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PHARMACIST LIABILITY: THE DOORS OF LITIGATION ARE OPENING

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I. INTRODUCTION

"Danger at the drugstore: Too many pharmacists fail to protect consumers against potentially hazardous interactions of prescription drugs."[1]

Headlines such as this from *U.S. News & World Report* indicate an increasing awareness that pharmacists have a much greater role in health care today than ever before.[2] The days when a pharmacist's sole duty consisted of accurately filling and dispensing prescriptions are gone.[3] Today, pharmacists take on a more active role in the health care system,[4] encompassing more responsibilities and consequently greater liabilities.[5]

Until recently, successful litigation against pharmacists who correctly filled prescriptions was virtually nonexistent.[6] Attempts to impose liability upon pharmacists under theories of strict liability,[7] duty to warn,[8] and breach of warranty[9] were

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1. Susan Headden et al., *Danger at the Drugstore*, U.S. NEWS & WORLD REPORT, Aug. 26, 1996, at 46.

2. *See id.*

3. *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 (1991).

4. *See* discussion *infra* Part II.B.

5. *See* discussion *infra* Part IV.

6. *See* discussion *infra* Part II.A.

7. *See* discussion *infra* Part II.A.2.

8. *See* discussion *infra* Part II.A.3.

9. *See* discussion *infra* Part II.A.4.

largely unsuccessful.[10] However, recent changes in legislation,[11] case law,[12] and pharmacists' new role in health care[13] have increased pharmacists' liabilities.[14]

In 1990, Congress enacted the Omnibus Budget Reconciliation Act ("OBRA 90"), which codified the duties of pharmacists and required states to implement new programs to provide better patient care.[15] OBRA 90 requires pharmacists to monitor patients' drug therapy, intervene (i.e., suggest changes to drug therapy to optimize patient care) when necessary, and provide patient education prior to dispensing prescriptions.[16]

In 1994, the Arizona Court of Appeals asserted that the prior "no duty to warn" cases were wrongly decided.[17] In *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[18] the court concluded that the prior courts had misinterpreted the meaning of the duty to warn and confused it with the pharmacist's standard of care.[19] Two years later, in *Baker v. Arbor Drugs, Inc.*,[20] the Michigan Court of Appeals ruled that a pharmacy may voluntarily assume a duty to warn its customers.[21] In *Baker*, the court held that the defendant pharmacy had voluntarily assumed a duty to warn and to prevent harmful drug interactions when it advertised and promoted this

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10. *See* discussion *infra* Part II.A.2–4.

11. *See* discussion *infra* Part II.B.3.

12. *See* discussion *infra* Part II.B.1.

13. *See* discussion *infra* Part II.B.4.

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

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

16. *See* 42 U.S.C. § 1396r-8(g)(1)(A) (1994).

17. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994).

18. *Id.* at 1132.

> In response to Shrake's motion to dismiss, appellants presented an affidavit from an expert stating that the standard of care applicable to a pharmacist includes 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. at 1134.

19. *See id.* The court concluded that pharmacists owe a duty of reasonable care and left it for the trial court to determine what standard of care to apply. *See id.* at 1132–33.

20. Baker v. Arbor Drugs, Inc., 544 N.W.2d 727 (Mich. Ct. App. 1996).

21. *See id.* at 731.

ability to its customers.[22] These recent court decisions, as well as the expanding role of pharmacists in health care today,[23] demonstrate the need for courts to reevaluate the traditional limits on pharmacist liability.[24]

Part II of this comment traces pharmacist liability from its traditional bases[25] to the most recent court decisions.[26] Part III presents the issue of whether to expand pharmacist liability based on the changes in the pharmacy profession.[27] Part IV provides an analysis of recent changes in case law,[28] pharmacy law,[29] and the pharmacy profession[30] that contribute to the increase in pharmacists' liability. Consistent with the active role pharmacists perform in health care delivery today,[31] Part V proposes abandoning the traditional limits on pharmacist liability.

II. BACKGROUND

A. *The Traditional Role and Liability of Pharmacists*

Pharmacists have always occupied an important position in the drug distribution system by ensuring the accurate delivery of prescription drugs.[32] The need for accuracy resulted in pharmacist liability as a matter of law for errors in filling prescriptions. However, courts have traditionally found no pharmacist liability when a prescription is filled accurately.[33]

This section discusses the traditional bases of pharmacist liability: no strict liability, no liability for a pharmacist's failure to warn of a drug's adverse effects, and no liability under breach of warranty theories.[34] Next, this section addresses the recent case law and legislation that attack the traditional

22. *See id.*
23. *See* discussion *infra* Part II.B.4.
24. *See* discussion *infra* Part II.A.
25. *See* discussion *infra* Part II.A.
26. *See* discussion *infra* Part II.B.1–2.
27. *See* discussion *infra* Part III.
28. *See* discussion *infra* Part IV.C.
29. *See* discussion *infra* Part IV.C.1.
30. *See* discussion *infra* Part IV.
31. *See* discussion *infra* Part IV.
32. *See* David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439 (1996).
33. *See id.*
34. *See* discussion *infra* Part II.A.2–4.

notions of pharmacist liability by finding pharmacists liable for failure to warn of adverse drug effects.[35] Finally, this section examines the changing role of pharmacists in health care today and the effects of that change on pharmacists' liability.[36]

1. *Pharmacists Are Liable as a Matter of Law for Errors Filling Prescriptions*

Traditionally, pharmacists were responsible for the accurate processing of prescription orders—assuring that the right patient receives the correct drug, dosage, and directions for use.[37] This technical approach reflects the lack of independent judgment in the pharmacist's traditional role by holding pharmacists liable for all errors made when filling prescriptions.[38] This traditional role of pharmacists usually results in negligence as a matter of law for any such errors.[39]

In an oft-cited 1971 wrongful birth case, *Troppi v. Scarf*,[40] a pharmacist negligently filled a prescription for birth control pills with the wrong medication.[41] As a result of this error, the plaintiff became pregnant and gave birth to a healthy child.[42] The Michigan Court of Appeals held that the pharmacist had an absolute duty to dispense the correct drug, and was therefore liable for the "harm" resulting from dispensing the wrong medication.[43]

Courts also recognize that, in addition to filling prescriptions without error, a pharmacist may have a duty to verify, or refuse to fill, a prescription that contains a patent or obvious error on its face.[44] In *Nichols v. Central Merchandise*,[45] a Kansas appellate court stated that a pharmacist has a duty not only to fill prescriptions accurately, but also to be alert for

35. *See* discussion *infra* Part II.B.1–2.
36. *See* discussion *infra* Part II.B.3–4.
37. *See* Brushwood, *supra* note 32, at 443.
38. *See id.*
39. *See* DeCordova v. State, 878 P.2d 73, 76 (Colo. Ct. App. 1994).
40. Troppi v. Scarf, 187 N.W.2d 511 (Mich. Ct. App. 1971).
41. *See id.* at 512.
42. *See id.* at 513.
43. *See id.*
44. *See, e.g.*, McKee v. American Home Prods. Corp., 782 P.2d 1045, 1049 (Wash. 1989).
45. Nichols v. Central Merchandise, Inc., 817 P.2d 1131 (Kan. Ct. App. 1991).

clear errors or mistakes on the face of a prescription.[46] According to the *Nichols* court, because there were no clear errors on the face of the plaintiff's prescription, such as inadequate instructions or an inappropriate medication, the pharmacist did not violate any legal duties to the patient.[47]

2. *No Strict Liability for Injuries When a Prescription Is Accurately Filled*

A majority of courts refuse to hold pharmacists who accurately fill prescriptions strictly liable for injuries to patients caused by defective drugs.[48] Prescription medications, as consumer products, traditionally have been viewed as an exception to the usual product liability rules.[49] Product liability in drug injury cases is usually characterized by substantial deference to both drug manufacturers and pharmacies.[50] The courts justify their deferential treatment of pharmacies by defining pharmacists as service providers of drugs, as opposed to retail sellers of drugs.[51] Historically, courts usually exempt service providers from the rigors of strict liability.[52]

In addition to classifying pharmacists as service providers and not sellers of medications, courts compare pharmacists to drug manufacturers, who are not subject to strict liability.[53] Pharmacists, as suppliers, cannot choose what drug to make available to consumers, nor can patients, as consumers, freely choose which drug to buy.[54] In the restricted dis-

46. *See id.* at 1133.

47. *See id.* at 1133–34.

48. *See, e.g.*, Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988) (concluding strict liability upon pharmacist to be illogical and inequitable); Kampe v. Howard Stark Prof'l Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct. App. 1992) (holding that a pharmacist's duty is fulfilled by properly filling a legally written prescription); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App. 1977) (refusing to apply strict liability for injuries resulting from the use of a drug that was dispensed in strict compliance with the physician's order).

49. *See* Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 200–01 (1987).

50. *See id.* at 199–201.

51. *See* McLeod v. W.S. Merrell Co., 167 So. 2d 901, 903 (Fla. Dist. Ct. App. 1964) (holding that a pharmacist performs a service as opposed to a sale).

52. *See Leesley*, 518 N.E.2d at 762; *Kampe*, 841 S.W.2d at 223; *Batiste*, 231 S.E.2d at 275.

53. *See* Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991).

54. *See id.*

tribution system of prescription drugs, the public is not forced to rely on pharmacists to obtain the products it needs.[55]

Finally, patients rely on their physicians to assess the risks inherent in prescription drugs.[56] Since a pharmacist cannot substitute his judgment for that of the physician, holding pharmacists strictly liable would provide no safety incentive for patients.[57] Pharmacists' lack of influence over the marketing of prescription drugs argues against strict liability, which assumes that retailers pressuring manufacturers will provide safety incentives.[58] Thus, when a pharmacist dispenses medication in accordance with a validly written prescription, and such medication causes injury to a patient due to a defect, the pharmacist usually avoids strict liability.[59]

3. *No Duty to Warn of a Medication's Adverse Effects*

In addition to the service provider exception for pharmacists,[60] two rules limit applying strict liability to pharmacists who accurately fill prescriptions. The first is the prescription drug exception for products considered "unavoidably unsafe." The second is the learned intermediary doctrine, which exempts both pharmacists and drug manufacturers from liability for failure to warn and places upon prescribing physicians the responsibility of warning patients of the potential risks of a prescription drug.[61] The drafters of the Restatement of

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55. *See id.*

56. *See id.*

57. *See id.* at 1138.

58. *See generally*, David B. Brushwood & Richard R. Abood, *Strict Liability in Tort: Appropriateness of the Theory for Retail Pharmacists*, 42 FOOD DRUG COSM. L.J. 269 (1987).

59. Although the American Law Institute provides for strict liability of the seller of a product in the Restatement (Second) of Torts section 402A, comment k to section 402A provides an exception for retail pharmacists. Comment k provides: "There are some [drugs] which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). As such, the seller of such a product will avoid strict liability. Comment k effectively provides a defense for manufacturers as well as any other "sellers" of unavoidably unsafe drugs. *See id.*

60. *See* Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988); Kampe v. Howard Stark Prof'l Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct. App. 1992); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App. 1977).

61. *See* Kathy Laughter Laizure, Note, *The Pharmacist's Duty to Warn When Dispensing Prescription Drugs: Recent Tennessee Developments*, 22 MEM.

Torts created the unavoidably unsafe exception out of deference to vital medications, such as antibiotics and vaccines, that offer substantial benefits to public health.[62] The learned intermediary doctrine derives from the theory that physicians are in the best position to choose the appropriate medication and advise patients of the inherent risks of treatment.[63]

Applying the unavoidably unsafe exception and the learned intermediary doctrine, most courts find that pharmacists owe no duty to warn patients of the inherent risks of drugs.[64] The majority of courts identify physicians, the learned intermediaries between manufacturers and patients, as the proper medical professionals to warn patients of the possible risks of prescription drugs.[65] Thus, the sole obligation of pharmacists is merely to dispense prescriptions accurately,[66] with the absence of any error effectively immunizing pharmacists from liability.[67]

a. *The* Stebbins *Case*

In the 1987 case of *Stebbins v. Concord Wrigley Drugs, Inc.*,[68] the plaintiff alleged that she sustained injuries as a result of the failure of a physician and pharmacist to warn her of the sedative side effects of a prescribed medication.[69] The court affirmed summary judgment of the negligence claim in favor of the pharmacy on the grounds that the dispensing

ST. U. L. REV. 517, 522–26 (1992).

62. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k.

63. *See* Gibbs & Mackler, *supra* note 49, at 198.

64. *See* Pysz v. Henry's Drug Store, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984) (holding that it is the physician's duty to know the drug and properly monitor the patient); *Leesley*, 518 N.E.2d at 763 (declining to subject pharmacists to liability for failing to give warnings when a physician has not requested warnings); Adkins v. Mong, 425 N.W.2d 151, 154 (Mich. Ct. App. 1988) (concluding a pharmacist has no duty to monitor or intervene with a customer's reliance on drugs prescribed by a physician); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387–88 (Mich. Ct. App. 1987) (holding a pharmacist owes no duty to warn of possible side effects of a prescription where the prescription is proper on its face and neither the physician nor manufacturer has required any warning be given to the patient by the pharmacist).

65. *See supra* note 64.

66. *See Stebbins*, 416 N.W.2d at 387–88.

67. *See Leesley*, 518 N.E.2d at 760 (applying the learned intermediary doctrine to pharmacists); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 274 (N.C. Ct. App. 1977) (holding that without an allegation that the drug dispensed differed from the drug prescribed, the pharmacist escapes liability).

68. *Stebbins*, 416 N.W.2d at 381.

69. *See id.* at 383.

pharmacist had no duty to warn the plaintiff of the potential side effects of the drug.[70] Finding no authority within its jurisdiction regarding a pharmacist's duty to warn patients directly, the court relied on other jurisdictions' failure to impose such a duty in granting summary judgement.[71]

b. *The* Adkins *Case*

Generally, the physician is still viewed as the only health care professional with the duty to warn.[72] In *Adkins v. Mong*,[73] the plaintiff alleged negligence and malpractice on the part of a pharmacist for supplying the plaintiff with excessive amounts of prescription drugs over a six-year period, which resulted in severe drug addiction.[74] The plaintiff asserted that the pharmacist's failure to warn of the addictive nature of the drugs resulted in his addiction.[75] Further, the plaintiff claimed the pharmacist had a duty to monitor patients. Specifically, the plaintiff alleged that the pharmacist should maintain a detailed and accurate patient profile, use this profile to identify addicted customers, and act on this information by either refusing to fill prescriptions, notifying the physician, or warning the customer.[76]

The *Adkins* court looked to other jurisdictions to address the issue of whether the pharmacist owed such a duty.[77] The court concluded that other jurisdictions consistently reject the existence of this duty, holding that pharmacists owe no duty to warn.[78] The court held that "there exists no legal duty on the part of a pharmacist to monitor and intervene with a customer's reliance on drugs prescribed by a licensed treating physician."[79]

70. *See id.* at 387.
71. *See id.* (conceding that while a pharmacist may have greater knowledge of a drug's propensities, it is still the physician's duty to know the drug prescribed and to monitor and warn).
72. *See id.*
73. Adkins v. Mong, 425 N.W.2d 151 (Mich. Ct. App. 1988).
74. *See id.* at 152.
75. *See id.*
76. *See id.*
77. *See id.* at 152–53.
78. *See id.* at 154.
79. *Adkins*, 425 N.W.2d at 154.

c. *The* McKee *Case*

A year later, based on facts similar to *Adkins*, the court in *McKee v. American Home Products Corp.*[80] held that a pharmacist who accurately filled a prescription issued by a licensed physician had no duty to warn the customer of the potential hazards associated with the drug.[81] The plaintiff in *McKee* brought a negligence action against pharmacists who correctly filled her validly written prescriptions for amphetamines over the course of a ten-year period.[82] The plaintiff asserted that the pharmacists were negligent for dispensing the drugs over such an extended period of time without warning her of the serious side effects, including the drug's abuse and addictive potential.[83]

The *McKee* court took the position that a supplier of drugs has no "duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug."[84] The court held that under the learned intermediary doctrine,[85] the physician, rather than the pharmacist, should (1) be aware of the risks and benefits of drug therapy, (2) use this knowledge to determine the best course of therapy for the patient, and (3) apprise the patient of any potential hazards of therapy.[86] Further, the court noted that imposing a duty to warn upon pharmacists would (1) impose liability on pharmacists who have no legal authority to select the appropriate drug therapy for patients, (2) force pharmacists to intervene in matters where only physicians are competent, and (3) interfere with the physician-patient relationship by requiring pharmacists to practice medicine without a license.[87]

Finding no general duty to warn, the *McKee* court addressed whether actual or constructive knowledge of the inappropriateness of prolonged drug treatment should affect the duty to warn.[88] While the court found that pharmacists

80. McKee v. American Home Prods. Corp., 782 P.2d 1045 (Wash. 1989).
81. *See id.* at 1055–56.
82. *See id.* at 1047.
83. *See id.*
84. *Id.* at 1055–56.
85. *See* Leesley v. West, 518 N.E.2d 758, 760 (Ill. App. Ct. 1988).
86. *See McKee*, 782 P.2d at 1049–50.
87. *See id.* at 1050–53.
88. *See id.* at 1052.

should be alert for obvious or known errors in a prescription,[89] it recognized that without access to a patient's complete medical history, a pharmacist may not know that a particular drug is contraindicated.[90] Further, the court emphasized that without the benefit of this medical history, a pharmacist cannot determine the propriety of a particular drug regimen.[91] Finally, the court stated that the duty to warn a patient of the dangerous propensities of a prescription drug rests solely with the prescribing physician, not the pharmacist.[92]

d. *The* Coyle *Case*

In *Coyle v. Richardson-Merrell, Inc.*,[93] a 1991 case rejecting the pharmacist's duty to warn, the plaintiffs argued that their pharmacist had a duty to warn them about the potential birth defects associated with an anti-nausea drug used during pregnancy.[94] In rejecting the duty to warn, the court stated:

> While the patient is entitled to know, and a doctor has a duty to inform the patient of any dangers or side effects associated with a drug recommended for treatment, we see no sound reason for imposing on pharmacists the duty to supply information about the risks of drugs that have already been prescribed. On the contrary, such a rule would have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing.[95]

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89. *See id.* Examples of patent errors pharmacists should be aware of include "obvious lethal dosages, inadequacies in instructions, known contraindications, or incompatible prescriptions." *Id.* at 1053 (citations omitted).

90. *See id.* at 1053. A contraindication is "any condition which renders a particular line of treatment improper or undesirable." DORLAND'S POCKET MEDICAL DICTIONARY 166 (23d ed. 1982).

91. *See McKee*, 782 P.2d at 1053.

> A prescription which is excessive for one patient may be entirely reasonable for the treatment of another. To fulfill the duty which the plaintiff urges us to impose would require the pharmacist to learn the customer's condition . . . . To accomplish this, the pharmacist would have to interject himself into the doctor-patient relationship and practice medicine without a license.

Id. at 1053 (quoting Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 553 (Ill. App. Ct. 1985)).

92. *See id.*

93. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991).

94. *See id.* at 1384. The plaintiffs were the parents of a child born with malformed limbs allegedly caused by the anti-nausea drug Bendectin, a prescription drug manufactured by Merrell Dow. *See id.*

95. *Id.* at 1386.

In other words, requiring pharmacists to warn could confuse patients. Specifically, such a duty would interject individuals who do not have access to patients' medical history into the drug dispensing process after their physicians already provided the necessary warnings.[96]

4. *No Liability Under Breach of Warranty Theories*

Despite recognizing the pharmacist as a service provider and not a seller of drugs,[97] and acknowledging the majority view that pharmacists have no duty to warn,[98] some courts nevertheless attempt to apply the Uniform Commercial Code ("U.C.C.") to pharmacist-patient transactions.[99] Courts apply breach of implied and express warranties under the U.C.C. to impose liability upon pharmacists.[100]

a. *No Liability Under an Express Warranty*

Under the express warranty theory, a consumer may hold a seller liable if the seller expressly warrants that the product is as promised or described.[101] Holding pharmacists liable under an express warranty theory, however, usually fails.[102]

Two critical elements of express warranties are not present in the normal pharmacist-patient interaction.[103] First, for an express warranty to apply, the pharmacist must give express assurances to the patient that the product is not defective.[104] Such assurances are rare in the typical pharmacy-patient interaction.[105] Second, the necessary "basis of the

96. *See id.* at 1387.

97. *See supra* note 48 and accompanying text.

98. *See supra* Part II.A.3.

99. Article Two of the Uniform Commercial Code (U.C.C.) governs the sale of goods. It states that a "[s]eller means a person who sells or contracts to sell goods." U.C.C. § 2-103(d) (1978). Additionally, a "sale consists in the passing of title from the seller to the buyer for a price." U.C.C. § 2-106(1).

100. *See* Leesley v. West, 518 N.E.2d 758 (Ill. App. Ct. 1988); Batiste v. American Home Prods. Corp., 231 S.E.2d 269 (N.C. Ct. App. 1977); Makripodis v. Merrell Dow Pharm., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987).

101. The express warranties provide: "Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." U.C.C. § 2-313(1)(a).

102. *See infra* note 109.

103. *See infra* note 109.

104. *See* U.C.C. § 2-313(1)(a).

105. Since drug companies compound the typical prescription outside of the pharmacy, a pharmacist cannot assure that the drug is free of defects.

bargain" is seldom established between the pharmacist and patient[106] since the pharmacist does not induce the patient to purchase the medication. Without these two elements of express warranties, there can be no liability for pharmacists under an express warranty theory.[107]

b. *No Liability Under an Implied Warranty of Merchantability*

As a result of the difficulty with invoking the express warranty provision of the U.C.C., some plaintiffs assert claims based on a theory of implied warranty.[108] The implied warranty of merchantability[109] (i.e., that the goods are fit for their ordinary purpose) and the implied warranty of fitness[110] (i.e., that the goods are fit for a particular purpose) arise when goods are sold by a merchant in the business of selling such goods. Actions against a pharmacist to recover damages from a defective drug based on these implied warranties fail.[111]

Courts reject the implied warranty theories on three different bases. First, the existence of an implied warranty of fitness for a particular purpose requires a customer's reliance on the seller's skill and judgment in providing a suitable product.[112] Since the patient relies only on the physician's judgment, no liability arises for the pharmacist based on this implied warranty.[113]

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106. *See* U.C.C. § 2-313(1)(a).

107. The main flaw in the "basis of the bargain" theory is that the pharmacist does not select the medication for the patient and, as such, is only providing a service rather than acting as a seller. *See* Sparks v. Kroger Co., 407 S.E.2d 105 (Ga. Ct. App. 1991).

108. *See* McCleod v. W.S. Merrell Co., 174 So. 2d 736 (Fla. 1965); Batiste v. American Home Prods. Corp., 231 S.E.2d 269 (N.C. Ct. App. 1977); Makripodis v. Merrell Dow Pharm., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987).

109. *See* U.C.C. § 2-314. The implied warranty of merchantability is defined as "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." *Id.*

110. *See* U.C.C. § 2-315. The implied warranty of fitness states:

> Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

Id.

111. *See supra* note 100.

112. *See* U.C.C. § 2-315.

113. *See, e.g., McCleod*, 174 So. 2d at 738; *Batiste*, 231 S.E.2d at 276.

Second, there is no single "ordinary purpose"[114] to warrant a prescription drug. The particular purpose for any drug depends upon the physician's assessment of the fitness of the drug for a given patient's medical condition.[115] Therefore, a pharmacist's warranty could only be to ensure that a given prescription is correctly labeled and dispensed according to the physician's directions.[116]

Finally, courts reject the implied warranty theories by defining the dispensing pharmacist as a provider of services and not a seller of drugs.[117] As a provider of services, rather than a merchant of goods, no implied warranty arises as a result of the sale of a prescription drug.[118]

B. *Pharmacists' Liabilities Increase as Pharmacists' Duties Expand*

Over the last decade, the tradition of granting immunity to pharmacists who accurately process prescriptions has eroded.[119] With this erosion, pharmacists have become recognized as vital, proactive professionals in the health care field.[120]

Of course, pharmacists must continue to be error-free in the processing of prescriptions. Furthermore, they must become increasingly prescription "gatekeepers," assuring the appropriate use of medications and consulting with physicians to clarify and remedy any potential problems with prescribed medications.[121] With this new gatekeeping role, a minority of courts require pharmacists to provide patients with appropriate warnings regarding potential adverse conse-

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114. *See* U.C.C. § 2-314(c).

115. *See supra* note 100.

116. *See* Makripodis v. Merrell Dow Pharm., Inc., 523 A.2d 374, 377 (Pa. Super. Ct. 1987).

117. *See, e.g.*, Murphy v. E.R. Squibb & Sons, Inc., 710 P.2d 247, 252 (Cal. 1985).

118. *See id.* at 253.

119. *See, e.g.*, Hooks SuperX, Inc., v. McLaughlin, 642 N.E.2d 514, 519 (Ind. 1994) (recognizing that pharmacists also have a duty to further society's goal of preventing the overuse and misuse of prescription drugs); Pittman v. Upjohn Co., 890 S.W.2d. 425, 435 (Tenn. 1994) (finding a pharmacy has a duty to warn of dangerous drug propensity when no warning had been given by a physician).

120. *See* Laizure, *supra* note 61, at 535 (reviewing a higher standard of care to which professionals are held in their field, and finding pharmacists, as trained professionals, are held to this professional standard of care).

121. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994).

quences of prescription medications.[122]

1. *Pharmacists Have a Duty to Warn of a Prescription's Adverse Effects*

a. *The* Dooley *Case*

In 1990, the Tennessee Court of Appeals departed from the no-duty-to-warn line of cases.[123] The plaintiffs in *Dooley v. Everett*[124] were the parents of a child diagnosed with asthma who suffered irreversible neurological injuries due to ingesting toxic levels of an asthma medication.[125] The child took the asthma medication as dispensed by the defendant pharmacy for three months, during which time the pharmacy also filled an antibiotic prescription for the child.[126] The package insert for the antibiotic warned of a possible drug interaction between the antibiotic and the asthma medication that could produce toxic levels of the asthma drug.[127] The defendant pharmacy gave no notice or warning to either the physician or the plaintiffs.[128]

Evidence presented to the trial court showed that the pharmacist was unaware of the possible drug interaction or the serious problems it posed to the patient. Thus, the trial court granted summary judgment in favor of the pharmacy.[129] The appellate court disagreed, holding that the plaintiffs' evidence was sufficient to withstand summary judgment.[130]

In reversing the trial court, the appellate court relied heavily on an affidavit by a practicing pharmacist, which set forth the standard of care for the practice of pharmacy in both local and similar communities.[131] This standard of care in-

122. *See* Guillory v. Dr. X, 679 So. 2d 1004, 1010 (La. Ct. App. 1996) (holding that a pharmacist has a duty to warn patients or notify the prescribing physician that the prescription creates substantial risk of harm to the patient).

123. *See* Pysz v. Henry's Drug Store, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984); Leesley v. West, 518 N.E.2d 758, 763 (Ill. App. Ct. 1988); Adkins v. Mong, 425 N.W.2d 151, 154 (Mich. Ct. App. 1988); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387–88 (Mich. Ct. App. 1987).

124. Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).

125. *See id.* at 382.

126. *See id.*

127. *See id.*

128. *See id.*

129. *See id.*

130. *See Dooley*, 805 S.W.2d at 386.

131. *See id.* at 382–83.

cluded (1) maintaining a patient profile system; (2) reviewing the profile to determine, among other things, if any drugs would interact with patients' current medications; (3) warning patients of any possible interactions; and (4) advising patients of symptoms of toxicity.[132] Based on this expert proof that the pharmacist negligently failed to warn of the potential interaction, the appellate court reversed the summary judgment.

b. *The* Riff *Case*

In 1986, a Pennsylvania appellate court, in *Riff v. Morgan Pharmacy,*[133] affirmed a verdict and judgment against a pharmacy for failure to warn.[134] The court concluded that the plaintiff stated a valid claim for liability due to the pharmacist's failure to instruct the patient regarding the maximum dosage and possible side effects from exceeding that dosage.[135] In fact, the prescription presented to the pharmacist did not advise of a maximum safe dosage for a dangerous and potentially toxic migraine drug.[136] The pharmacist accurately filled the prescription and provided the dosage instructions as written by the physician, without giving any warnings.[137] Unaware of any danger, the plaintiff exceeded the maximum safe dosage and suffered severe injuries.[138] In holding the pharmacist liable, the court, like the *Dooley* court,[139] looked to the professional community to ascertain the standard of care required of a reasonably prudent pharmacist.[140] The court held that "the testimony of the medical ex-

132. *See id.* at 383.
133. Riff v. Morgan Pharmacy, 508 A.2d 1247 (Pa. Super. Ct. 1986).
134. *See id.*
135. *See id.* at 1253–54.
136. *See id.* at 1249. The prescription for 12 migraine suppositories (Cafergot) read only "insert one every 4 hours for headache" and failed to advise of the maximum safe dosage of no more than two per migraine attack and no more than five per week. *Id.* at 1249–50.
137. *See id.* at 1249.
138. *See id.*
139. *See* Dooley v. Everett, 805 S.W.2d 380, 385 (Tenn. Ct. App. 1990).
140. *See Riff*, 508 A.2d at 1250–51. The court reasoned:

> 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 consistant [sic] with the best interests of the patient.

Id. at 1253.

perts, both physicians and pharmacists, established that the conduct of . . . [the] pharmacists fell below the level of reasonable conduct in the practice of pharmacy."[141]

c. *The* Lasley *Case*

In a bold 1994 decision, the Arizona Court of Appeals rejected outright the traditional no-duty-to-warn argument.[142] In *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[143] the court held that a pharmacy owes patients a duty of reasonable care and that the trial court erred in holding the pharmacy owed no duty to warn as a matter of law.[144]

The pharmacy in *Lasley* dispensed an addictive medication to the plaintiff for thirty years without ever informing the patient of the drug's addictive nature.[145] The pharmacy denied it owed a duty to warn of the drug's dangerous properties or to keep track of the patient's reliance on the prescribed drug.[146] The *Lasley* court disagreed, determining that a question existed as to whether a pharmacist's reasonable standard of care includes the duty to warn of adverse side effects.[147] The *Lasley* court rejected the approach of earlier no-duty-to-warn cases[148] and chose to follow the analysis of *Dooley*.[149] The court determined that the pharmacy did owe the patient a duty of reasonable care and that failure to warn might constitute a breach of that duty.[150]

2. *Voluntary Assumption of the Duty to Warn: The* Baker *Case*

A Michigan Court of Appeals decision set a new standard in 1996 by affirming pharmacists' duty to warn in *Baker v. Arbor Drugs, Inc.*[151] The patient in *Baker* had been taking an

141. *Id.*
142. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994).
143. *Id.* at 1129.
144. *See id.* at 1130.
145. *See id.* at 1131.
146. *See id.*
147. *See id.* at 1132.
148. *See supra* Part II.A.3.
149. *See* Dooley v. Everett, 805 S.W.2d 380, 384 (Tenn. Ct. App. 1991) (noting the distinction between duty and standard of care); *see also supra* Part II.B.1.a.
150. *See Lasley*, 880 P.2d at 1129.
151. Baker v. Arbor Drugs, Inc., 544 N.W.2d 727 (Mich. Ct. App. 1996).

antidepressant medication for several years.[152] The patient had his cold medications filled at Arbor Drugs, where he also received his antidepressant medication.[153] At the time Arbor Drugs filled the patient's prescriptions for the cold medications, it had a computerized drug interaction detection system that detected a serious drug interaction between the antidepressant and the cold medications.[154] The pharmacist claimed she did not see the interaction indicated on the computer, probably because a technician overrode the interaction notification.[155] Receiving no warnings, the patient took the medications as prescribed and suffered serious side effects.[156]

The issue before the Michigan Court of Appeals was whether the pharmacy had voluntarily assumed a duty to its customers to prevent prescription drug interactions.[157] The Michigan court looked to previous cases but found no dispositive decisions on the issue of pharmacists' duty of care.[158] However, because Arbor Drugs implemented and advertised its new computerized drug detection system to the public, claiming the system prevented harmful drug interactions, the court agreed with the plaintiff that Arbor Drugs voluntarily assumed a duty of care to its patients.[159] The holding in *Baker* does not extend to all duty-to-warn cases; however, it encompasses those situations where a pharmacist or pharmacy voluntarily assumes a duty, then fails to perform that duty with

152. *See id.* at 729. The patient was taking an antidepressant belonging to a class of drug (monoamine oxidase inhibitors) that are known to cause severe complications if taken with certain foods or other medications. *See id.*

153. *See id.*

154. *See id.*

155. *See id.*

156. *See id.* at 729. As a direct result of the drug interaction, the patient suffered a stroke, and then committed suicide, claiming in a suicide note that, among other things, the stroke was too much for him to handle. *See id.*

157. *See Baker*, 544 N.W.2d at 729.

158. *See id.* at 731.

159. *See id.* The following is an example of the defendant's commercials advertising its computerized drug interaction detection system:

> Do you know what happens when you bring your prescription to Arbor Drugs? First, it's checked for insurance coverage and screened for possible drug interactions and therapeutic duplication. That's done very quickly by the Arbortech Plus computer. Then your prescription is filled and labelled [sic]. That's done very carefully, by your Arbor pharmacist. The bottom line? Your prescription is not just filled quickly, it's filled safely. Only at the Arbor Pharmacies. You can't get any better.

Id. at 731.

ordinary care.[160]

3. *OBRA 90: Establishing the Minimum Standard of Care*

In rejecting the traditional no-duty-to-warn standard, the *Dooley, Riff,* and *Lasley* courts focused on determining the appropriate standard of care expected of professional pharmacists.[161] In doing so, these courts relied on community standards of pharmacy practice and on expert testimony.[162] Congress helped to establish pharmacists' minimum standards of care by passing the Omnibus Budget Reconciliation Act of 1990,[163] which contained provisions affecting how pharmacists handle prescription processing.[164]

The goal of OBRA 90, as it relates to pharmacists, is to improve patient drug therapy by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical effects.[165] OBRA 90 mandates that pharmacists take a more active role in drug therapy by inquiring into patients' conditions, reviewing their relevant medical history, and performing drug counseling.[166] To carry out this mandate, OBRA 90 requires each state to provide drug use review programs to improve the quality of pharmaceutical care. States must establish drug use review boards, comprehensive prospective and retrospective drug reviews performed by a pharmacist, and require pharmacists to obtain medical histories on each patient.[167] Finally, OBRA 90 specifically requires pharmacists to discuss with patients the common and potentially severe side effects of prescribed drugs, as well as any potential drug interactions.[168]

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160. *See id.* at 733 n.1.

161. *See supra* notes 124, 133, and 142.

162. *See supra* Part II.B.1.a–c.

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

164. *See* 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

165. *See id.* § 1396r-8(g)(1)(A).

166. *See id.* § 1396r-8(g)(2)(A).

167. *See id.* § 1396r-8(g)(2)(A)(ii)(II).

168. The specific requirements of this provision of OBRA 90 are:

> (I) 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 (consis-

"The OBRA 90 statutes were drafted to provide states with wide latitude for implementation, however, most have followed the OBRA 90 requirements."[169] For example, the patient counseling rules adopted by California are representative of, and consistent with, the OBRA 90 mandate.[170] California requires pharmacists to provide each patient with an oral consultation that includes "[p]recautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered."[171] In addition to the minimum oral consultation requirement, pharmacists must also advise the patient regarding "[t]herapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur."[172]

Besides establishing a duty to counsel, the California rules also require pharmacists to maintain medication records on all patients. These records must include "patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions," if they relate to drug therapy.[173] Furthermore, California pharmacists must "re-

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tent with State law respecting the provision of such information), 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.

Id. § 1396r-8(g)(2)(A)(ii).

169. 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, 132 (1994).

170. *See* CAL. CODE REGS. tit. 16, § 1707.2 (1997).

171. *Id.* § 1707.2(c)(2).

172. *Id.* § 1707.2(d)(6).

173. *Id.* § 1707.1(a)(1)(C).

view the patient's drug therapy and medication record before each prescription drug is sold."[174] California also requires pharmacists to give notice to their customers that the pharmacist provides "professional prescription dispensing and professional consultation."[175]

The impact of OBRA 90[176] on the duties of pharmacists, together with the duty-to-warn cases such as *Dooley*, *Riff*, and *Lasley*, have altered the role of pharmacists.[177] Today, the pharmacist's job goes beyond merely counting and pouring medications—pharmacists play an active role as true "health care professionals."[178] OBRA 90 recognized some of these expanded duties by requiring pharmacists to monitor patients' therapy and consult patients and physicians on optimal therapy.[179]

4. *Expanding Pharmacists' Duties in Managed Care Organizations*

A new area of pharmacy, born out of the competitive forces of health care economics, is the managed care pharmacist.[180] Managed care organizations ("MCOs") are health care organizations that attempt to control health care costs by centralizing health care decisions and restricting the physicians' treatment choices.[181] One method of restricting physician choice is through the use of drug formularies, which require physicians to select drugs from a given list of MCO-approved

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174. *Id.* § 1707.3.

175. *Id.* § 1707.2(f). The "prominently posted" notice to consumers states:

> [T]his pharmacy shall provide its current retail price of any prescription . . . prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided. The services provided by this pharmacy, in addition to professional prescription dispensing and professional consultation, are checked below. In comparing prescription prices it is important to consider the services provided.

Id.

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

177. *See supra* notes 124, 133, and 142.

178. *See* Green, *supra* note 3, at 1476.

179. *See* 42 U.S.C. § 1396r-8(g)(2)(A)(ii) (1994).

180. *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).

181. *See id.* at 1264.

drugs.[182] The use of drug formularies by MCOs limits the physician's role as a learned intermediary who freely selects from alternative treatments.[183]

Affecting the lives of more than 100 million patients in 1994, health care through MCOs now represents a significant portion of pharmacy business.[184] As members of pharmacy and therapeutics committees, pharmacists play a vital role in making drug formulary decisions that promote therapeutic guidelines and minimize drug benefit expenses.[185] As decision-makers in MCOs, pharmacists have a significant impact on limiting the alternative treatment options available to physicians.[186]

In addition to pharmacists' ability to select which drugs to make available to patients through drug formulary restrictions,[187] pharmacists may, in some states, directly select and prescribe drug therapy for patients.[188] Eleven states grant pharmacists the limited right to prescribe certain medications.[189] This new privilege for pharmacists may, in some cases, challenge the application of the learned intermediary doctrine.[190]

III. IDENTIFICATION OF THE PROBLEM

According to the traditional, and still majority, view, pharmacist liability is restricted to those instances where the pharmacist made an error processing a prescription.[191] A pharmacist is generally immune from liability for injuries resulting from prescription medicines if he or she accurately filled the prescription.[192]

182. *See id.*
183. *See id.*
184. *See* F. Randy Vogenberg & Douglas J. Pisano, *Pharmacy and Managed Care: Legal Issues on the Horizon*, DRUG BENEFIT TRENDS, May 1996, at 14.
185. *See* John D. Jones, *How a PBM Develops Its Drug Formulary*, DRUG BENEFIT TRENDS, June 1998, at 37.
186. *See* Barry R. Furrow, *Enterprise Liability for Bad Outcomes From Drug Therapy: The Doctor, the Hospital, the Pharmacy, and the Drug Firm*, 44 DRAKE L. REV. 377, 433 (1996).
187. *See* Cooper, *supra* note 180, at 1264.
188. *See* Headden et al., *supra* note 1, at 49.
189. *See id.*
190. *See* discussion *supra* Part II.A.3.
191. *See* discussion *supra* Part II.A.1.
192. *See* discussion *supra* Part II.A.2.

A few recent cases reject this tradition by finding that pharmacists have a duty to warn patients of potential adverse effects of their prescription drugs.[193] Relying on the legislative mandate of OBRA 90[194] and on an expanded view of pharmacists' duty, courts have begun to enlarge the limits of pharmacist liability.[195] This comment addresses whether the traditional grant of immunity to pharmacists who accurately fill prescriptions should survive in light of the recent cases holding that pharmacists have a duty to warn.[196] In addition, with the expanding role of pharmacists in health care today,[197] courts must reassess pharmacist liability in areas such as strict liability,[198] breach of warranty,[199] and duty to warn.[200]

IV. ANALYSIS

The traditional view of pharmacist liability may be changing as pharmacists' role in the health care industry evolves.[201] Advances in technology, such as computer systems that maintain patient profiles and automatically warn of drug interactions, expand the capabilities and responsibilities of pharmacists.[202] Pharmacists have a responsibility to patients beyond the mere technical accuracy of prescription order processing; this responsibility may include a duty to warn.[203] Pharmacists' responsibilities in MCOs (where pharmacists restrict physician access to medications through the use of drug formularies)[204] and as authorized prescribers, may necessitate revisiting the application of both the learned intermediary doctrine[205] and breach of warranty theories.[206]

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193. *See* discussion *supra* Part II.B.1.

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

195. *See* discussion *supra* Part II.B.1.

196. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994); Riff v. Morgan Pharmacy, 508 A.2d 1247 (Pa. Super. Ct. 1986); Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).

197. *See* discussion *infra* Part IV.

198. *See* discussion *infra* Part IV.B.

199. *See* discussion *infra* Part IV.D.

200. *See* discussion *infra* Part IV.C.

201. *See* Laizure, *supra* note 61, at 535 (noting professionals, including pharmacists, are held to a higher standard of care in their fields because of their superior knowledge).

202. *See id.*

203. *See supra* Part II.B.1.

204. *See supra* Part II.B.4.

205. *See supra* Part II.A.3.

A. *No Strict Liability for Traditional Pharmacists*

Viewing pharmacists as service providers and not sellers of medications, some courts refuse to apply strict liability to pharmacists.[207] The rationale behind this argument is that a service provider is not subject to liability as a supplier under the Restatement (Second) of Torts.[208] In *Coyle v. Richardson-Merrell, Inc.*,[209] which involved birth defects caused by a prescription medicine, the Pennsylvania Supreme Court declined to extend the rule of strict liability to pharmacists.[210]

The *Coyle* court ruled against application of the Restatement's standard when considering a pharmacist's role as a supplier of prescription drugs.[211] The court found strict liability inapplicable to pharmacists because the distribution system of prescription drugs is a restricted market.[212] In such a market, the patient does not rely on the pharmacist to obtain the products.[213] The patient relies only on the physician to order the medication and assess the risks and benefits inherent in the prescription drug.[214] The court also stated that holding pharmacists strictly liable provides no safety incentive because pharmacists cannot substitute their judgment for that of the physician.[215]

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206. *See supra* Part II.A.4.

207. *See* Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988); Kampe v. Howard Stark Prof'l Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct. App. 1992); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App. 1977).

208. *See* Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991). Section 402A of the Restatement states:

> 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 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.

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

209. *Coyle*, 584 A.2d at 1383.

210. *See id.* at 1385.

211. *See id.* at 1387.

212. *See id.*

213. *See id.*

214. *See id.*

215. *See Coyle*, 584 A.2d at 1387.

B. *Strict Liability Applicable for the Pharmacist's Expanded Role*

In light of pharmacists' expanding responsibilities, the criticisms of strict liability for pharmacists are less convincing today.[216] The classification of a pharmacist as only a service provider and not a seller is arguably incorrect. Under OBRA 90, pharmacists' obligations include monitoring drug therapies, discussing drug risks with patients, detecting potential drug interactions, and intervening when necessary to optimize patient care.[217] Pharmacists' role in MCOs, developing and enforcing drug formularies, indirectly involves them in drug selection for patients.[218] Patients no longer rely solely on physicians to select drug therapy.[219] Patients must now also rely on pharmacists' skills in determining which drugs are available for physicians' to select.[220] Finally, pharmacists' duties even include prescribing drugs in some jurisdictions.[221] These changes clearly reflect pharmacists' greater involvement in drug selection and drug sales.[222] As pharmacists' role in health care continues to expand,[223] categorizing pharmacists as service providers and not sellers, in order to avoid strict liability, is no longer valid.[224]

C. *The Pharmacist's Duty to Warn of a Drug's Potential Hazards*

In addition to the traditional view that pharmacists are not subject to strict liability, most courts continue to hold that pharmacists also have no duty to warn patients of potential hazards of prescription drugs.[225] While pharmacists still have an absolute duty to fill prescriptions accurately and be alert for obvious or patent errors on the face of prescriptions, pharmacists do not have a duty to question the judgment of physicians as to the propriety of prescriptions.[226]

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216. *See supra* Part II.B.
217. *See supra* Part II.B.3.
218. *See supra* Part II.B.4.
219. *See supra* Part II.B.4.
220. *See* Cooper, *supra* note 180, at 1264.
221. *See* Headden et al., *supra* note 1, at 46.
222. *See* Cooper, *supra* note 180, at 1264.
223. *See supra* Part II.B.4.
224. *See supra* Part II.A.2.
225. *See supra* Part II.A.3.
226. *See, e.g.*, McKee v. American Home Prods. Corp., 782 P.2d 1045 (Wash.

The courts in *McKee v. American Home Products Corp.*[227] and *Adkins v. Mong*[228] held that pharmacists owed no duty to warn customers of the potential hazards associated with prescribed drugs. These cases relied upon the traditional role of the pharmacist as a service provider and held that the duty to warn should remain with the physician.[229]

More recent cases, however, find that pharmacists do have a duty to warn of the potential hazards of drugs.[230] In *Dooley v. Everett*,[231] the court looked to the appropriate standard of care for pharmacists, and stated: "The fact that the pharmacy owes its customers a duty in dispensing prescription drugs is without question."[232] The court also noted that "one who undertakes to render services in the practice of a profession or trade is required to exercise skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities."[233] The court reasoned:

> Duty is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk. What defendant must do or must not do, is a question of the standard of conduct required to satisfy the duty. The distinction is one of convenience only, and it must be remembered that the two are correlative, and one cannot exist without the other.[234]

The *Dooley* court also found the learned intermediary doctrine inapplicable based on pharmacists' duty to their customers. The court held that pharmacists owe their customers a duty of reasonable care in filling prescriptions, but left it to the trier of fact to determine what level of care is required.[235]

1989).

227. *Id.*

228. Adkins v. Mong, 425 N.W.2d 151 (Mich. Ct. App. 1988).

229. *See id.* at 154; *McKee*, 782 P.2d at 1051–54.

230. *See supra* Part II.B.1.

231. Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).

232. *Id.* at 386.

233. *Id.* at 385 (citing RESTATEMENT (SECOND) OF TORTS § 299A (1965)).

234. *Id.* at 384 (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53, at 356 (5th ed. 1984)).

235. *See id.* at 386.

In *Riff v. Morgan Pharmacy*,[236] the court stated that a pharmacist, as a trained professional, has "an affirmative duty to read the prescription and to be aware of patent inadequacies in the instructions."[237] According to the court:

> Fallibility is a condition of human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertance [sic]. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, [and] pharmacists . . . have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and ommissions [sic] of the other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother's keeper.[238]

In *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[239] the Arizona Court of Appeals continued the *Dooley* and *Riff* trend by also rejecting the earlier no-duty-to-warn cases.[240] The court cautioned against confusing duty with the applicable standard of conduct and explained: "Specific details of conduct do not determine whether a duty exists but instead bear on whether a defendant who owed a duty to the plaintiff breached the applicable standard for care."[241] The court concluded that the defendant pharmacy in *Lasley* owed the patient a duty of reasonable care and remanded the case for the trier of fact to determine the appropriate standard of care.[242]

The crux of the *Lasley* decision was that prior courts had confused the concept of duty with that of the standard of care.[243] *Lasley* declared that pharmacists owe their patients a duty of reasonable care commensurate with their profession.[244] However, despite the use of expert testimony to help establish the pharmacist's standard of care, the precise scope

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236. Riff v. Morgan Pharmacy, 508 A.2d 1247 (Pa. Super. Ct. 1986).
237. *Id.* at 1253.
238. *Id.*
239. Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994).
240. *See id.* at 1134.
241. *Id.* at 1132 (quoting Markowitz v. Arizona Parks Board, 706 P.2d 364 (Ariz. 1985)).
242. *See id.* at 1134.
243. *See id.* at 1132.
244. *See id.*

of that standard continues to perplex courts.[245] The minimum scope of duty, however, has now been legislatively established with the enactment of OBRA 90.[246]

1. *OBRA 90: Establishing a Minimum Standard of Care*

OBRA 90's goal for pharmacists is to improve patient drug therapy and decrease the cost of caring for patients.[247] OBRA 90 requires pharmacists to take a more active role in patient care by inquiring into patients' conditions, maintaining a medical history profile for each patient, and performing drug counseling prior to dispensing medications.[248] While the policy goals of OBRA 90 may be desirable, the OBRA 90 provisions nevertheless place additional liability upon pharmacists.[249] In addition to the effects of OBRA 90 on strict liability analysis,[250] pharmacists now appear to have a legislatively mandated duty to warn.[251]

Earlier courts such as *McKee* and *Adkins* shielded pharmacists from liability for the duty to warn by holding that (1) pharmacists lacked an understanding of, and access to, patients' medical history; (2) pharmacists had no duty to monitor and intervene with patients' ongoing treatment; and (3) requiring pharmacists to warn would interfere with the doctor-patient relationship.[252] OBRA 90's mandated changes in the pharmacist's duties, however, now negate the force of these arguments.[253]

Under OBRA 90, pharmacists must obtain, record, and maintain patients' medical histories.[254] The medical history must include disease states,[255] allergies, drug reactions, and a

245. *See, e.g.*, Green, *supra* note 3, at 1477.

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

247. *See* 42 U.S.C. § 1396r-8(g)(1)(A) (1994).

248. *See supra* Part II.B.3.

249. *See* Brenda Jones Quick, *The Cost of the Omnibus Budget Reconciliation Act of 1990*, 2 J. PHARMACY & L. 145 (1994).

250. *See supra* Part IV.B.

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

252. *See* Adkins v. Mong, 425 N.W.2d 151, 154 (Mich. Ct. App. 1988); McKee v. American Home Prods. Corp., 782 P.2d 1045, 1049 (Wash. 1989).

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

254. *See id.*

255. Disease states are medical conditions such as diabetes, hypertension, and AIDS.

comprehensive list of patients' current medications.[256] Using this medical history, pharmacists are required by OBRA 90 to assess the propriety of each new prescription drug and offer to discuss with patients any significant matters, including directions, dosage, precautions, use, and any potentially significant side effect or interactions.[257] Instead of applying the learned intermediary doctrine and shielding pharmacists from liability, courts must consider the pharmacist the new learned intermediary and impose liability for the failure to warn.[258]

2. *Assumption of the Duty to Warn: The* Baker *Case*

While OBRA 90 helps to establish the minimum standard of care required of pharmacists, *Baker v. Arbor Drugs, Inc.*[259] established a duty of care when pharmacists voluntarily assume a duty to monitor for adverse drug interactions.[260] In *Baker*, the Michigan Court of Appeals concluded that when a pharmacy implements and advertises that its new computerized drug detection system prevents harmful drug interactions, the pharmacy owes a duty of care to its customers to identify and prevent drug interactions.[261] Although the *Baker* decision did not discuss the minimum standard of care pharmacists owe to patients in general, the decision addressed those instances where a pharmacy voluntarily assumes a duty to warn.[262] The court correctly held that a duty to warn exists whenever a pharmacy voluntarily assumes this duty.[263]

California may also have opened the doors of litigation to pharmacists' assumption of duty when it implemented the mandates of OBRA 90.[264] California requires pharmacists not only to provide drug consultation to patients, but also to notify their customers of the professional consultation available by prominently displaying a notice of the services provided.[265]

256. *See* 42 U.S.C. § 1396r-8(g)(2)(A)(ii).
257. *See id.*
258. *See, e.g.*, Gibbs & Mackler, *supra* note 49 (explaining the rationale of a learned intermediary).
259. Baker v. Arbor Drugs, Inc., 544 N.W.2d 727 (Mich. Ct. App. 1996).
260. *See id.* at 731.
261. *See id.*
262. *See id.*
263. *See id.*
264. *See* CAL. CODE REGS. tit. 16, § 1707.2 (1997).
265. *See id.* § 1707.2(f).

By notifying their customers of this service, a pharmacy, like the pharmacy in *Baker*, may be liable for assumption of the duty to warn.[266]

D. *Pharmacists May Be Liable Under Breach of Warranty Theories*

Just as OBRA 90 and pharmacists' expanding role in health care delivery[267] affect the analysis of pharmacy liability in duty-to-warn[268] and strict liability cases,[269] courts must also reevaluate the breach of warranty analysis.[270] Liability under express warranty theory has not applied to pharmacists because, traditionally, pharmacists gave no express assurances in the typical pharmacy-patient interaction and no basis of the bargain could be established between patients and pharmacists.[271] Though courts generally find no liability under breach of warranty theories,[272] the justifications for the failure to apply the breach of warranty are no longer persuasive.[273]

First, as the role of the pharmacist expands, express assurances may now occur.[274] As pharmacists become more involved in MCOs and drug formulary selection, they indirectly select medications for patients by limiting physicians' choices.[275] Additionally, courts may view OBRA 90's mandate that the pharmacist monitor and intervene when necessary into a patient's drug therapy as an assurance to patients that the pharmacist will use sound clinical judgment to ensure optimum drug therapy.[276] Second, if a patient relies on a pharmacist's professional judgment when selecting the medications to allow on the drug formulary, and on a pharmacist's

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

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

268. *See* Laizure, *supra* note 61, at 522–26.

269. *See* discussion *supra* Part IV.A–B.

270. *See* discussion *supra* Part II.A.4.

271. *See* McCleod v. W.S. Merrell Co., 174 So. 2d 736 (Fla. 1965); Batiste v. American Home Prods. Corp., 231 S.E.2d 269 (N.C. Ct. App. 1977); Makripodis v. Merrell Dow Pharm., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987).

272. *See* Leesley v. West, 518 N.E.2d 758 (Ill. App. Ct. 1988); *Batiste*, 231 S.E.2d at 269; *Makripodis*, 523 A.2d at 374.

273. *See* discussion *supra* Part II.A.4.

274. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994).

275. *See* Furrow, *supra* note 186, at 433.

276. *See* 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

clinical skills to monitor and intervene,[277] then a basis of the bargain is also established.[278]

Similarly, plaintiffs may now invoke liability on an implied warranty theory.[279] First, patients no longer rely only on a physician's judgment for drug product selection.[280] Patients now also rely on pharmacists because of pharmacists' involvement in drug product selection through formulary restrictions and direct prescribing.[281] Second, although the particular purpose for any drug prescribed still depends on the physician's judgment[282] (unless the pharmacist is acting as a prescriber[283]), pharmacists also indirectly select the drug for a particular purpose by limiting the available drugs on the formularies.[284] Third, based on the fact that pharmacists now participate in drug product selection, pharmacists now also satisfy the requirement of being merchants of those selected drugs for the purposes of implied warranty.[285] Thus, for both express and implied warranty theories, the expanding role of pharmacists in health care delivery weakens the arguments against imposing liability.[286]

V. PROPOSAL

Pharmacists' traditional role in the health care arena focused solely on drug distribution and the accurate dispensing of medications to the customer.[287] The majority of courts held pharmacists not liable for injuries resulting from prescribed medications that were accurately dispensed.[288] Since physicians were the only medical professionals with access to pa-

277. *See* discussion *supra* Part II.B.3–4.
278. *See* Sparks v. Kroger Co., 407 S.E.2d 105 (Ga. Ct. App. 1991).
279. *See* U.C.C. § 2-314 to -315 (1978).
280. *See* Cooper, *supra* note 180, at 1264.
281. *See id.*
282. *See* McCleod v. W.S. Merrell Co., 174 So. 2d 736 (Fla. 1965); Batiste v. American Home Prods. Corp., 231 S.E.2d 269 (N.C. Ct. App. 1977); Makripodis v. Merrell Dow Pharm., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987).
283. *See* Headden et al., *supra* note 1, at 46.
284. *See* Jones, *supra* note 185, at 37.
285. *See* Murphy v. E.R. Squibb & Sons, Inc., 710 P.2d 247 (Cal. 1985).
286. *See supra* Part II.B.4.
287. *See* Brushwood, *supra* note 32, at 443.
288. *See, e.g.*, Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988); Kampe v. Howard Stark Prof'l Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct. App. 1992); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App. 1977).

tients' health history and, therefore, the learned intermediaries, physicians effectively insulated pharmacists and manufacturers from liability.[289] These traditional stereotypes are no longer accurate and the courts should abandon the limits of liability traditionally afforded pharmacists.[290]

Pharmacists today *are* involved in the drug selection process and thus courts should consider pharmacists sellers of drugs as well as service providers.[291] Such a distinction could result in strict liability for pharmacists. Under OBRA 90, pharmacists must now monitor patients' drug therapy and, when necessary, intervene to recommend changes to that drug therapy.[292] In addition, pharmacists select which medications are available for patient use through their involvement with drug formulary development.[293] Finally, in some jurisdictions, pharmacists may prescribe drugs, which requires patients to rely on pharmacists to obtain their medication.[294] Thus, strict liability may be appropriate against pharmacists in certain circumstances.

For similar reasons, courts should reevaluate pharmacist liability under breach of warranty theories.[295] The increased role pharmacists play in health care today significantly weakens the arguments limiting liability under breach of warranty theories.[296] Pharmacists today select drug products through drug formulary development and direct prescribing.[297] Patients must now rely on both pharmacists' judgment in allowing and excluding certain drugs from formularies, as well as physicians' judgment in selecting from the limited options available.[298] Finally, patients will rely on pharmacists'

289. *See* Pysz v. Henry's Drug Store, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984); *Leesley*, 518 N.E.2d at 763; Adkins v. Mong, 425 N.W.2d 151, 154 (Mich. Ct. App. 1988); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387–89 (Mich. Ct. App. 1987).

290. *See* discussion *supra* Part II.B.

291. *See* Headden et al., *supra* note 1, at 49.

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

293. *See* Harry DeMonaco, *Health Outcomes and Formulary Concerns*, INFECTIONS MED., 13B, at 36 (Supp. 1996). "In general, formularies provide cost minimization. For the most part, they are not constructed for quality-of-cure issues but simply for cost-of-care considerations." *Id.* at 37.

294. *See* Headden et al., *supra* note 1, at 49.

295. *See* discussion *supra* Part IV.D.

296. *See* Furrow, *supra* note 186, at 433.

297. *See* Vogenberg & Pisano, *supra* note 184, at 14.

298. *See id.*

consultation with respect to the risks and benefits of drug therapy, and as a basis of the bargain when purchasing medications.[299]

The majority approach of not holding pharmacists liable for failure to warn of a drug's potential hazards has already been attacked.[300] The 1993 implementation of OBRA 90[301] now sets the minimum standard of care for pharmacists, including duties to monitor, intervene, and counsel.[302] At a minimum, courts should hold pharmacists to a standard of care consistent with OBRA 90's mandate. In addition, courts should remain flexible in setting this minimum standard of care as the role of pharmacists continues to expand in health care and pharmacists assume greater responsibilities in ensuring competent patient care.[303]

VI. CONCLUSION

The role of the pharmacist in the health care industry has evolved from merely counting and pouring, to an active role as a gatekeeper in the drug therapy process.[304] As drug therapy becomes more complex and managed care changes the relationship between physicians and patients, the role pharmacists play as "drug counselors" becomes more important.[305] The minimum standards set by OBRA 90, combined with the computerized records of patients' medical histories and drug regimens, yield realistic expectations for greater responsibilities of pharmacists.[306]

Moreover, pharmacists are involved in drug product selection through managed care organizations and those organizations' use of drug formularies.[307] Pharmacists must monitor patients' medical histories, identify problems with drug therapy, intervene when necessary to prevent harm, and

299. *See* Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994).

300. *See* Leesley v. West, 518 N.E.2d 758, 762 (Ill. App. Ct. 1988); Kampe v. Howard Stark Prof'l Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct. App. 1992); Batiste v. American Home Prods. Corp., 231 S.E.2d 269, 275 (N.C. Ct. App. 1977).

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

302. *See id.*

303. *See* Green, *supra* note 3, at 1468.

304. *See id.* at 1474–75.

305. *See* Furrow, *supra* note 186, at 433.

306. *See* discussion *supra* Part II.E.4.

307. *See* Jones, *supra* note 185, at 37.

counsel patients to decrease the risk of side effects and increase the benefits of drug therapy.[308] As the pharmacist's role in health care continues to expand, the justifications for limiting pharmacist liability become less persuasive.[309]

Pharmacists are a vital link in health care delivery today. The public's reliance on the pharmacy profession increases as the public becomes aware of the pharmacist's greater role. Courts should recognize these new responsibilities by holding pharmacists legally responsible when reasonably preventable harm occurs.

308. *See* West & Smith, *supra* note 169, at 132.
309. *See* discussion *supra* Part II.B.3–4.

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