

Prescription for Compromise: Maintaining Adequate Pharmacist Care Contraindicates Imposition of a General Duty to Warn

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I. INTRODUCTION

Courts traditionally have imposed no duty upon pharmacists to warn patients of the adverse effects of prescription drugs.¹ However, professional progression and tort litigation have chipped away steadily at this no-duty rule,² spurring a new trend where courts hold pharmacists liable for failing to warn patients³ on either a defective- or inadequate-warning theory.⁴

This trend abrogates the Learned Intermediary Doctrine⁵ (the Doctrine) embodied in the Restatement (Third) of Torts.⁶ The Learned Intermediary Doctrine provides that the prescribing physician is the “learned intermediary” between the drug manufacturer and the patient. As such, the prescribing physician is in the best position to assess the danger of a prescription drug to a patient because the physician knows the patient’s needs and can evaluate the drug’s effects and contraindications in light of those

1. See David J. Marchitelli, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R. 5th 393 (2002).

2. See Carol Ukens, Community Practice, *Florida Judge Rules on Pharmacist Duty to Warn*, DRUG TOPICS, Apr. 7, 2003, at 24.

3. *Id.* Courts now may require pharmacists to warn patients of the harmful effects of prescription drugs.

4. See Brian L. Porto, Annotation, *Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug*, 79 A.L.R. 5th 409 (2003).

5. See Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R. 5th 127 (1998).

6. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) & cmt. b, reporters’ note to cmts. b, d (1998).

needs.⁷ Thus, the physician becomes responsible for warning the patient and passing on instructions or warnings provided by the drug manufacturer.⁸ This doctrinal structure precludes manufacturer liability for defective warning.⁹

Traditionally, the Doctrine also shielded pharmacists from negligence liability.¹⁰ The modern trend, however, holds pharmacists liable for negligence if they fail to warn patients of a prescription drug's adverse effects.¹¹ While several theories support pharmacist liability,¹² imposing such liability may have fatal effects on the efficiency and efficacy of "pharmacist care" given pharmacists' precarious position in the health care system and the increasing demand for prescriptions.¹³

These effects include the practice of pharmacy's professional regression and the inability of pharmacists to provide heightened care.¹⁴ Imposing liability on pharmacists in this fashion encourages

7. "[P]hysicians are best situated to assess patients' needs for medication, so they alone should have a duty to warn about potential drug interactions." Porto, *supra* note 4, § 2a, at 414.

8. *Id.*

9. See, e.g., Walls v. Alparma USPD, Inc., No. 1010645, 2004 Ala. LEXIS 40 (Ala. Mar. 5, 2004). "[W]e rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as to not be fully appreciated by the consumer." *Id.* at *4.

Under strict products liability, minimally effective drugs with extreme side effects may still be pursued under a defective-design theory rather than a failure-to-warn theory and would not be affected by application of the Learned Intermediary Doctrine. See discussion *infra* note 45.

10. See Karina Fox, Note, *A Weighty Issue: Will Pharmacists Survive the Fen-Phen Feeding Frenzy?* Kohl v. American Home Products Corporation and a Pharmacist's Duty to Warn of the Dangers of Prescription Drugs, 2001 BYU L. REV. 1349, 1357 (2001).

11. See, e.g., Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 517-18 (Ind. 1994) (finding a duty to warn in the pharmacist-patient relationship).

12. Some policy concerns that courts evaluate are preservation of the physician-patient relationship, prevention of drug related injuries, and avoidance of unnecessary costs. See *id.*

13. "Pharmacist care" in this Note refers generally to the services pharmacists provide patients including dispensing of medication, counseling and drug therapy assessment. The National Community Pharmacists Association (NCPA) defines Pharmacist Care® as "a comprehensive approach to pharmacist-directed patient care management through which community pharmacists provide an expanded level of patient care that focuses on disease prevention and wellness and includes monitoring, evaluating, counseling, intervening, and directing medication-related therapies to enhance patient care and improve health outcomes." NCPA, About NIPCO, at http://www.ncpanet.org/nipco/about_nipco.shtml (last visited Sept. 29, 2004). The National Institute for Pharmacist Care Outcomes (NIPCO) "is the national accrediting organization for pharmacist care education and training programs leading to the pharmacist care Diplomate credential." *Id.*

14. See discussion *infra* Part III.B.

pharmacists to act contrary to public policy to prevent negative ramifications on society and the practice of pharmacy, by operating on a virtual “don’t ask, don’t tell” policy¹⁵ or closing up shop altogether. Obviously, this type of behavior harms the public welfare.¹⁶

Given the critical and delicate balance between effective and affordable health care in the United States,¹⁷ the Learned Intermediary Doctrine must continue to apply conventionally to prescribing physicians,¹⁸ shielding pharmacists from certain liability. Instituting a modified general no-duty rule may be the compromise between the traditional approach and the modern trend that the system needs.¹⁹

15. Strict-products-liability defective-warning cases achieve the same goal as negligence defective-warning cases: incentivizing optimal levels of safety. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (1998). Accordingly, in the rare situation where a pharmacist has no real or constructive knowledge of the dangers of a prescription drug for a particular patient, he cannot be held liable for failing to warn the patient about those dangers because such liability would not help achieve the stated goal. Presumably, then, if pharmacists refuse to ask patients about their medical history (don’t ask), they would not be liable for failing to warn (don’t tell) in either strict liability or negligence because they do not have the requisite knowledge. Furthermore, courts generally do not impose strict liability on pharmacists, finding that pharmacists are service providers rather than retail sellers of drugs. *See, e.g.,* McLeod v. W.S. Merrell Co., 167 So. 2d 901, 903 (Fla. Dist. Ct. App. 1964).

16. Recognition of a pharmacist’s duty to warn in certain situations may further society’s interest in preventing the use and misuse of prescription drugs. *See* Hooks Super X, Inc. v. McLaughlin, 642 N.E.2d 514, 519 (Ind. 1994) (recognizing the pharmacist’s duty to further society’s goal of preventing the overuse and misuse of prescription drugs). Moreover, the checks-and-balances relationship between prescribing physicians and dispensing pharmacists provides more opportunity to find and correct errors in prescriptions or to recognize possible contraindications. *See* Lasley v. Shrake’s Country Club Pharmacy, Inc., 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994) (advocating pharmacists’ new role as prescription “gatekeepers”); Pittman v. Upjohn Co., 890 S.W.2d 425, 435 (Tenn. 1994) (recognizing pharmacy’s duty to warn of a drug’s dangerous propensities when no warning had been given by the physician).

17. *See generally* Jeanne Schulte Scott, *Universal Health Care Revisited*, HEALTHCARE FIN. MGMT., June 1999, at 32. Imposing liability on any industry increases the cost of production and that cost is ultimately passed on to the consumer. As cost increases, health care becomes less available to lower-income individuals. Our health care law seeks a balance between adequate treatment and easy access to medical services. As of 1999, forty-four million Americans did not have health insurance, which demonstrates the instability of the system. *Id.*

18. This Note does not discuss possible theories of liability for failure to warn that may apply to manufacturers of prescription drugs. A different analysis applies to cases involving direct-to-consumer advertising or lifestyle drugs, for example. In such cases, the Learned Intermediary Doctrine may not apply to shield manufacturers from liability.

19. *See* discussion *infra* Part IV.

In Part II of this Note, I first examine the policy behind the Doctrine's application to the manufacturer-physician-patient relationships and its more recent application in prescription drug cases. I then discuss the application of the Doctrine to the physician-pharmacist-patient relationship by examining: the public policy involved in such application, the reasons why courts vitiate such application, the cases imposing liability on pharmacists for failing to fulfill their traditional duty to dispense medications accurately, the modern approach to pharmacist liability, the cases imposing a duty to warn on pharmacists, and the legislative and regulatory authority behind the pharmacist's expanded professional duties. Finally, I address cases in which courts have imposed no general duty to warn on pharmacists.

In Part III, I analyze the negative impact of the duty to warn. I discuss how the duty abrogates the Learned Intermediary Doctrine and how it may have severe consequences on the health care industry by limiting pharmacists' care. The duty forces pharmacists to over-emphasize risks to compensate for potential liability, interferes with the physician-patient relationship, and increases the cost of health care.

Part IV advocates that courts subject pharmacists to negligence liability only upon voluntary assumption of a duty to warn. Furthermore, Part IV advocates that when such a duty is implied, pharmacists ought to be held to a professional standard of care.

Part V concludes that imposing liability on pharmacists for failing to warn about adverse effects of prescription drugs endangers the equilibrium of the health care system and the physician-patient relationship. Following the proposed approach to pharmacist liability strikes a balance between traditional common law and modern legal trends.²⁰

20. The no-duty rule should only pertain to pharmacists' traditional duties. If a pharmacist affirmatively assumes a duty not traditionally imposed on him, he may face liability for negligent fulfillment of that assumed duty. See discussion *infra* Parts II.B.2.b.3 and IV.

II. DEVELOPMENT

A. Learned Intermediary Doctrine

1. Origin and Authority of the Doctrine

Ordinarily, strict products liability law imposes a duty on the manufacturer of a product to warn consumers of the inherent dangers in using its product.²¹ Failing to comply with this duty makes that product defective and subjects the manufacturer to liability for the defect.²² However, prescription drugs are treated differently.²³

The Learned Intermediary Doctrine shields drug manufacturers from liability and relieves them of the duty to warn patients, if they warn prescribing physicians of the drug's dangers.²⁴ Physicians, in

21. "One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect." RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 (1998). The Restatement also provides that "[a] product is defective when, at the time of sale or distribution, it . . . is defective because of inadequate instructions or warnings." *Id.* § 2.

A product . . . is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Id. § 2(c).

22. *Id.*

23. Prescription drugs are classified as unavoidably unsafe products because they inevitably harm some patients while healing others. *Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988). Consequently, prescription drugs are not "defective" if "properly prepared and accompanied by proper directions and warnings. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

24. *See id.* §

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect

(b) [A] prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device

(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d)

(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 . . . prescribing and other health-care providers who

turn, must warn patients of the dangers of the drugs they prescribe.²⁵ Almost all states have adopted the Doctrine and some have even codified it.²⁶

2. Policy Reasons Supporting the Doctrine

In the past, courts applied the Learned Intermediary Doctrine with confidence because of the physician's unique ability to accurately weigh the potential risks of prescribing a drug against the drug's benefits to a patient.²⁷ Courts assumed that the physician was in a far better position than the patient to understand a drug's complexities as well as the pharmaceutical industry's esoteric terminology and to translate that knowledge into something a patient could understand.²⁸ Courts also assumed that the physician was in a better position than the drug manufacturer to know the individual needs and idiosyncrasies of the patient.²⁹ Finally, courts found that direct consumer warnings may scare patients from taking drugs—patients may give too much weight to frighteningly candid instructions meant to shield manufacturers from liability and choose not to take a

are in a position to reduce the risks of harm in accordance with the instructions or warnings.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998). The comments to this section recognize that “the obligation of a manufacturer to warn about risks attendant to the use of drugs . . . traditionally has required warnings directed to health-care providers and not to patients.” *Id.* at cmt. b.

25. *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1125 (Ill. 2002) (explaining that under the Learned Intermediary Doctrine, manufacturers have a duty to warn physicians and physicians have a duty to convey those warnings to their patients).

26. *See, e.g.*, N.C. GEN. STAT. § 99B-5(c) (2003) (“[N]o manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to the consumer if an adequate warning or instruction has been provided to the physician.”).

27. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b (1998) (“[O]nly health-care providers 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.”).

28. *Walls v. Alpharma USPD, Inc.*, No. 1010645, 2004 Ala. LEXIS 40 *1, *6–7 (Ala. Mar. 5, 2004).

29. *See Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922 (Utah 2003) (finding the physician to be the “best conduit” for warnings from the manufacturer because of his combination of medical training and “individual understanding of the patient's needs”).

particular drug when it is in their best interest to do so.³⁰ A physician may be able to explain away the patient's concerns.³¹

But the health care system is changing and the premises that courts rested their opinions on are changing as well. For instance, as the liquidity of the health care system increases,³² the physician's knowledge of the patient's entire health situation decreases.³³ Patients often see multiple doctors and it is rare that any one of these doctors will know about any or all of the patient's other doctors.³⁴ And because the patient may not willingly reveal their whole medical picture, physicians sometimes prescribe a medication without comprehensive knowledge of the medication's risks for that patient.³⁵

Moreover, manufacturers are now advertising directly to consumers,³⁶ and it is unclear whether these manufacturers have a

30. See *In re Certified Questions*, 358 N.W.2d 873, 883 (Mich. 1984) (discussing further policy reasons for salvation of the Learned Intermediary Doctrine). There are additional theoretical bases for the Learned Intermediary Doctrine as well:

[P]hysicians may be in a superior position to convey meaningful information to their patients, as they must do to satisfy their duty to secure informed consent. . . . Finally, because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients.

Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158–59 (1992). According to a study sponsored by the U.S. Chamber of Commerce, “sixty-nine percent of patients said they would be concerned about taking a drug after reading packaging information about possible serious side effects, while 20 percent would avoid taking the drug altogether.” *Lawsuits Dramatically Erode Drug Sales*, DRUG INDUS. DAILY, July 16, 2003.

31. See *In re Certified Questions*, 358 N.W.2d at 883 (reasoning that package inserts or other forms of direct consumer warning, read without the keen medical eye of a physician, may upset even the “most sophisticated patient”); *Landsell v. Am. Home Prods. Corp.*, 1999 U.S. Dist. LEXIS 22540, at *1, *16–17 (N.D. Ala. Oct. 26, 1999) (imposing a duty to warn would interfere with the physician-patient relationship); Noah, *supra* note 30, at 157–59 (“[C]ourts do not wish to intrude upon the doctor-patient relationship . . . warnings that contradict information supplied by the physician will undermine the patient's trust in the physician's judgment.”).

32. More frequently than ever, patients are free to see multiple doctors for any number of ailments. It is rare that only one physician will treat any given patient. See Jill Casson Owen, *The Pharmacist's Duty to Warn*: *Lasley v. Shrake's Country Club Pharmacy*, 37 ARIZ. L. REV. 677, 697 (1995).

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

34. *Id.*

35. See Owen, *supra* note 32.

36. Manufacturers started marketing directly to consumers in the 1980s, beginning with the Upjohn Company's Rogaine campaign. See *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245,

duty to warn.³⁷ This direct advertising adds yet another obstacle to the already complicated physician-patient relationship because patients now “enter offices with ‘preconceived expectations about treatment.’”³⁸

But imposing liability on a drug manufacturer for a failure to warn is not the answer. This will only discourage valuable prescription drug research and development and dramatically increase the cost of these drugs for the consuming public.³⁹ Pharmaceutical manufacturers must undertake a costly and lengthy research application process to market and distribute a legal drug.⁴⁰ This process may cost the manufacturer as much as \$800 million,⁴¹ without accounting for civil defense costs. Excessive litigation could

1251 (N.J. 1999); W. John Thomas, *Direct-to-Consumer Pharmaceutical Advertising: Catalyst for a Change in the Therapeutic Model in Psychotherapy?*, 32 CONN. L. REV. 209, 210–11 (2000). From 1996 to 2000, spending on direct-to-consumer advertising more than tripled, rising from \$791 million to nearly \$2.5 billion. Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498, 499–501 (2002).

37. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. e (1998).

38. *Perez*, 734 A.2d at 1260 (quoting Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 157 (1999)). “Physicians complain that it is impossible to compete with pharmaceutical companies’ massive advertising budgets and resign themselves to the fact that if consumers make enough noise, they will eventually relent to patient pressure.” Terzian, *supra*, at 158 (footnotes omitted). Not surprisingly, some courts have held that “neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn” in these direct marketing cases. *Perez*, 734 A.2d at 1262–63. Requiring the manufacturer to warn the patient/consumer directly also raises questions as to the adequacy of the warning. These issues ordinarily do not arise when warnings are directed only at learned intermediaries. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY PROBLEMS AND PROCESS 442 (4th ed, 2000); see also *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985).

39. *Brown*, 751 P.2d at 479. Some commentators argue that slowing down the pharmaceutical creation and certification process is a good thing and prevents harmful drugs like Ephedra from slipping through the cracks. But this same delay may also prevent beneficial research and development.

40. A benefit of this application process is that compliance with FDA regulations raises a rebuttable presumption of adequacy of the warning to the learned intermediary. *In re Meridia Products Liability Litigation*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004); *Perez v. Wyeth Lab.*, 734 A.2d 1245, 1259 (N.J. 1999).

41. Ceci Connolly, *Price Tag for a New Drug: \$802 Million; Findings of Tufts University Study Are Disputed by Several Watchdog Groups*, WASH. POST, Dec. 1, 2001, at A10. However, cash outlay maybe far less—an average of \$107.6 million pre-tax. *Rx R&D Myths: The Case Against the Drug Industry’s R&D “Scare Card”*, PUB. CITIZEN, July 2001, at 6, available at <http://www.citizen.org/documents/acfdc.pdf> (last visited Sept. 21, 2004).

cripple the industry. These reasons, among others, support affirmation of the Learned Intermediary Doctrine.⁴²

B. Pharmacists' Liability for Failure to Warn and the Learned Intermediary Doctrine

1. Strict Liability

Courts typically refuse to impose liability on pharmacists under strict products liability law.⁴³ They reason that such a result would not further public policy interests in the prescription drug context because the pharmacist exercises no control over the drug company⁴⁴ and cannot prevent the company from manufacturing harmful drugs.⁴⁵ Hence, imposing strict liability on a pharmacist punishes the pharmacist for something he cannot prevent.⁴⁶

42. See discussion *infra* Part III.

43. See, e.g., *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991); see also Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 24 AM. J.L. & MED. 417, 421 (1998) (noting RESTATEMENT (SECOND) OF TORTS § 402A cmt. k as support for the courts' positions).

44. This assumes that the pharmacist is not a managed care pharmacist. Managed care organizations attempt to control health care costs by centralizing health care decisions and restricting physicians' treatment choices in part by using drug formularies—approved lists. Pharmacists help make drug formulary decisions and thus may have some impact on drug manufacturers in this scenario. See Richard M. Cooper, *Some Effects of the Clinton Health Care Reform Proposals on Regulated Aspects of the Pharmaceutical Industry*, 24 SETON HALL L. REV. 1260 (1993); John D. Jones, *How a PBM Develops Its Drug Formulary*, DRUG BENEFIT TRENDS, June 1998, at 37.

45. See *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 292 (S.D.N.Y. 2001) (“One of the purposes of imposing strict liability or liability for breach of warranty on retailers is to encourage retailers to pressure manufacturers to make safer products. Yet this goal is lost on pharmacists, who have little or no impact on a manufacturer’s marketing of prescription drugs.”). Physicians, however, have a far more direct impact on manufacturers through their ability to select particular drugs to prescribe to their patients.

46. See *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247, 253 (Cal. 1985). The court rejected the application of strict liability to pharmacists on several public policy reasons: if pharmacists were held strictly liable, they might try to avoid dispensing any drug that posed even a remote risk of harm “although such medications may be essential to the health or even the survival of patients”; pharmacists may feel compelled to choose expensive drugs from established manufacturers to ensure a pharmacy receives maximum protection from suit; because the physician who prescribes the drug and the manufacturer who produces the drug may be able to avoid strict liability, it would be “unfair and burdensome” to impose that liability on pharmacists who only provides drugs on a physician’s order. *Id.* at 253; see also *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986) (predicting that the imposition of strict liability on pharmacists would cause them to be insurers of a drug’s safety,

2. Negligence

In recent years, industry demands have required pharmacists to do far more than accurately fill a prescription.⁴⁷ These new duties expose pharmacists to liability in negligence for taking actions or failing to take actions that are outside the scope of their traditional duties.⁴⁸ Here, while most courts still apply the Learned Intermediary Doctrine,⁴⁹ the trend is changing⁵⁰ and the pharmacist is becoming more susceptible to liability for failure to warn patients of a prescription drug's harm.⁵¹

a. Pharmacists' Traditional Liability

Pharmacists traditionally are held to a high standard of care in dispensing medication because of the consequences of even a

requiring additional testing and costs that would pass onto the consumer and be harmful rather than beneficial to society).

Plaintiffs in prescription drug cases also pursue pharmacists for failing to warn under the Uniform Commercial Code and a theory of express or implied warranty of merchantability. *See, e.g., Rezulin*, 133 F. Supp. 2d at 286. Most courts decline to find pharmacists liable for breach of express or implied warranties for the same reasons that they reject imposition of strict liability. *Id.* at 292; *see also* *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 74 (Ga. Ct. App. 1998); *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1383 (Pa. 1991); *supra* note 45 and text accompanying notes 43–45. Because pharmacists do not manufacture prescription drugs and do not prescribe a particular course of drug therapy for a patient, they cannot be required to warranty the drugs without being able to inspect each drug for fitness or to evaluate the patient's drug therapy. It would be impossible for pharmacists to perform a chemical analysis on each pill they count.

47. These requirements include counseling patients about drug therapy and warning them of adverse effects of prescription drugs.

48. Traditionally, the pharmacist's only duty was to accurately fill a valid prescription. Huang, *supra* note 43, at 428.

49. The District Court for the Southern District of New York found that "[a]lmost every state confronted with the question has declined to impose on pharmacists a duty to warn of intrinsic dangers of prescription drugs . . . these states have not limited their holdings for failure to warn claims but have shielded pharmacists from liability on theories of strict liability and breach of warranty as well." *Rezulin*, 133 F. Supp. 2d at 289 (footnote omitted).

50. *See, e.g., Lasley v. Shrake's Country Club Pharmacy*, 880 P.2d 1129, 1129 (Ariz. Ct. App. 1994); *Hooks Super X, Inc. v. McLaughlin*, 642 N.E.2d 514, 514 (Ind. 1994); *Dooley v. Everett*, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990).

51. *See* R. Paul Asbury, Comment, *Pharmacist Liability: The Doors of Litigation Are Opening*, 40 SANTA CLARA L. REV. 907 (2000) (examining the expansion in pharmacist liability and advocating that pharmacists be scrutinized as professionals under the law).

miniscule error.⁵² This standard of care is heavily enforced by courts,⁵³ which require, as a minimum, that a pharmacist accurately fill a prescription and ensure that the prescription is not contaminated.⁵⁴ Courts will not tolerate any lapse in judgment no matter how honest the error.⁵⁵

Courts also require pharmacists to recognize clear errors in prescriptions such as “lethal dosages, inadequate instructions . . . and incompatible prescriptions.”⁵⁶ A pharmacist must verify the prescription with the prescribing physician when a prescription drug is facially and recognizably incorrect.⁵⁷

However, the courts do not impose a duty upon the pharmacist to warn the patient of contraindications or side effects; such a duty would invoke the Learned Intermediary Doctrine. For instance, a Texas court of appeals found that a pharmacist had “no generalized duty to warn patients of potential adverse reactions to prescription drugs” in *Morgan v. Wal-Mart Stores, Inc.*⁵⁸ The court found the traditional Learned Intermediary Doctrine applicable, reasoning that it is the physician’s duty to warn the patient of a drug’s negative effects, not the pharmacist.⁵⁹ The Washington Supreme Court has also held that a pharmacist has no duty to warn the patient of the adverse side effects of a particular prescription drug.⁶⁰ The court relied on the Learned Intermediary Doctrine and limited the pharmacist’s duty to filling prescriptions, noticing clear errors in those prescriptions, and attempting to correct those errors.⁶¹ Missouri

52. Marchitelli, *supra* note 1, at § 2a; *see also* Huang, *supra* note 43.

53. Pharmacists have been found liable for “mistakes . . . in filling of a prescription, sale of substances other than those requested by . . . prescribing physicians, mislabeling the contents of a prescription container . . . and violation of explicit statutory . . . requirements dealing with the practice of pharmacy.” Marchitelli, *supra* note 1, at § 2a (footnotes omitted).

54. *See Johnson v. Walgreen Co.*, 675 So. 2d 1036, 1037 (Fla. Dist. Ct. App. 1996).

55. *See* Huang, *supra* note 43, at 428; *see also* Brushwood, *supra* note 33, at 439.

56. Huang, *supra* note 43, at 429.

57. *Id.*; *see also* Riff v. Morgan Pharmacy, 508 A.2d 1247, 1252 (Pa. Super. Ct. 1986) (finding that a pharmacist breached his duty to exercise due care by failing to “warn the patient or notify the prescribing physician of the obvious inadequacies appearing on the face of the prescription”).

58. 30 S.W.3d 455, 469 (Tex. Ct. App. 2000).

59. *Id.* The court clarified that it did “not imply that pharmacists may not warn patients” but “that pharmacists are not legally obligated to do so.” *Id.*

60. *McKee v. Am. Home Prod. Corp.* 782 P.2d 1045, 1055–56 (Wash. 1989).

61. *Id.* at 1049–53.

also followed this rule until 1999.⁶² In *Kampe v. Howard Stark Professional Pharmacy, Inc.*,⁶³ the Missouri Court of Appeals held that “[b]y properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty to” the patient.⁶⁴ The court refused to impose liability on a pharmacist to warn of the adverse effects of a prescription drug.⁶⁵

b. Pharmacists’ Modern Liability

Modern courts are beginning to recognize pharmacists’ heightened place in the health care industry⁶⁶ and to hold them to a professional standard of care—the standard of care, skill and intelligence, which ordinarily characterizes the profession.⁶⁷ Under this modern approach, it is much easier for courts to create duties and impose liability on pharmacists, including liability for failure to warn.

62. The Missouri Court of Appeals explicitly overruled the traditional rule in *Homer v. Spalitto*, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999).

63. 841 S.W.2d 223 (Mo. Ct. App. 1992).

64. *Id.* at 227.

65. *Id.* at 226. The court refused to interpret section 338.010 of the Revised Statutes of Missouri as setting forth the duties of a pharmacist, relegating that section of the statute to definitional purposes only. *Id.* The court also rejected application to the case of section 338.015.2, which states: “All pharmacists *may* provide pharmaceutical consultation and advise to persons concerning the safe and therapeutic use of their prescription drugs” (emphasis added). *Id.* at 226. The court reasoned that the use of “may” in the statute allowed for discretion on the part of the pharmacist. *Id.* at 226. The court also found the standards imposed by the American Pharmaceutical Association to be insufficient, as non-legal authorities, to impose a legal duty on pharmacists. *Id.*; see also Samuel H. Kalman & John F. Schlegel, *Standards of Practice for the Profession of Pharmacy*, AM. PHARMACY, Mar. 1979, at 21. Despite the age of the standards, they have not been revised.

66. See *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514, 519 (Ind. 1994); *Pittman v. UpJohn Co.*, 890 S.W. 2d 425,435 (Tenn. 1994)

67. See, e.g., *Lasley v. Shrake’s Country Club Pharmacy*, 880 P.2d 1129, 1132–33 (Ariz. Ct. App. 1994). The Arizona Court of Appeals noted:

Health care providers and other professionals . . . are held to a higher standard of care than that of the ordinary prudent person when the alleged negligence involves the defendant’s area of expertise. . . . [T]he standard is based on “the usual conduct of other members of the defendant’s profession in similar circumstances” We impose this higher standard of care upon pharmacists because they are professionals in the health care area.

Id. (quoting *Bell v. Maricopa Med. Ctr.*, 755 P.2d 1180, 1182 (Ariz. Ct. App. 1988)).

(1) Knowledge Creates Duty

Courts may impose a duty to warn on a pharmacist if the pharmacist is aware or should be aware of additional information about a particular patient, such as that patient's prescription drug consumption. This duty originated long ago in cases like *Fuhs v. Barber*,⁶⁸ where a pharmacist recommended that a patient take a drug other than that prescribed by her physician which resulted in the patient's injury.⁶⁹ Similarly, the Supreme Court of New York held a pharmacist liable for failure to warn a known alcoholic patient against a drug's contraindication to alcohol in *Hand v. Krakowski*.⁷⁰ The court found that the pharmacist's failure to warn violated his duty of ordinary care.⁷¹ Additionally, the Illinois Supreme Court has found that pharmacists with certain knowledge have a duty to warn. In *Happel v. Wal-Mart Stores, Inc.*⁷² the defendant pharmacy knew of the patient's allergy to aspirin, but dispensed to her a drug that was specifically contraindicated for patients with an aspirin allergy.⁷³ The court stated that a factually specific "duty to warn exists where . . . a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger."⁷⁴

Courts will also impose a duty to warn on a pharmacist if the pharmacist is aware that a drug has particularly addictive propensities. For example, the Arizona Supreme Court, held that a pharmacist had a duty to warn of the addictive nature of a

68. 36 P.2d 962 (Kan. 1934).

69. "The court explained that pharmacists must act with extreme caution and prudence when instructing customers as to the use of their compounds . . . in such circumstances, even the slightest negligence may subject the pharmacist to liability." Huang, *supra* note 43, at 432 (discussing *Fuhs v. Barber*, 36 P.2d 962, 964 (1934)).

70. 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982).

71. *Id.*

72. 766 N.E.2d 1118, 1129 (Ill. 2002).

73. *Id.* at 1120.

74. *Id.* at 1129. The court relied heavily on the facts of the case, including the fact that the pharmacy computer system must have been manually overridden to allow the drug to be dispensed and such manual override first requires contacting a physician to confirm the prescription, which did not happen. *Id.* at 1121.

prescription drug in *Lasley v. Shrake's Country Club Pharmacy, Inc.*⁷⁵ The court reasoned that the pharmacist owed the patient a "duty of reasonable care" and that drug counseling fell within that reasonable duty.⁷⁶

(2) Duty of Reasonable Care

Many courts also hold pharmacists to a judicially imposed standard of care. For instance, in *Dooley v. Everett*,⁷⁷ the Tennessee Court of Appeals found a violation of a pharmacist's duty of care where the defendant pharmacy gave no warning to the physician or to the patient that a drug it dispensed was contraindicated for the asthma medication the patient was taking.⁷⁸ The court relied on an affidavit of a practicing pharmacist to determine the pharmacy industry's standard of care, which included warning patients of possible drug interactions.⁷⁹ Likewise, in *Riff v. Morgan Pharmacy*,⁸⁰ a court looked to the professional community to dictate an appropriate standard of care.⁸¹ In *Riff*, a pharmacist failed to instruct a patient as to the maximum dosage and possible risks of exceeding that dosage.⁸² Unaware of the danger associated with the drug, the patient exceeded the safe dosage and suffered injury.⁸³

75. 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994). Appellant's definition of the pharmacist's duty included "a responsibility to advise a customer of the addictive nature of a drug, to warn of the hazards of ingesting two or more drugs that adversely interact with one another, and to discuss with the physician the addictive nature of a prescribed drug and the dangers of long-term prescription of the drug." *Id.*

76. *Id.* at 1130.

77. 805 S.W.2d 380, 380 (Tenn. Ct. App. 1990).

78. *Id.* at 382.

79. *Id.* at 382-83, 385-86.

80. 508 A.2d 1247 (Pa. Super. Ct. 1986).

81. *Id.* at 1250-51. The court determined:

It is not for this Court to delineate the precise bounds of a medical professional's responsibilities. It is for the medical community to determine what degree of vigilance is required in this respect. They are in the best position to balance the interests and prescribe a standard of conduct which is consistent with the best interests of the patient.

Id. at 1253.

82. *Id.* at 1247.

83. *Id.* at 1249.

Missouri courts now adopt the modern approach to pharmacist liability. In *Horner v. Spalitto*,⁸⁴ a pharmacist filled a patient's prescription for a central nervous system drug at a rate three times the regular dose and a prescription for another central nervous system drug.⁸⁵ Because the pharmacist was aware that the first drug's effects were enhanced when taken with other central nervous system drugs, he called the prescribing physician before dispensing the drugs and the physician affirmed the prescriptions and the doses for the pharmacist.⁸⁶ The court stated that a "duty is an obligation imposed by law to conform to a standard of conduct toward another to protect others against unreasonable, foreseeable risks"⁸⁷ and that the pharmacist's duties could extend beyond accurately filling a prescription.⁸⁸ It determined that the pharmacist's duty changed with the circumstances of each particular case, but was always commensurate with the care and prudence "which a reasonably careful and prudent pharmacist would exercise."⁸⁹ The court did not determine if the pharmacist actually fulfilled his duty, leaving that determination to the jury on remand.⁹⁰ Instead, it stated that the pharmacist's duty in a particular case may require him to warn patients of the adverse effects of drug use.⁹¹ This case signals a change in the way the Missouri courts view the pharmacist's duty to warn.

(3) Assumption of Duty

Courts sometimes recognize that pharmacists voluntarily assume a duty to warn patients when they provide patients with detailed lists of warnings or when they advertise. For example, in *Cottam v. CVS Pharmacy*,⁹² the pharmacy had implemented a computer system

84. 1 S.W.3d 519 (Mo. Ct. App. 1999).

85. *Id.* at 520–21.

86. *Id.* at 521.

87. *Id.* at 522 (quoting *Hoover's Dairy Inc. v. Mid-America Dairymen, Inc.*, 700 S.W.2d 426, 431 (Mo. 1985)).

88. *Id.*

89. *Id.*

90. *Id.* at 522–24.

91. *Id.*

92. 764 N.E.2d 814 (Mass. 2002).

designed to provide its customers with written information about the risks and side effects of prescription drugs.⁹³ The court stated that when a pharmacy provides a “detailed list of warnings, or, by way of advertising, promises to provide customers with information, it may thereby undertake a duty to provide complete warnings and information.”⁹⁴ Similarly, in *Baker v. Arbor Drugs, Inc.*,⁹⁵ a pharmacy had used a computer system that detected contraindications in a patient’s prescription drug use.⁹⁶ The pharmacy advertised the system as one designed to detect harmful drug interactions.⁹⁷ The court found that the pharmacy voluntarily assumed a duty of care when it implemented the system and advertised to patients that this system would detect harmful drug interactions for its customers.⁹⁸

c. Pharmacists’ Statutory Duty

(1) OBRA 90 and State “Pharmacy Acts”

Some courts impose a duty to warn on pharmacists in reaction to the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).⁹⁹ OBRA 90 expands pharmacists’ traditional role and requires them to deliver direct patient care.¹⁰⁰ It requires pharmacists to discuss potential contraindications and possible interactions and how to avoid them with Medicaid patients.¹⁰¹ These requirements constitute

93. *Id.* at 818.

94. *Id.* at 823.

95. 544 N.W.2d 727 (Mich. Ct. App. 1996).

96. *Id.* at 729.

97. *Id.*

98. *Id.*

99. Pub. L. No. 101-508, 104 Stat. 1388 (codified in various sections of 42 U.S.C.). OBRA 90 requires pharmacists to become more active in patients’ drug programs through the implementation of drug use review (DUR) programs. *See* 42 U.S.C. § 1396r-8(g) (2003).

100. Judyth Pendell, *The Adverse Side Effects of Pharmaceutical Litigation*, AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES PUB., Sept. 2003, at 5.

101. OBRA 90 requires states to enact legislation imposing more stringent standards for pharmacists, including:

(1) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist’s professional judgment (consistent with State law respecting the provision of such information), the

additional statutory duties on pharmacists that do not exist in common law,¹⁰² and while OBRA 90 was designed to only apply to pharmacists serving Medicaid patients,¹⁰³ many states have extended OBRA 90 to cover all prescriptions dispensed by pharmacists.¹⁰⁴ Under the operation of each state's "Pharmacy Act,"¹⁰⁵ courts are more willing to attach liability to a pharmacist for failure to warn—even outside the Medicaid realm.¹⁰⁶

(2) APA Standards

The American Pharmaceutical Association's "Standards of Practice for the Profession of Pharmacy,"¹⁰⁷ which address the

pharmacist deems significant including the following:

- (aa) The name and description of the medication.
- (bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.
- (cc) Special directions and precautions for preparation, administration and use by the patient.
- (dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
- (ee) Techniques for self-monitoring drug therapy.
- (ff) Proper storage.
- (gg) Prescription refill information.
- (hh) Action to be taken in the event of a missed dose.

42 U.S.C. § 1396r-8(g)(2)(A)(ii) (2000).

102. Huang, *supra* note 43, at 434–35.

103. *Id.*, see also Owen, *supra* note 32, at 689.

104. See Michael J. Holleran, *The Pharmaceutical Access and Prudent Purchasing Act of 1990: Federal Law Shifts the Duty to Warn from the Physician to the Pharmacist*, 26 AKRON L. REV. 77, 79 (1992) (reasoning that once pharmacists are held to a higher standard for Medicaid patients, it would be absurd to hold them to a lower standard of care for non-Medicaid patients). Colorado, Connecticut, Hawaii, Minnesota, Puerto Rico, South Carolina and Wyoming were the only states or territories as of 1995 that did not require counseling for all patients. Owen, *supra* note 32, at 690 (citing the National Association of Boards of Pharmacy, 1994–95 NABP Survey of Pharmacy Law). Missouri's regulation became effective February 26, 1993. MO. CODE REGS. ANN. tit. 4, § 220-2.190 (2004).

105. 25 AM. JUR. 2D *Drugs and Controlled Substances* § 69 (1964).

106. Huang, *supra* note 43, at 435. For examples of "Pharmacy Acts," see KAN. STAT. ANN. § 65-636 (Supp. 2002); 63 PA. CONS. STAT. § 390-5 (2003). These provisions are also known as "Pharmacy Practice Acts," see, e.g., 225 ILL. COMP. STAT. 85/3 (2003).

107. Kalman, *supra* note 65.

pharmacist's practice in miniscule detail,¹⁰⁸ also place responsibility upon the pharmacist to counsel patients about any possible adverse effects of prescription drugs.¹⁰⁹ Additionally, individual state pharmaceutical associations have also adopted model standards of conduct which guide the pharmacist's duties.¹¹⁰ Many courts, however, reject the contention that these standards establish a pharmacist's legal duty to warn because they are simply not legal authorities.¹¹¹

(3) Missouri Statutory Duties

Neither Missouri's statutes nor its regulations limit the pharmacist's extended duties to Medicaid patients.¹¹² And despite the

108. *Id.* The Standards include "responsibilities related to general management and administration, processing the prescription, patient care, and education of other health care professionals and patients." Owen, *supra* note 32, at 691.

109. Kalman, *supra* note 65, at 31.

110. See, e.g., Montana Pharmacy Association, *Standards of Practice* (2003), available at <http://www.rxmt.org/stndofprac.pdf>. Montana's standards provide that counseling a patient should cover the following topics:

- 3.1.1.1 Name of the medication
- 3.1.1.2 Purpose of the medication
- 3.1.1.3 Dosage form
 - 3.1.2.1 Dosing schedule
 - 3.1.2.2 Duration of therapy
 - 3.1.2.3 Special directions
 - 3.1.2.4 Storage recommendations
 - 3.1.2.5 Missed dose information
 - 3.1.2.6 Refill information
- 3.1.3.1 Expected outcomes
- 3.1.3.2 Precautions
- 3.1.3.3 Common possible side effects
- 3.1.3.4 Possible interactions
- 3.1.3.5 Techniques for self-monitoring.

Id. § (II)(B)3.1.

For information on the Missouri State Board of Pharmacy, see generally <http://pr.mo.gov/pharmacists.asp> (last visited Oct. 28, 2004).

111. See *Adkins v. Mong*, 425 N.W.2d 151, 153 (Mich. Ct. App. 1988) (refusing to be influenced by non-legal authorities in light of persuasive case law); *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 226 (Mo. Ct. App. 1992) (rejecting the argument that non-legal authorities impose legal duties).

112. See MO. REV. STAT. §§ 338.010–198 (2003); MO. CODE REGS. ANN. tit. 4, §§ 220-2.010 to -2.900 (2003).

permissive language of the statutes,¹¹³ the regulations require pharmacists to counsel patients and to maintain patient information databases.¹¹⁴ These standards have forced a change in the way the Missouri courts view the pharmacist's duty to warn: the courts now adopt the modern approach to pharmacist liability.¹¹⁵

d. No Liability for Failure to Warn

Some courts continue to reject pharmacist liability for failure to warn. For instance, in *Stebbins v. Concord Wrigley Drugs, Inc.*,¹¹⁶ the court found that in dispensing drugs, a pharmacist had no duty to warn.¹¹⁷ And in *Adkins v. Mong*,¹¹⁸ the Michigan Court of Appeals relied on its sister jurisdictions' consistent rejection of a duty to find that pharmacists have no legal duty to intervene in the physician-patient relationship.¹¹⁹ These courts defend their choice to adhere to the traditional no-duty rule through the Learned Intermediary Doctrine or through public policy.

(1) Learned Intermediary Doctrine Applies

In *In re Rezulin Products Liability Litigation*,¹²⁰ a New York court found that Mississippi's Learned Intermediary Doctrine applied to claims against pharmacies for failing to warn of the dangers associated with the drug.¹²¹ The Supreme Court of Utah also agrees that the Learned Intermediary Doctrine must shield pharmacists to

113. See discussion *supra* note 65.

114. MO. CODE REGS. ANN. tit. 4, § 220-2.190 (2003). *Horner v. Spalitto*, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999).

115. See *Horner*, 1 S.W.3d at 522 (holding that duty, as a matter of law, is to "exercise the care and prudence that a reasonably careful and prudent pharmacist would exercise in the same or similar circumstances" and leaving the specific requirements of that duty to the fact-finder).

116. 416 N.W.2d 381 (Mich. Ct. App. 1987). In *Stebbins*, the pharmacist failed to warn a patient of the sedative side effects of a prescribed medication. *Id.* at 383.

117. *Id.* at 387-88 (Mich. Ct. App. 1987). The court relied on other jurisdictions' refusal to impose a duty to warn on pharmacists. *Id.*

118. 453 N.Y.S.2d 121 (N.Y. App. Div. 1982).

119. 425 N.W.2d at 154. In *Adkins*, a defendant pharmacist never warned a patient of the addictive nature of the prescription drug and the patient became severely addicted. *Id.* at 152.

120. 133 F. Supp. 2d 272, 272 (S.D.N.Y. 2001).

121. *Id.* at 288 (applying the Learned Intermediary Doctrine to shield pharmacists from liability for failing to warn).

preserve its efficacy in products liability law.¹²² And in *Fakhouri v. Taylor*,¹²³ an Illinois court found no duty to warn even when a pharmacist knew the drug dispensed had been prescribed in a dangerous quantity.¹²⁴ Using the Learned Intermediary Doctrine, the court found it illogical and unreasonable to impose a greater duty on a pharmacist than on the drug's manufacturer.¹²⁵ The court also refused to find such a duty in the Illinois Pharmacy Act.¹²⁶

(2) Public Policy

In *Coyle v. Richardson-Merrell, Inc.*,¹²⁷ the Supreme Court of Pennsylvania found that public policy precluded the imposition of a duty on a pharmacist to warn of risks of drugs that were already prescribed.¹²⁸ Although the plaintiffs alleged that the pharmacist should have informed them of the potential birth defects associated with an anti-nausea drug used during pregnancy, the court determined that such a requirement would undermine the physician-patient relationship and violate public policy.¹²⁹

III. ANALYSIS

A. Abrogation of Learned Intermediary Doctrine

The Learned Intermediary Doctrine is founded upon several assumptions about the relationship between patients and their physicians: physicians can best evaluate a patient's medical needs

122. *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 929 (Utah 2003). The court stated that "so long as a pharmacist's ability to distribute prescription drugs is limited by the highly restricted, FDA-regulated drug distribution system in this country, and a pharmacist cannot supply a patient with prescription drugs without an intervening physician's prescription, we will not impose a duty upon the pharmacist to warn of the risks associated with the use of prescription drugs." *Id.*

123. 618 N.E.2d 518 (Ill. Ct. App. 1993).

124. *Id.* at 519.

125. *Id.* at 521.

126. *Id.* at 521–22; see also Pharmacy Practice Act of 1987, 225 ILL. COMP. STAT. act 85 (2004).

127. 584 A.2d 1383, 1383 (Pa. 1991).

128. *Id.* at 1386.

129. *Id.*

and drug sensitivities,¹³⁰ patients may wish to participate in the decision as to whether or not to take a particular drug and wish to discuss that drug's risks with the physician,¹³¹ physicians can provide ongoing supervision of the patient's continued use of the drug,¹³² and physicians are best trained and best positioned to manage possible side effects that may occur as a result of taking a particular drug.¹³³ By creating a pharmacist's duty to warn, courts undermine the Doctrine's principles because the duty interferes with the physician-patient relationship¹³⁴ and damages the quality of pharmacist care.¹³⁵

B. Consequences of Duty to Warn

1. Over-Emphasized Risks

The application of a duty to warn to pharmacists undoubtedly increases their likelihood of being sued. Fear of litigation may incite pharmacist defensiveness and trigger an instinct of self-preservation.¹³⁶ Consequently, to avoid potential liability, the pharmacist may overemphasize the risks and seriousness of side effects of the drugs he dispenses.¹³⁷ Because patients already tend to worry about the warnings given to them by health care professionals and package inserts,¹³⁸ adding the pharmacist's hyperbolic warning to

130. Pendell, *supra* note 100, at 5.

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.* at 8.

135. Jennifer L. Smith, Note, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2002 HOUS. J. HEALTH L. & POL'Y 187, 189 (2002).

136. See Pendell, *supra* note 100, at 9.

137. *Id.* This is supported by statistical data. See Harris Interactive, *Pharmaceutical Liability Study Report on Findings*, July 15, 2003. The U.S. Chamber Institute for Legal Reform commissioned Harris Interactive to conduct a study among three target populations: physicians, pharmacists, and patients. The study centered on the issue of pharmaceutical product liability litigation and how it affected each of the three groups. The study is available at <http://www.legalreformnow.com/resources> (last visited Aug. 14, 2004). In fact, two in five pharmacists indicate that they over-emphasize the possible side effects of a drug for this very reason. *Id.*

138. Pendell, *supra* note 100, at 9–13 (discussing the effects of pharmaceutical litigation on patients); see also *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 467 (Tex. Ct. App. 2000) (finding that patients would be overwhelmed by warnings given by the pharmacist and not take

the decision-making process may cause patients to fear a risk that is non-existent, and may discourage them from taking a beneficial drug.¹³⁹

2. Decreased Quality of Care

An increased workload would erode the quality of the pharmacist's practice.¹⁴⁰ The increasing demand on pharmacists generates dissatisfaction with the profession, especially with regard to the pharmacist's ability or inability to counsel patients.¹⁴¹ Furthermore, a pharmacist's fear of liability will impose an even greater demand on the pharmacists, which correlates to errors in prescriptions and failure to counsel patients,¹⁴² leading to even more liability.

3. Interference in Physician-Patient Relationship

Imposing a duty to warn on pharmacists interferes with the sensitive physician-patient relationship.¹⁴³ Despite continual changes in pharmacist education, pharmacists still lack the education and the intimate knowledge of a patient's entire medical history necessary to competently advise the patient of the risks of taking a particular drug.¹⁴⁴ The duty to warn creates "antagonistic relations between

the medication prescribed by their doctors).

139. Pendell, *supra* note 100, at 9–13.

140. BUREAU OF HEALTH PROFESSIONS, DEP'T OF HEALTH AND HUMAN SERVS., THE PHARMACIST WORKFORCE: A STUDY OF THE SUPPLY AND DEMAND FOR PHARMACISTS 53–56 (2000), available at <ftp://ftp.hrsa.gov/bhpr/nationalcenter/pharmacy/pharmstudy.pdf> (last visited Oct. 5, 2004) [hereinafter THE PHARMACIST WORKFORCE]. Pharmacists now operate out of community retail centers and work almost forty-five hours per week filling an average of 182 prescriptions per day. *Id.*

141. Harris Fleming, Jr., *No Rest for the Weary*, DRUG TOPICS, June 21, 1999, at 39 (discussing a Drug Topics/Hospital Pharmacist Report Time/Workload Study).

142. THE PHARMACIST WORKFORCE, *supra* note 140, at 73 (identifying reports that increasing demands on pharmacists lead to increased errors in their practices).

143. For cases in which the court expresses this concern, see, e.g., Fakhouri v. Taylor, 618 N.E.2d 518, 521 (Ill. Ct. App. 1993); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1385–86 (Pa. 1991); Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 467 (Tex. Ct. App. 2000); McKee v. Am. Home Prods. Corp., 782 P.2d 1045, 1051 (Wash. 1989).

144. See Smith, *supra* note 135, at 211–12 (discussing the trends in expanding education of pharmacists).

pharmacists and physicians” as they compete for an accurate and appropriate remedy for a patient’s medical condition.¹⁴⁵ And while some courts believe a duty to warn would promote camaraderie and encourage pharmacists and physicians to work together,¹⁴⁶ a rivalry is much more likely.¹⁴⁷

4. Increased Cost

Exposing pharmacists to increased liability increases their costs of doing business because of the high litigation defense expenses. Costs of litigation naturally increase costs of health care—not only patients’ insurance rates,¹⁴⁸ but also medical malpractice premiums.¹⁴⁹ Those searching for answers have “targeted trial lawyers, accompanied by anecdotal allegations of frivolous lawsuits and run-away juries awarding outlandish judgments.”¹⁵⁰

145. *McKee*, 782 P.2d at 1053 (deciding that this antagonism would result from pharmacists constantly questioning every prescription they fill).

146. *See, e.g.*, *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514, 519 (Ind. 1994) (positing that working together serves the best interests of the patient).

147. The same rivalry exists between physicians and pharmaceutical manufacturers. Physicians and pharmaceutical manufacturers are supposed to work together for the common good of the patients who use prescription drugs. The recent trend however, is quite the opposite. The pressure on physicians from litigious patients has become too much to bear; physicians are more willing to blame drug manufacturers than before. Physicians now assert claims against these manufacturers under several different theories of liability including economic loss, tort, consumer protection and deceptive trade practices, and other fraud and contract based claims. *See generally* Edward J. Sebold & John Q. Lewis, *Physician Suits Against Pharmaceutical and Medical Device Manufacturers: Friend Turned Foe?*, MEALEY’S EMERGING DRUGS AND DEVICES, July 20, 2002.

148. *See* Jeanne Schulte Scott, *Malpractice Reform Is Dead; Long Live Malpractice Reform*, 57 HEALTHCARE FIN. MGMT. 32 (2003) [hereinafter Scott, *Malpractice*]. In a recent report, the United States General Accounting Office (GAO) found that losses from medical malpractice litigation, both in judgments and settlements, made up the largest part of insurers’ costs. U.S. GEN. ACCOUNTING OFFICE, *MEDICAL MALPRACTICE INSURANCE 16* (2003), available at <http://www.gao.gov/new.items/d03702.pdf>. According to the GAO, these costs have been the primary cause of rate increases over the long run. *Id.* Jeanne Schulte Scott, a health care lobbyist in Washington D.C., suggests a solution: a true “no-fault” medical malpractice indemnity system which “needs to be resurrected from the ashes of the 1993 Clinton health plan.” Scott, *Malpractice, supra*, at 32. While such drastic action may not be necessary, medical malpractice litigation reform remains a hot political topic and pharmacist liability for failure to warn plays a part in the discussion.

149. *Id.*

150. *Id.*

IV. PROPOSAL

The best way for courts to address a pharmacist's liability for failing to warn patients of adverse effects of prescription drugs is to modify the general no-duty rule.¹⁵¹ In the United States, we refuse to impose liability for negligence where the alleged tortfeasor owes no duty to the injured party.¹⁵² For example, courts traditionally have held that there is no affirmative duty to rescue even if such rescue would not negatively affect the rescuer.¹⁵³

Pharmacists should have no general affirmative duty to warn,¹⁵⁴ however, pharmacists may assume a duty to warn by voluntarily counseling patients or by advertising an ability to detect and prevent the harmful effects of prescription drugs.¹⁵⁵ This assumed duty would then subject pharmacists to negligence liability. Simply not warning a patient about a prescription's adverse effects would be nonfeasance, for which no liability would be imposed.¹⁵⁶ Affirmatively warning inadequately or incorrectly would be misfeasance, for which liability would be imposed.¹⁵⁷

Taking this proposal one step further, the standard of care to which pharmacists should be held once they assume the duty to warn a patient of the harmful effects of drugs should be a professional

151. This proposal, of course, presumes no statutory impediment to the court's analysis. I advocate the same approach for the statutory duty as I do for the common law; however, the focus of this proposal is on the *court's* approach to pharmacist liability for failure to warn.

152. *Rudolph v. Arizona B.A.S.S. Fed'n*, 898 P.2d 1000, 1002 (Ariz. Ct. App. 1995) (finding that a defendant who does not owe a duty to a plaintiff cannot be liable for the plaintiff's injury even if the defendant acted negligently).

153. See, e.g., *Jackson v. City of Joliet*, 715 F.2d 1200, 1202 (7th Cir. 1983) (finding no general common law duty to rescue a stranger in distress, even absent any cost to the rescuer). Courts draw a distinction between misfeasance and nonfeasance to reach this result. See John M. Adler, *Relying upon the Reasonableness of Strangers: Some Observations About the Current State of Common Law Affirmative Duties to Aid or Protect Others*, WIS. L. REV. 867, 872 (1991) ("The common law's reluctance to require one to render aid to a stranger rests upon the distinction between misfeasance and nonfeasance.") (footnote omitted). Misfeasance requires affirmative action while nonfeasance is simply failure to act. Section 314 of the Restatement (Second) of Torts similarly adopts this reasoning.

154. See discussion *supra* Part III for support of this notion.

155. In the future, courts may determine other methods by which pharmacists assume a duty to warn, but voluntary counseling and service advertising are the two most frequent ways courts have already recognized an assumed duty on the part of the pharmacist.

156. See *supra* note 153.

157. See *id.*

standard of care.¹⁵⁸ This approach would liken pharmacists professionally to physicians, recognizing the industry's professional progress, without allowing pharmacists to usurp the role of the physician. Courts could use industry custom and conduct to determine what should and should not have been done upon assuming the duty to warn.¹⁵⁹ This method would also allow pharmacists and patients to make a choice regarding the type of pharmacist care they desire: if pharmacists wish to professionalize their practice, they must be willing to subject themselves to negligence liability; if patients desire professional pharmacist care, they must be willing to absorb the additional costs of the liability imposed on their pharmacists.¹⁶⁰ This modified general no-duty rule is a compromise between traditional common law immunity and modern common law increased liability. Such a doctrine keeps the pharmacist from interfering in the physician-patient relationship while maintaining the equilibrium between quality care and affordable cost in the health care system.

V. CONCLUSION

The pharmacists' role in the health care industry continues to evolve as does the imposition of liability on pharmacists for failure to warn patients of the adverse effects of prescription drugs.¹⁶¹ The modern litigation trend finds more and more ways to hold a pharmacist liable for this failure to warn.¹⁶² To prevent interference in

158. Negligence law treats professionals differently than "non-professionals". See generally DOMINICK VETRI ET AL., *TORT LAW AND PRACTICE* 189–209 (2d ed. 2002). An example of the professional standard of care is "a degree of care, skill and proficiency exercised by reasonably careful, skillful, and prudent practitioners in the same class to which he belongs, acting under the same or similar circumstances." *Vergara v. Doan*, 593 N.E.2d 185, 186 (Ind. 1992).

159. For professionals, custom sets the standard of care and deviation from that custom constitutes breach of duty. Custom evidence is conclusive in establishing the standard of care. See VETRI, *supra* note 158, at 189.

160. Regardless of this choice, prescribing physicians must still warn patients of a drug's adverse effects and drug manufacturers must still provide package inserts. So, patients will still have two remaining sources for this information if they choose a non-professional pharmacist.

161. 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, 1474–75 (1991).

162. See discussion *supra* Part II.B.3.b.

the delicate physician-patient relationship and to prevent the unbalancing of the current health care system, this expanded liability must have limits. Through a modified general no-duty rule, pharmacists may still be held liable in negligence for duties they assume by voluntary counseling or by advertising their services. Meanwhile, pharmacists who cannot undertake these additional tasks face no fear of additional liability. The modified general no-duty rule is an adequate compromise.