacists rather than address the malfeasance of doctors, drug manufacturers, or the careless patient.¹⁴⁰ Therefore, a middle position between the strict liability of Restatement of Torts (Second) section 402A comment k and a pure negligence scheme is appropriate. According to some commentators, Restatement (Third) of Torts strikes the proper balance between patient/consumers and the interests of the drug manufacturers and pharmacists that the pure negligent and strict liability schemes lack.¹⁴¹ In particular, the Restatement (Third) of Torts section 6(d) allocates the burden of the duty to warn to those parties that are in the best position to bear it, namely doctors and drug manufacturers rather than the pharmacists.¹⁴² Doctors and health care professionals have extensive knowledge of the patient's history, while drug manufacturers are in a position to know about the drugs' possible side effects or negative interactions. In a liability scheme such as that provided by the Restatement (Third) of Torts section 6(d), the pharmacist's role is to fill the prescription properly for the patient, as the prescribing doctor requires.¹⁴³ Consequently, only where the pharmacist fails to exercise due care in filling a prescription as prescribed by a physician will a pharmacist be found negligent.¹⁴⁴

Therefore, to provide a unified standard, Congress should take action to clarify the ambiguity caused by the various Restatements. Such clarity can be achieved by adopting and therefore preempting state law with a federally-mandated law similar to Restatement (Third) of Torts: Products Liability section 6(d).¹⁴⁵ The adoption of a standard based on this section would reinforce the learned intermediary standard and stem the trend towards imposing a new duty to warn on pharmacists. Alternatively, the framers of the Restatement should specifically amend the Restatement (Third) of Torts to address the role and responsibilities of pharmacists.

140. See generally Carr & Bowers, *supra* note 65, at 20.

141. See Dreier, *supra* note 35, at 258.

142. Section 6(d)(1) of the Restatement (Third) of Torts provides:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings;

or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

RESTATEMENT (THIRD) OF TORTS § 6(d)(1) (1998).

143. See generally Conning *the IADC Newsletters*, 68 DEF. COUNS. J. 245, 255 (2001).

144. See generally Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1387 (Pa. 1991).

145. See generally Arthur B. Mark, III, *United States v. Morrison, The Commerce Clause and the Substantial Effects Test: No Substantial Limit on Federal Power*, 34 CREIGHTON L. REV. 675 (2001) (discussing the limits of commerce clause power).

Alternatively, if Congress is unwilling to adopt a universal provision that would strengthen the learned intermediary standard as discussed above, drug manufactures should be compelled to indemnify pharmacists for a certain portion of their liability exposure or the medical malpractice insurance needed to cover that exposure. The question then becomes one of risk allocation and risk of loss should be placed on those participants who are best able to bear it, namely doctors, not pharmacists and customers.¹⁴⁶ While it is arguable that large pharmacy chains like Wal-Mart have the deep pockets to cover the liability exposure presented by the imposition of a duty to warn, higher costs for medication will be passed on to customers. Furthermore, the centralization of the duty on doctors might further exasperate the medical malpractice insurance crisis leading to much-needed reform of the overall health care system.

V. CONCLUSION

While the underlying goal of protecting the consumer by imposing a duty to warn of known contraindications is laudable, the trend towards imposing a duty to warn on pharmacists poses the potential for a myriad of negative consequences. Many of the problems stem from the tendency to undermine the foundations of the learned intermediary standard and others from the increased costs of prescription drugs. Rather than imposing a new, burdensome duty on pharmacists, Congress should pass legislation to provide a nationally unified approach towards the duty to warn of both the drug's negative side effects and known contraindications. Such a response would allocate the burden on those participants that are in the best position to bear it—the drug companies and doctors. For those reasons, Congress should take the opportunity to pass a nationalized liability scheme similar to that of Restatement (Third) of Torts: Products Liability section 6.

146. See Terence C. Green, *Licking, Sticking, Counting, and Pouring—Is that All Pharmacists Do?* McKee v. American Home Products Corp., 24 CREIGHTON L. REV. 1449, 1471 (1991) (arguing that pharmacists, due to their expanded role, training, and profits, should bear the risk of liability and litigation costs).