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THE PHARMACIST'S DUTY TO WARN: TOWARD A KNOWLEDGE-BASED MODEL OF PROFESSIONAL RESPONSIBILITY

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I. Introduction

Plaintiffs in pharmacist malpractice litigation channeled their creativity in a new direction during the 1980s' alleging that defendant pharmacists breached a duty to warn about potential adverse drug effects, and that an adequate warning by the pharmacist would have prevented harm to a patient caused by a drug that the pharmacist dispensed.[1] This is a novel type of claim that expands on traditional malpractice actions against pharmacists based on alleged inaccuracy in filling a prescription.[2] As is often the case with expansions into new areas of liability, the judiciary has been reluctant to accept the idea that pharmacist malpractice should be broadened to include liability for nonfeasance[3] in addition to misfeasance.[4]

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1. This Article examines the duty to "warn" rather than the duty to "counsel." While warning is simply the provision of information, counseling is the provision of information plus assistance with understanding and decisionmaking. The allegations contained in complaints against pharmacists uniformly allege failure to "warn" rather than failure to "counsel," although the pharmacy literature consistently addresses "counseling." *See infra* notes 75-77 and accompanying text.

2. In this Article, the only malpractice actions considered are those based on the tort of negligence. Pharmacists have been afforded exempt status from the general rule of retailer liability under a strict liability theory. This exemption is based on the special character of pharmacists as health care retailers and on the special character of the product they purvey. *See, e.g.*, Murphy v. E. R. Squibb & Sons, Inc., 40 Cal. 3d 672, 710 P.2d 247, 221 Cal. Rptr. 447 (1985). *See generally* Brushwood & Abood, *Strict Liability in Tort: Appropriateness of the Theory for Retail Pharmacists*, 42 Food Drug Cosm. L.J. 269 (1987).

3. Nonfeasance is omissive negligence: the failure to perform some act that ought to be performed. Black's Law Dictionary 950 (5th ed. 1979). For example, the failure of a pharmacist to monitor drug therapy or warn of adverse drug effects, even though a prescription has

In a decade noted for concern with the "malpractice crisis," a cautious judicial approach to expanded liability is both understandable and appropriate. Nevertheless, under some circumstances, courts have begun to require that pharmacists not simply fill prescriptions exactly as they are written, but that pharmacists also actively promote safe and effective drug use. Technically correct prescription filling may no longer be an absolute guarantee against liability, if the pharmacist could have done something more to help the patient manage the risks of drug use.

Organized pharmacy recognizes that pharmacists have a responsibility beyond retrieving the correct medication, properly packaging it, and accurately labeling it.[5] The pharmacist's responsibilities correspond with three separate mandates that flow from three distinct identities. Pharmacists are frequently identified as gatekeepers at the end of a complex drug distribution system.[6] Because of the important position they occupy within this system, pharmacists have been given an accurate mandate,[7] and the functions that accompany this mandate are the central focus of professional responsibility within traditional pharmacy practice. Pharmacists also are readily identifiable as retail merchants who offer an essential consumer product that the public usually cannot acquire through means other than by a pharmacist filling a prescription. As retail businesspersons and purveyors of this

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been filled correctly, is nonfeasance.

4. Misfeasance is comissive negligence: the improper performance of some act that a person may lawfully do. BLACK'S LAW DICTIONARY 902 (5th ed. 1979). For example, filling a prescription with the wrong drug, or filling a prescription with the right drug but labeling the container with the wrong directions for use, is misfeasance.

5. The Standards of Practice promulgated by the American Pharmaceutical Association states, among other things, that the pharmacist "[a]dvises patient of potential drug-related or health-related conditions which may develop from the use of the medication for which patient should seek other medical care." ABA, *Standards of Practice for the Profession of Pharmacy*, 19 AM. PHARMACY 134, 143 (1979).

6. In 1961, M. R. Stephens, Director of Enforcement of the Federal Food and Drug Administration, made the following comment about the importance of the pharmacist's role in drug distribution:

> There has been an amazing revolution in the drug field in the last two decades that has contributed enormously to combating ill health and has been a major factor in the dramatic advances of medical science. Clearly, in this scheme of things the pharmacist plays a most vital role. [The pharmacist's] responsibility as the custodian and dispenser of our national drug supply is both great and grave.

Stephens, *Report from the Food and Drug Administration*, 13 FOOD DRUG COSM. L.J. 148 (1962).

7. In the drug distribution chain, accuracy is emphasized through observance of Food and Drug Administration "Good Practices Regulations" (i.e., Good Manufacturing Practices, Good Laboratory Practices). *See, e.g.*, J. O'REILLY, FOOD AND DRUG ADMINISTRATION 23-1 (rev. perm. ed. 1989). The objective of the good practices regulations is to establish front-end quality assurance by which mistakes are prevented, rather than tail-end quality assurance by which mistakes are detected and (perhaps) rectified. While there is no such thing as "Good Dispensing Regulations" applicable to the pharmacist, an accuracy mandate can be assumed to flow from a desire to assure that a strong chain is not weakened at its final link.

product, pharmacists have been given an efficiency mandate,[8] which is constantly reinforced by drug-related cost containment measures such as generic substitution and government restrictions on pharmaceutical reimbursement levels. Recently a new mandate has begun to emerge from the pharmacist's identity as a health care provider. The quality mandate,[9] which relates to the pharmacist's health care role, asserts that if patients are underinformed about medications and misuse them to their detriment, then pharmacists are at least partially responsible for adverse outcomes.

This Article examines trends in the law and in pharmacy practice as they coalesce to create expanded responsibilities for the pharmacist. The analysis proceeds mindful of the dangers inherent in unlimited expansion of professional and legal responsibilities,[10] and suggests a theoretical basis for limiting the expansion of a pharmacist's legal responsibilities. This Article further suggests that while the specter of legal liability can serve as a constant reminder of professional responsibilities, legal developments should reflect changes in professional practice, not create them.[11] Judges, both trial

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8. Courts have been suspicious of legislation that forbids price advertising by pharmacists, even though the legislation is intended to promote quality patient care by discouraging constant switches from one pharmacy to another. *See* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976) (price advertising prohibition violates the first amendment right of freedom of speech, and an advertising ban has no effect on professional standards); Texas State Bd. of Pharmacy v. Gibson's Discount Center, Inc., 541 S.W.2d 884 (Tex. Civ. App. 1976) (requirement that pharmacists post a list of prices of the 100 most commonly prescribed drugs coupled with a prohibition of all other price advertising is also constitutionally invalid). *But see In re* C.V.S. Pharmacy Wayne, 116 N.J. 490, 561 A.2d 1160 (1989) (statute making it "grossly unprofessional conduct" for a pharmacist to advertise discounts or rebates in connection with the sale of drugs and medications is not an unwarranted exercise of economic protectionism, because such advertising could lead to destructive price wars that would erode the integrity of pharmaceutical services).

9. At least one court has referred to pharmacists as part of the "health care team." Riff v. Morgan Pharmacy, 353 Pa. Super. 21, 33, 508 A.2d 1247, 1253 (1986). The court also stated, "If the consensus of the medical community is that a safety net of overlapping responsibilities is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man's human frailty." *Id.* at 33, 508 A.2d at 1253-54.

10. Bold talk of new responsibilities for pharmacists must not be misinterpreted as eagerness to expand exposure to liability for malpractice. *See* Duckworth, *The Potential Liability of Pharmacists Arising from Announcements of New Standards and Codes of Practice*, 43 FOOD DRUG COSM. L.J. 1 (1988).

11. The special nature of the health care professionals has long been recognized in tort law, with courts being reluctant to expand on recognized medical custom. A rare case in which the judiciary refused to defer to custom as a determinant of the legal standard is Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (1975). In that case, the Washington Supreme Court required that ophthalmologists conduct routine diagnostic tests for glaucoma to patients under the age of forty, even though the prevailing custom was not do so. This approach has not been widely followed. *See, e.g.*, Capron, *Tort Liability in Genetic Counseling*, 79 COLUM. L. REV. 618, 625 n.22 (1979). The landmark informed consent case of Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972) held that risk disclosure requirements should be set by law rather than by physicians, but less than a majority of jurisdictions have followed that approach. *See* Presi-

and appellate, must draw a line between realistic and unrealistic expectations toward pharmacists. Decisions about risk in drug therapy traditionally have balanced patient autonomy[12] against caregiver beneficence[13] in determining the level of required risk disclosure. Unrealistic judicial expectations could artificially tilt the delicate balance in the wrong direction, imposing unnecessary burdens on pharmacists and damaging the quality of decisions about risk.[14]

II. The Challenge for Pharmacy

The 1980s ended with the pharmaceutical profession facing an uncertain future. Pharmacists are highly respected by the public,[15] and they have existed as a group separate from other health care providers for thousands of years.[16] Yet the 1990s will require pharmacy to meet challenges from al-

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dents Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Vol. 3, app. L (Washington, D.C., U.S. Gov. Printing Office, 1982).

12. Patient autonomy requires that persons make their own evaluations and choices when their own interests are at stake. If individuals are viewed as agents with their own unique approach to life (their values, interests, attitudes, etc.), then it would be disrespectful of individuals to reject their considered judgments or to deny them the liberty to act on those judgments. Under the principle of autonomy, a person who is a competent decisionmaker is free to use a medicinal drug in a way that is less than optimally safe and effective, if the generally recognized "right way" to use the drug interferes with the person's lifestyle.

13. The principle of beneficence, and the companion principle of nonmaleficence, require that we do or promote good, and that we refrain from acting in ways that will harm or injure others. These principles might support withholding risk-related information from a patient, if the information would cause the patient to not use the drug or to alter the beneficial way in which a drug is used.

14. The costs of overwarning have been recognized:

> The unexamined premise that warnings are not costly in risk-utility balancing is, in our considered opinion, highly questionable. Warnings, in order to be effective, must be selective. They must call the consumer's attention to a danger that has a real probability of occurring and whose impact will be significant. One must warn with discrimination since the consumer is being asked to discriminate and react accordingly. The story of the boy who cried wolf is an analogy worth contemplating when considering the imposition of a warning in a case of rather marginal risk.

Twerski, Weinstein, Donaher, & Piehler, *The Use and Abuse of Warnings in Product Liability—Design Defect Litigation Comes of Age*, 61 Cornell L. Rev. 495, 514 (1976).

The harm that comes from overwarning or from unnecessary warnings is not simply that a patient might forego needed therapy, but additionally, that risk disclosure would interfere with patient participation in rational decisionmaking.

15. Pharmacists consistently rank toward the top of a Gallup public opinion poll designed to measure perceptions of honesty and ethics of various professional groups. *See, Pharmacists Rank First in Poll*, 28 Am. Pharmacy 2 (1988); *see also* Cosler, Schulz, Baldwin, & Cohen, *Consumer Preference for Personal Drug Information Source: Relationship to Perceived Importance of Drug Class*, 20 Drug Intelligence and Clinical Pharmacy 138 (1986) [hereinafter Cosler].

16. The history of the pharmacy profession goes back at least as far as ancient Egypt and

ternative drug distribution systems, such as mail order prescription plans[17] and physician dispensing operations.[18] Such systems threaten the traditional pharmacy paradigm characterized by a local pharmacist who is given a prescription, fills it, and then delivers the medication to the waiting patient.

Two separate but distinct economic developments currently are having a major impact on pharmacy practice. The business side of pharmacy is being affected by a retailing shift toward discounting and self-service,[19] while the health care side of pharmacy is being influenced by cost-containment measures designed to curtail rapidly rising health care expenditures.[20] With these two forces acting in tandem, it is inevitable that payment to pharmacists for services in dispensing medications will at times be viewed by some policy makers as an unnecessary expense that can be eliminated without having a negative impact on the quality of health care.[21] In response to this view, the pharmacy profession must demonstrate to policy makers that a medication dispensed by a pharmacist is of greater value than a medication distributed through other means.

To meet this challenge, pharmacy has developed and conducted scientifically rigorous cost/benefit and cost/effectiveness analyses, which generally tend to show health care outcomes can be improved by pharmacist participation in drug therapy decisions, and pharmacists can add value to the drug product.[22] The results of these studies justify the cost of the pharmacist in

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Babylonia, where evidence is found that a class of preparers of medicines existed separate from those who prescribed and administered drugs. *See* Sonnedecker, *Evolution of Pharmacy*, REMINGTON'S PHARMACEUTICAL SCIENCES 8 (A. Gennaro ed. 1985).

17. *See* Munro, *Regulation of Mail Order Pharmacy*, 12 J. LEGAL MED. 1 (1990).

18. *See* Abood, *Physician Dispensing: Issues of Law, Legislation and Social Policy*, 14 AM. J. L. & MED. 308 (1989); Trytek, *Physician Dispensing of Drugs: Usurping the Pharmacist's Role*, 9 J. LEGAL MED. 637 (1988).

19. Corporate chain pharmacies have largely replaced independent pharmacist-owned practices in many areas, and this change has led to disagreement over the future of pharmacy. *See* Rite Aid Corp. v. Board of Pharmacy, 421 F. Supp. 1161 (D.N.J. 1976) (disciplinary action against chain pharmacy by board of pharmacy composed only of independent pharmacists does not violate due process, because a chain store poses no greater financial threat to an independent pharmacy than the financial threat posed by another competing independent pharmacy).

20. Pharmacists have successfully lobbied for state-level legislation that would require insurance companies to compensate pharmacists at a "usual and customary" level, rather than a lower level unilaterally dictated by the insurance company. These statutes have been held to be preempted by federal law under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1144 (1988). *See* Blue Cross & Blue Shield v. Peacock's Apothecary, Inc., 567 F. Supp. 1258 (N.D. Ala. 1983).

21. Federal administrative agencies have been reluctant to authorize payment for expensive state-of-the-art pharmacy services, even though evidence indicates that such services may reduce the total cost of patient care. *See* Memorial Hosp./Adair County Health Center, Inc., v. Bowen, 829 F.2d 111 (D.C. Cir. 1987).

22. *See* MacKeigan & Bootman, *A Review of Cost-Benefit and Cost-Effectiveness Analyses of Clinical Pharmacy Services*, 2 J. PHARM. MARKETING & MGMT. 63 (1988); *see also* Working Group Bibliography, *Payment for Cognitive Services: The Future of the Profession*, 29 AM. PHARMACY 768 (1989).

the long run, due to overall health care savings.[23] The impressive results of these studies have not consistently proved convincing to health policy makers or to the public they represent. When budgets are tight, a "live for today" attitude predominates. Such an attitude is not conducive to hard decisions about health care costs (or other policy issues such as energy and waste disposal), where sacrifices today are balanced against rewards in the future. Because the outcome-oriented economic approach has met with limited success, organized pharmacy has begun to approach the challenge to demonstrate added value by focusing on the drug-taking process, not just the outcome of using a drug product, and by considering value added in the present as well as in the future.[24]

Fortunately for pharmacy, the search for an opportunity to demonstrate added present value to drug therapy is not a long one. Medication users are demanding increased professional counseling about the proper use of drugs.[25] Coincidentally, pharmacists are properly trained and strategically placed to supply this counseling. The value added to drug therapy by pharmacist counseling of patients is more subjective and more difficult to measure than the cost savings the economic approach demonstrates. Nevertheless, patient counseling by pharmacists can add value that may be more significant than future cost savings, by increasing patient participation in drug therapy and by improving the validity of choices made by patients concerning the risks and benefits of drugs.

Pharmacist-patient interaction promotes respect for self-determination. Under this view, when pharmacists provide counseling along with the drug product, it is not as a courtesy or as an extension of ongoing treatment, it is from a sense of duty that correlates with the patient's right to be counseled. By interacting with patients and assuming responsibility for medication misuse and adverse outcomes, pharmacists add present value to the drug therapy process. If policymakers ignore the value added to drug therapy by pharmacist-patient interaction, then policymakers are partially responsible for patients being underinformed in a way that may lead to medication mis-

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23. *See, e.g.*, Cooper, *Cost Savings: The Value of the Pharmacist*, 1 J. PHARM. PRACTICE 173 (1988).

24. *See* Manasse, *Medication Use in an Imperfect World: Drug Misadvertising as an Issue of Public Policy*, 46 AM. J. HOSP. PHARM. pt. 1, at 929 (1989); 46 AM. J. HOSP. PHARM. pt. 2, at 1141 (1989).

25. Morris, Grossman, Barkdoll, Gordon & Soviero, *A Survey of Patient Sources of Prescription Drug Information*, 74 AM. J. PUBLIC HEALTH 1161 (1984) [hereinafter Morris]. A comprehensive federal program designed to provide patients with more information about prescription drugs was the victim of Reagan era deregulation. A program that would have required the distribution of information leaflets (known as patient package inserts) was established in 1980, 45 Fed. Reg. 60,754 (1980), but the program was abolished in 1982, 47 Fed. Reg. 39,147 (1982). The policy rationale behind the abolition of the program was not that patients have no need for additional information about prescription drugs, but rather that expanding private sector initiatives can and are providing patients with the additional information they need. *Id.* at 39,147-48.

use and adverse outcomes.

III. Framing the Issue of Pharmacist Duty

During the 1980s there were twenty-three reported judicial opinions dealing with the pharmacist's duty to do more than correctly fill a prescription.[26] Before 1980, no reported opinions had squarely considered the issue of expanded pharmacist responsibilities within a meaningful contemporary context.[27] The cases reported during the 1980s typically follow a progression from the plaintiff's allegation that the pharmacist should have provided a warning of risks to the patient,[28] through a judicial analysis of the pharmacist's relationship with the physician,[29] to a conclusion based on the physician's primary responsibility for the patient.[30] The allegation that the pharmacist had a duty to warn the patient is usually answered with an explanation that contacting the prescriber[31] is a second exculpatory option for the pharmacist. Moreover, under a wide range of circumstances, no ac-

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26. Ealy v. Richardson-Merrell, Inc., 97 Prod. Liab. Rep. (CCH) ¶ 11,236 (D.D.C. 1987); Raynor v. Richardson-Merrell, Inc., 643 F. Supp. 238 (D.D.C. 1986); Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85 (E.D. Pa. 1986); Jones v. Irvin, 602 F. Supp. 399 (S.D. Ill. 1985); Stafford v. Nipp, 502 So. 2d 702 (Ala. 1987); Pysz v. Henry's Drug Store, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984); Leesley v. West, 165 Ill. App. 3d 135, 518 N.E.2d 758 (1988); Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985); Kinney v. Hutchinson, 449 So. 2d 696 (La. Ct. App. 1984); Adkins v. Mong, 168 Mich. App. 726, 425 N.W.2d 151 (1988); Stebbins v. Concord Wrigley Drugs, Inc., 164 Mich. App. 204, 416 N.W.2d 381 (1987); Bikowicz v. Nedco Pharmacy, Inc., 100 A.2d 702, 474 N.Y.S.2d 616 (1984); Hand v. Krakowski, 89 A.2d 650, 453 N.Y.S.2d 121 (1982); Ferguson v. Williams, 92 N.C. App. 336, 374 S.E.2d 438 (1988); Docken v. Ciba-Geigy, 86 Or. App. 277, 739 P.2d 591 (1987); Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 361 Pa. Super. 589, 523 A.2d 374 (1987); Quinn v. Memorial Medical Center, 764 S.W.2d 915 (Tex. Civ. App. 1989); Perkins v. Winsor Hosp. Corp., 142 Vt. 305, 455 A.2d 810 (1982); McKee v. American Home Prods., 113 Wash. 2d 701, 782 P.2d 1045 (1989).

27. *See infra* notes 99-106 and accompanying text.

28. The plaintiff's case against the pharmacist usually focuses on the patient-pharmacist relationship, alleging that the pharmacist failed to meet a duty to directly warn the patient. Only one case, Eldridge v. Eli Lilly & Co., 138 Ill. App. 3d 124, 485 N.E.2d 551 (1985), states the pharmacist owed the patient a duty to contact the prescriber, and it held that the pharmacist had no duty to warn the patient.

29. The defendant's case usually focuses on the physician-pharmacist relationship, with the primary argument being that the pharmacist merely follows doctor's orders, and that if there is any problem with undisclosed risks of prescribed medication, the prescriber should be considered the wrongdoer.

30. Jurists seem to be in awe of the physician-patient relationship, affording it virtually sacred status. The conclusion is generally that pharmacist action for the patient's benefit would harm the physician-patient relationship. This widely accepted view is offered without justification.

31. Cases alleging pharmacists' failure to warn the patient are usually brought when the pharmacist failed to do anything whatsoever. They could inartfully be phrased as "failure to do something" cases. The pharmacist can usually escape liability by contacting the prescriber even without warning the patient. *See infra* notes 90-98 and accompanying text.

tion may be required at all.[32]

A. *A Significant Case Summarizes the Decade*

The 1989 case of *McKee v. American Home Products Corp.*,[33] from the Supreme Court of Washington, stands out from the other pharmacist failure-to-warn cases of the 1980s for several reasons. First, it is from a state supreme court rather than an intermediate appellate court. Second, it is a five-to-four split opinion with lengthy analysis by both the majority and dissent. Third, it is from a state with a mandatory patient counseling regulation applicable to pharmacists.[34] Finally, it was highly publicized, causing significant controversy within the pharmacy profession even before the court released the opinion.[35]

The plaintiff in *McKee* had prescriptions for an amphetamine-like drug that the two defendant pharmacists filled accurately for ten years.[36] The drug was prescribed for appetite suppression.[37] It is well known that the effectiveness of the drug does not usually extend beyond several weeks, while there are significant potential adverse effects from extended use of the drug.[38] The plaintiff became addicted to the drug, and sued the physician, drug manufacturer, and pharmacists under a failure to warn theory.[39] This particular opinion dealt only with the claims against the pharmacists.[40]

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32. *See infra* notes 90-98 and accompanying text.

33. McKee v. American Home Prods. Corp., 113 Wash. 2d 701, 782 P.2d 1045 (1989).

34. At the time the pharmacist defendants in *McKee* dispensed the drugs that harmed the plaintiff, the mandatory patient counseling regulation was slightly different from the current regulation. *See infra* note 141. The earlier regulation did not contain the language regarding the need to counsel patients receiving refills, but otherwise was substantially similar to the current regulation.

35. *See, e.g.*, White, *Pharmacist's Legal Dilemma: To Warn Or Not To Warn?*, DRUG STORE NEWS/INSIDE PHARMACY (Feb. 20, 1989); Rosendahl, *Are You Ready For Another Mandate?*, 132 DRUG TOPICS 24 (July 4, 1988).

36. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1046. The drug is phendimetrazine tartrate, known also under the trade name Plegine.

37. *Id.*

38. Under warnings in the entry for Plegine, the *PDR* states: "Amphetamines and related stimulant drugs have been extensively abused, and the possibility of abuse of Plegine should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program." Under indications, the following statement appears: "Plegine is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction." The plaintiff in *McKee* alleged that the pharmacist defendants should have warned her of the adverse effects of the drug, particularly because of the lack of efficacy over prolonged periods of time, and because they frequently saw her and knew she was not overweight. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1047, 1052.

39. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1047, 1052.

40. The plaintiff alleged she should have received risk assessment information. *Id.* at ____, 782 P.2d at 1047. Had the information been provided, she said she would have stopped using the drug. *Id.* Nevertheless, it is difficult to say that the pharmacists were in no position to

The majority held that the pharmacists had no duty to warn the plaintiff, and thus, the pharmacists could not be held liable.[41] The majority reasoned that the plaintiff's failure to present any expert testimony from a pharmacist concerning the applicable standard of care was fatal to the plaintiff's claim.[42] Although the court could have stopped at that point, it went on to address the substantive issue of the pharmacist's duty to warn because of "the importance of the issue and the public interest therein."[43]

The court examined the pharmacist-physician relationship; and the majority concluded that, without the benefit of a patient's medical history, a pharmacist is not qualified to determine the propriety of a particular drug regimen.[44] Imposing such a duty, the majority stated, would require the pharmacist to question the physician's judgment regarding the appropriateness of each customer's prescription.[45] The pharmacist would be second guessing numerous prescriptions to avoid liability.[46] This duty would not only place an undue burden on pharmacists, but would also be likely to create antagonistic relations between pharmacists and physicians.[47]

The majority opinion deferred to the physician as the proper person to provide drug warnings to patients. This deference was based primarily on the rationale that "[r]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment."[48] The majority

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evaluate risks and benefits (one basic rationale for not requiring that pharmacists provide drug choice information on risk assessment). Because this drug is not beneficial beyond several weeks, and the risks are well known, there would be no great difficulty balancing significant risks against no benefit and determining which way the balance tips. In circumstances such as this, being knowledgeable about drugs may be sufficient to make a judgment about a patient taking the drug, even though no other information about the patient is available. When an adverse drug effect is of high incidence, then drug-specific knowledge is also patient-specific knowledge, because the effect is virtually certain to occur.

41. *Id.* at ____, 782 P.2d at 1055.

42. *Id.* at ____, 782 P.2d at 1052. In an earlier case, Young v. Key Pharmaceuticals, 112 Wash. 2d 216, 770 P.2d 182 (1989), the same court held that a pharmacist may not testify as an expert witness on a physician's standard of care in prescribing medications. The *McKee* opinion adopts the corresponding view that a physician may not testify as an expert on a pharmacist's standard of care in dispensing medications. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1048. The *Young* case is also cited in *McKee* as support for the position that pharmacists are not qualified to make judgments regarding the materiality of risks, and therefore cannot warn patients of potential risks. *Id.* at ____, 782 P.2d at 1051. The initial logic regarding the qualifications of a pharmacist as expert witness on the issue of prescribing may make good sense. But it does not logically follow that pharmacists lack the expertise necessary to provide a warning of risk to patients because they lack the expertise necessary to prescribe medication.

43. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1048.

44. *Id.* at ____, 782 P.2d at 1051.

45. *Id.* at ____, 782 P.2d at 1053.

46. *Id.*

47. *Id.*

48. *Id.* at ____, 782 P.2d at 1051.

clearly believed that warnings by pharmacists were undesirable because "unnecessary warnings to the patient could cause unfounded fear and mistrust of the physician's judgment, jeopardizing the physician-patient relationship and hindering treatment."[49]

The majority attempted to reconcile its opinion with two previous cases that had favored imposing pharmacist liability. The majority conceded that "pharmacists have a duty to be alert for patent errors in a prescription, for example: obvious lethal dosages, inadequacies in the instructions, *known* contraindications, or incompatible prescriptions, and to take corrective measures."[50] Nevertheless, the majority concluded that a pharmacist does not have a duty to question a physician's judgment as to the propriety of a prescription, or to warn patients of the hazardous side effects of drugs.[51]

The four dissenting justices refuted the majority's arguments by concentrating primarily on the pharmacist's knowledge and the duty to use that knowledge.[52] In response to the majority's concession, the dissenters ask rhetorically, "Isn't knowing that Plegine, an amphetamine, should be prescribed only for several weeks rather than 10 years within the definition of the majority's 'obvious lethal dosages, inadequacies in the instructions' or '*known* contraindications'?"[53] The author of the dissenting opinion stated he would have no difficulty holding that the pharmacists were negligent as a matter of law in not warning the plaintiff of Plegine's side effects.[54]

Despite its length and extensive reasoning, the *McKee* opinion did not produce a decisive analysis of pharmacist responsibility. By focusing almost entirely on the pharmacist-physician relationship, the opinion lacked a careful consideration of the pharmacist-patient relationship. The close five-to-four decision in *McKee* suggests that the judiciary may be on the brink of recognizing expansive warning responsibilities for pharmacists, without fully considering the health care context within which the responsibility would exist. This opinion is typical of the pharmacist failure-to-warn cases of the 1980s in that it did not develop a conceptual model of pharmacist responsibility, which can be used to resolve controversies based on specific facts.

B. *The Power Model of Pharmacist Responsibility*

The purpose of this Article is to propose a power model of pharmacist responsibility. This model requires action for a patient's benefit when a pharmacist knows of a risk to a patient, and when it is reasonably foreseeable that harm will result if a warning is not given to the patient. Contrary to the conclusion within the majority opinion in *McKee* and the numerous

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49. *Id.* at ____, 782 P.2d at 1054.
50. *Id.* at ____, 782 P.2d at 1053.
51. *Id.* at ____, 782 P.2d at 1055-56.
52. *Id.* at ____, 782 P.2d at 1056, (Dore, J., dissenting).
53. *Id.* at ____, 782 P.2d at 1063 (Dore, J., dissenting).
54. *Id.* at ____, 782 P.2d at 1056 (Dore, J., dissenting).

other cases that preceded it, this standard would not disrupt current practice, as long as its inherent limits are recognized. Central to an understanding of the power model is an appreciation of what a pharmacist generally knows, and when the materialization of a risk is reasonably foreseeable to a pharmacist filling a prescription.

Contextualization of the pharmacist's duty under a power model requires initial brief consideration of several common judicial presumptions about drug therapy, and their refutations. To justify the argument that a pharmacist is either unnecessary or harmful as a discloser of risks, three presumptions are frequently used. One presumption is that physicians currently are providing patients with sufficient information about drugs.[55] However, empirical data indicate this is not the case.[56] Courts also presume that a pharmacist who provides information about risk to a patient is "second-guessing"[57] the physician. An equally plausible explanation is that the pharmacist is reinforcing the physician. Empirical data show that physicians rec-

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55. This presumption has been justified by the following: "It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy." W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON TORTS 688 (5th ed. 1984) [hereinafter W. KEETON]. The context of this sentence makes it clear that the duty to warn is being given to the physician exclusive of the producer. No discussion of the pharmacist appears in the entire section. It may not logically follow that simply because the producer has no duty to warn the patient (even though he warned the physician) that the pharmacist has no duty to warn the patient.

56. *See, e.g.*, Keown, Slovic & Lichtenstein, *Attitudes of Physicians, Pharmacists, and Laypersons Toward Seriousness and Need for Disclosure of Prescription Drug Side Effects*, 3 HEALTH PSYCHOLOGY 1 (1984) (When pharmacists and physicians were asked to choose between full or partial disclosure of both the frequency and seriousness of side effects, 90% of pharmacists and 68% of physicians were in favor of partial, rather than full disclosure. However, only 33% of the general public favored partial disclosure, with the balance favoring full disclosure.); *see also* Morris, Grossman, Barkdoll & Gordon, *A Segmentational Analysis of Prescription Drug Information Seeking*, 25 MEDICAL CARE 953 (1987) (34% of patients surveyed were considered to be "uninformed" about medications).

57. The pejorative connotation to the phrase "second-guess" may lead to misunderstanding what risk disclosure by a pharmacist accomplishes. When a real estate agent or an accountant discloses potential legal pitfalls to a client, it is generally not considered to be second-guessing of the client's legal representation in a land transaction or tax matter. It is an additional effort to assure that actions being taken are informed and thoroughly evaluated. If pharmacist warnings really are not "second-guessing," but instead are assistance with patient care, then use of the phrase with extreme negative implications may hinder judicial consideration of the issue.

The origin of the oft-cited phrase appears to be the opinion in Jones v. Irvin, 602 F. Supp. 399 (S.D. Ill. 1985). In that opinion, a federal trial judge stated, "Placing these duties to warn on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability." *Id.* at 402. The judge is incorrect because not every prescription requires a warning, and there is no challenge to the physician's authority when a pharmacist reinforces or expands on information previously provided to the patient by the physician. Unfortunately, this careless comment has been referenced by appellate courts, and is on the verge of becoming doctrine. *See, e.g.*, McKee v. American Home Prods. Corp., 113 Wash. 2d 701, ____, 782 P.2d 1045, 1053 (1989).

ognize a risk-disclosure role for pharmacists.[58] A final significant presumption is that it is bad for a patient to modify drug use based on information from someone other than the physician.[59] Again, empirical studies suggest "informed noncompliance" may actually improve the quality of drug therapy.[60] Despite the existence of data to the contrary, the presumptions that give deference to physician authority may not be eradicated. However, the data should at least generate discussion of arguments that pharmacists' warnings are unnecessary or harmful.

Deference to physicians may be warranted under circumstances in which patient-specific knowledge is required to know of a risk, but unwarranted when drug-specific knowledge is required to know of a risk. Pharmacists know about drugs, and drug knowledge may be all that is necessary to warn of a risk. For example, if a drug may cause drowsiness or is best absorbed into the blood stream when taken on an empty stomach, a pharmacist may convey that information to a patient, without any knowledge of the patient's tendency to be sleepy or problems with absorption. In such circumstances the risks of sedation or subtherapeutic blood levels can be reduced.

The most commonly used rationale for deference to the physician is that only those who are qualified to evaluate a medical history and physically examine a patient have specific patient-related knowledge. However, there are many situations in which these abilities are not a prerequisite to risk disclosure. A pharmacist's knowledge of a drug may cause the pharmacist to know that the way in which a drug has been prescribed would pose a risk to any patient, no matter what their history or physical condition may be.

Some types of information about risk can only be recognized as significant by one who is trained to evaluate a medical history or examine a patient. For example, if a drug is risky for those who have frequent nose bleeds

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58. *See, e.g.*, Moss, Garnett & Steiner, *Physician Attitudes Toward Pharmacists Counseling Patients on Adverse Drug Reactions*, 37 AM. J. HOSP. PHARM. 243 (1980) (the results indicate that physicians would accept pharmacists as patient consultants in the area of adverse reactions, under the circumstances described to them, and especially on a partnership basis); *see also* Ritchez & Ranez, *Effect of Exposure on Physicians' Attitudes Toward Clinical Pharmacists*, 38 AM. J. HOSP. PHARM. 1459 (1981) (in a survey of physicians, 64% agreed that pharmacists should counsel patients, making this the most accepted nontraditional pharmacy task).

59. The worst case scenario is that a patient will forego drug use or will alter drug use, based on information provided by a thoughtless pharmacist, and will die due to the absence of therapeutic benefit. Apparently because of the remote possibility that this hypothetical case will occur, courts have been hesitant to recognize that any good can come from modifications in drug use based on pharmacists' warnings.

60. *See, e.g.*, Stimson, *Obeying Doctor's Orders: A View from the Other Side*, 8 SOC. SCI. & MED. 97 (1974) (from the point of view of patients and in terms of the social context of drug use, there are many reasons for not doing what the doctor says); *see also* Conrad, *The Meaning of Medications: Another Look at Compliance*, 20 SOC. SCI. & MED. 29 (1985) (what appears to be noncompliance from a medical perspective may actually be a form of asserting control over one's disorder).

or high blood pressure, only a physician, who is in a position to determine whether such a condition exists in a patient, can evaluate the risk. A pharmacist ordinarily cannot be expected to know whether a patient has such a condition. It is impossible for a pharmacist to routinely inquire about the many physiologic idiosyncrasies that may affect a patient presenting a prescription.[61]

On the other hand, a pharmacist may know things about a patient based on prior experience with that person. The Georgia Court of Appeals recently made the following observation in affirming a jury verdict against a pharmacist:

> There was a relationship of professional trust of a several years duration between Mrs. Gordon and pharmacist Frost. Frost was in a position of control over Gordon's health and welfare to the extent of properly dispensing needed medications, and as the evidence demonstrated, on occasion making other health recommendations, i.e., advising a non-prescription remedy. Moreover, Frost's position put her in the particular posture of familiarity with Mrs. Gordon's physical and/or emotional state by her ready and continuing access to the lengthy computerized documentation of Mrs. Gordon's prescribed medication in addition to personal exchanges and encounters with the customer relative to her health needs.[62]

The pharmacist's knowledge of the patient went beyond knowledge of the drugs themselves, and led to a duty that would not have existed in the absence of the longstanding relationship.

Foreseeability of harm,[63] as the second prong of the power model, operates to limit liability for failure to disclose a risk that was known but was unlikely to occur. As with knowledge, foreseeability may be drug-specific as well as patient-specific. Some risks are so highly probable that they warrant disclosure by a pharmacist no matter who the patient may be. Knowledge of the drug's characteristics makes the risk to the patient foreseeable. Other risks are equally well known, but occur infrequently and a pharmacist may

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61. This is not to say that pharmacists cannot interview patients and assemble such information when time and circumstances permit. In fact, this is done routinely by some pharmacists. The American Pharmaceutical Association's Standards of Practice for the Profession of Pharmacy states that the pharmacist "[i]nterviews the patient or his/her representative to obtain information for entry into patient record, patient profile, or family health record." 19 AM. PHARMACY 134, 142 (1979). Nevertheless, the realities of contemporary pharmacy practice would suggest that this optimistic standard cannot be met for every patient by every pharmacist, and it would be a mistake to consider as a malpractitioner every pharmacist who does not conduct this very time-consuming process.

62. Gordon v. Frost, 193 Ga. App. 517, ____, 388 S.E.2d 362, 366 (1989) (reversing judgment notwithstanding the verdict and reinstating a $220,000 jury verdict against the defendant pharmacist).

63. For a more in-depth discussion of the foreseeability issue, see *infra* notes 255-69 and accompanying text.

have no way to know of a patient's peculiar susceptibility. Such a risk is ordinarily unforeseeable to a pharmacist.

Acceptance of the power model of pharmacist responsibility requires recognition that patients have the right to be informed of the risks of drug use, and that pharmacists may have the information patients need.[64] Focusing solely on the physician as a source of information inefficiently squanders the pharmacist's expertise.[65] Nevertheless, the assistance a pharmacist can provide is limited. Current pharmacy practice patterns reflect a product-orientation that is in transition through a physician-orientation toward a patient-orientation. Adopting the power model, with knowledge and reasonable foreseeability of harm as the tests, will produce a standard that can accommodate changes in practice. In addition, legal requirements can expand to reflect practice trends and abilities.

IV. Patterns of Pharmacy Practice

Some scholars have referred to pharmacists as overtrained and underutilized.[66] After a five-year college education, pharmacists traditionally exercise less professional judgment than do journalists, architects, engineers, teachers, and other professionals with equivalent or lesser training. The limits placed on the pharmacist's exercise of professional discretion exist primarily because of the omnipotent position physicians occupy in health care. Generic substitution is the only discretionary function that pharmacists in recent years have been asked to perform.[67] Legislative authority to perform that function independent of physician supervision came only after repeatedly expressed consumer demand in the face of opposition from physicians and the pharmaceutical industry.[68]

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64. There is no clear evidence that pharmacists today are as well qualified as physicians to inform patients about drug risks, but there is also no evidence that they are not. In a drug distribution system in which pharmacists were expected to assume this role, they would undoubtedly do it well. One of the insidious costs of a status quo is that alternate modes of practice are not put to the test. The benefits of alternate modes are unknown and will not be missed. An unknown cost is nevertheless a cost.

65. The medical profession, unlike most institutions, is integrated horizontally. Unlike insurance agents, bankers, and others who give legal advice without authorization or supervision from an attorney, nurses and pharmacists are required to follow the instructions of the physician rather than exercise professional judgment. Vertical integration could improve therapeutic outcomes, because these professionals would be doing what they do best.

66. V. Fuchs, Who Shall Live? Health, Economics, and Social Choice 112-15 (1983).

67. In most states, the generic substitution law requires that the physician either specifically permit or specifically prohibit substitution by the pharmacist, so the decision to substitute is not solely that of the pharmacist. Once the decision to permit substitution has been made, however, the choice of which generic product to substitute for the trade name product is entirely up to the pharmacist. *See* Segal, Wantz & Brusadin, *Pharmacist's Decision Making in the Selection of Generic Pharmaceuticals*, 4 J. Pharm. Marketing & Mgmt. 75 (1989).

68. *See* Haddad, *Generic Drugs—Tomorrow's Market*, 33 Food Drug Cosm. L.J. 488 (1978); *see also* Fern, *Missouri's Drug Product Selection Law and Pharmacist Liability*, 24 St.

Pharmacists differ from most other nonphysician health care providers who act under physicians' orders, such as nurses and various therapists, because pharmacists have an independent practice not institutionally tied to the physician. However, true independence in pharmacy practice has never developed.[69] The evolution of modern pharmacy practice began with the "compounder pharmacist,"[70] who was an expert on the formulation of ingredients into a final product. That phase gave way to the "technical pharmacist,"[71] whose expertise is in drug distribution systems.

While distributive functions still predominate in pharmacy, the "clinical pharmacist"[72] is growing in importance. Clinical pharmacy purports

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LOUIS U.L.J. 135 (1979).

69. A complete history of the pharmaceutical profession is contained in G. SONNEDECKER, KREMERS ANN URDANG'S HISTORY OF PHARMACY (4th ed. 1976). The independent responsibility of the pharmacist to assure proper drug use has been fairly well defined within the realm of narcotic controlled substances. There is no question that when a pharmacist has good reasons to believe that a prescription for a narcotic has been issued for other than a legitimate medical use, the pharmacist must not dispense the prescribed medication. 21 C.F.R. § 1306.04 (1987). Yet, this function requires only that the pharmacist distinguish between medicine and nonmedicine, not that the pharmacist distinguish between good medicine and bad medicine. When a prescription is written for a medical purpose, the pharmacist still depends on the physician's medical judgment, and is not required to question whether the prescription represents the best medicine, as opposed to something that is less than the best medicine.

70. America was settled by Europeans who did not bring with them the developing European concept of pharmacy as a separate profession. The "apothecary" of colonial and frontier America usually functioned as both pharmacist and physician. Gradually, retail "druggists" (now considered a derogatory term by pharmacists) evolved, as medicinal preparations became more complex, and as the expertise to prepare them became more difficult to acquire. By the early 20th century, American pharmacy was experiencing healthy times. Although the specific mechanism of action of most drugs was not known, the scientific approach to medicine was developing, and pharmacists were called upon to create new ways of compounding medicines for administration to the patient. Together, the physician and pharmacist observed the results of these new creations, and determined what further modifications might result in improved therapy. The pharmacist's expertise related primarily to the product and its formulation, while the physician provided expertise relating to the patient and the effect of the drug. The compounder pharmacist's liability arose primarily as the result of the inclusion of a foreign substance in a prescription. *See, e.g.*, Cody v. Toller Drug Co., 232 Iowa 475, 5 N.W.2d 824 (1942); Connie's Prescription Shop v. McCann, 316 P.2d 823 (Okla. 1957).

71. Following World War II, large pharmaceutical manufacturers assumed the responsibility for formulating and producing drug products, and the emphasis in pharmacy practice switched from compounding, to the dispensing of already compounded products. Even then, however, the pharmacist's role in drug distribution required a high level of skill and expertise, because the slightest mistake could lead to injury or death. The technician pharmacist's liability arises primarily out of inaccurate prescription filling. *See infra* notes 83-89 and accompanying text.

72. By the early 1960s, the same trend in product development that had all but eliminated the need for extemporaneous compounding in retail pharmacies had created a need for drug therapy monitoring and for education of patients on drug use. The increasing complexity of pharmacotherapeutics, and the tendency of patients to seek medical assistance from several different practitioners, led to an increased likelihood that adverse drug reactions or interactions between drugs would occur. In the last two decades, a growing number of pharmacists have

to be patient-oriented rather than product-oriented. In reality, however, clinical pharmacy has frequently been implemented with a physician orientation, because it stresses concepts such as "noncompliance," in which the pharmacist's role is to assure that the patient will use a drug precisely the way the physician has ordered. To more fully implement the concept of added value, it may be necessary for pharmacy to shift again, this time toward a truly patient-oriented role. In this role the "advocacy pharmacist"[73] would serve the patient's best interests, unconstrained by many of the limits currently imposed through physician dominance in health care.

Before the 1950s, pharmacists were often taught *not* to tell patients anything about prescribed medications.[74] But patient counseling has played a significant role in pharmacy practice since the middle of the century. Many pharmacists today still practice within the technical model, and believe that it is their responsibility to tell the patient several important facts about a drug, but not to further elaborate. Frequently this responsibility is met through auxiliary labels or "stickers" affixed to the medication container.[75] The clinical pharmacist is more heavily involved in verbal counseling, providing assurance for the patient that the doctor knows what is best, and admonishing patients about problems that can arise if doctor's orders are not followed.[76] Pharmacists who embrace the advocacy model discuss benefits and detriments of drug therapy with the patient. They encourage the patient to assume responsibility for drug therapy, based on an understanding of a drug's pharmacological effects, within the framework of

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assumed a new professional role as overseers of drug therapy, and as therapeutic advisors to patients and to other health care professionals. For an insightful discussion of the shift toward clinical pharmacy, see Hepler, *The Third Wave in Pharmaceutical Education: The Clinical Movement*, 51 AM. J. PHARM. EDUC. 369 (1987).

73. The concept of the advocacy pharmacist has not yet fully developed. It is loosely based on the nursing model, which suggests that nurses have a responsibility to patients that supercedes their responsibility to physicians. The advocacy pharmacist would be a community based health care practitioner who would assist patients in developing an acceptable approach to medication use. *See* Pinch, *Patient Advocacy, Ethical Dilemmas and Decision Making: The Importance of Autonomy*, 32 IMPRINT 36 (1985); Schulz & Brushwood, *The Pharmacist's Role in Patient Care*, 21 HASTING CENTER REP. 12 (Jan.-Feb. 1991).

74. The 1952 version of the Code of Ethics of the American Pharmaceutical Association stated: "The pharmacist does not discuss the therapeutic effects or composition of a prescription with a patient. When such questions are asked, he suggests that the qualified practitioner is the proper person with whom such matters should be discussed." 13 J. AM. PHARM. A. PRAC. PHARM. ED. 722 (1952). *But see* Linn, *Indicated Versus Actual Behavior: The Pharmacist as Health Advisor*, 7 SOC. SCI. & MED. 191 (1973).

75. Morris & Moore, *Patient Education Materials Provided by Community Pharmacists*, 23 AM. PHARMACY 569 (1983).

76. *See, e.g.*, Gurwich & Swanson, *Clinical Pharmacy Practice in an Outpatient Clinic*, 15 J. AM. PHARM. A. PRAC. PHARM. ED. 392 (1975); Perry & Hurley, *Activities of the Clinical Pharmacist Practicing in the Office of a Family Practitioner*, 9 DRUG INTELLIGENCE & CLIN. PHARM. 129 (1975).

the patient's own lifestyle, values, and environmental factors.[77]

It is important for every professional to have goals and aspirations, and pharmacists can be proud that the advocacy model of practice is a goal toward which they aspire. But contemporary pharmacy practice remains circumscribed by physician preeminence. Optimistic talk from organized pharmacy about new and expanded patient care roles should not be confused with generally accepted practice standards. Pharmacists have a critical role to play in drug distribution and health care, but that role currently is limited. Legal analysis of pharmacy should reflect both the importance of the pharmacist in the drug distribution chain and the boundaries of conventional pharmacy practice.

V. The Traditional Approach to Pharmacist Malpractice

The legal duty required of the pharmacist has been described as "ordinary care,"[78] a "high degree of care,"[79] and "great care."[80] This semantic distinction accentuates the differing attitudes of courts toward the pharmacy profession. Nevertheless, the well-settled rule is that, to avoid negligence, a pharmacist is required to use that degree of care which a reasonable and prudent person would use under similar circumstances.[81] A pharmacist is bound to exercise the skill generally possessed by well-educated pharmacists who are considered competent in their profession, rather than the highest skill and learning, which can only be attained by a few men and women of rare genius, endowments, or opportunities.[82]

A pharmacist who fills a prescription in a way that differs from the doctor's prescription has breached the duty of ordinary care owed to the patient.[83] This principle is so well established that, even though the plaintiff bears the burden of proof in pharmacist malpractice litigation, the practical result is that evidence of a misfilling error raises an inference sufficient to

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77. *See* Conrad, *supra* note 60; Conrad, *The Noncompliant Patient in Search of Autonomy*, 17 Hastings Center Rep. 15 (1987).

78. Jones v. Walgreen Co., 265 Ill. App. 308, (1932).

79. Speer v. United States, 512 F. Supp. 670, 679 (N.D. Tex. 1981) *aff'd*, 675 F.2d 100 (5th Cir. 1982).

80. Fuhs v. Barber, 140 Kan. 373, ____, 36 P.2d 962, 963 (1934).

81. Expert testimony is permitted in a pharmacist malpractice case to show the custom and practice of other pharmacists in the community, and the custom and habit of the defendant pharmacist. *See, e.g.*, Burt v. Robb, 137 So. 2d 113 (La. Ct. App. 1962); Daniels v. Dick, 95 Kan. 72, 147 P. 845 (1915). However, a local custom may be irrelevant if that custom is to depart from a nationally recognized standard. *See* Hoar v. Rasmusen, 229 Wis. 509, 282 N.W. 652 (1938).

82. Taugler v. Ling, 127 Ohio St. 142, ____, 187 N.E. 19, 21 (1933).

83. *See* Annotation, *Druggists Civil Liability for Injuries Sustained as Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R.4th 270 (1981); 4 Negligence Compensation Cases Ann. 4th *Druggist's Liability*, 357 (1983); 32 Am. Jur. Trials *Pharmacist Liability* 375 (1985).

establish a virtual presumption of negligence. The pharmacist must then introduce evidence to rebut the presumption.[84] Most successful lawsuits against pharmacists have arisen from the failure of a pharmacist to accurately perform a mechanical task, resulting in an error involving the wrong drug, wrong dose, or wrong directions.[85]

As a practical matter, pharmacists may be the only health professionals who are required to practice in a completely error-free manner. It is generally accepted in tort law that an honest error in professional judgment, which with the benefit of hindsight seems wrong, but at the time was reasonable given the circumstances, is not actionable as negligence.[86] Thus, a doctor who prescribes two digoxin tablets daily when one would have been better, or who prescribes theophylline when ephedrine is the drug of choice, is seldom regarded as a malpractitioner, if it can be shown that the prescription was reasonable at the time it was issued. The harm that results from what is in retrospect viewed as a mistake in a prescription is forgiven as the unavoidable consequence of human judgment, which is not infallible.

Pharmacists, on the other hand, will virtually always be held liable if they instruct the same patient to use two digoxin tablets daily when one was prescribed, or if they dispense theophylline when ephedrine was ordered, and the patient suffers harm. It would be considered irrelevant that two digoxin tablets instead of one, or theophylline instead of ephedrine was reasonable for the patient. The fact that some harm to someone is inevitable because pharmacists are human, and humans are fallible, is no defense. Dispensing errors, unlike prescribing errors, are not forgiven. Perhaps this is because prescription dispensing is viewed as a nonjudgmental technical task. There can be no accommodation for an honest error in judgment when no judgment has been exercised.

In an authoritative and scholarly article published in 1959, Professor George Savage King reviewed the malpractice liability of pharmacists as reflected in reported cases.[87] Professor King's analysis related primarily to mechanistic errors that could occur during dispensing. Little attention was given to the potential for harm caused by the exercise of a pharmacist's pro-

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84. *See, e.g.*, Highland Pharmacy v. White, 144 Va. 106, 131 S.E. 198 (1926).

85. The breach of a pharmacist's general duty of care may rarely occur in circumstances other than traditional misfillings. A pharmacist breaches the duty of care by failing to observe signs of deterioration that are visible in a prepackaged pharmaceutical. Potter v. Krown Drugs, 214 So. 2d 198 (La. Ct. App. 1968). A pharmacist owes a specific duty to assure that a patient is competent to use rationally a dispensed drug. Trumbaturi v. Katz & Besthoff, 180 La. 915, 158 So. 16 (1934). There is likewise a duty to know the purposes of drugs dispensed. Tucker v. Graves, 17 Ala. App. 602, 88 So. 40 (1920). And there is also a duty to employ only persons who are qualified to work in a pharmacy. Corona Coal Co. v. Sexton, 21 Ala. App. 51, 105 So. 716 (1925).

86. *See, e.g.*, Estate of Smith v. Lerner, 387 N.W.2d 576 (Iowa 1986); Haase v. Garfinkel, 418 S.W.2d 108 (Mo. 1967).

87. King, *Liability for Negligence of Pharmacists*, 12 VAND. L. REV. 695 (1959).

fessional judgment, although Professor King predicted expanding liability for pharmacists.[88] The rationale underlying civil litigation involving pharmacists reflects the fact that as a matter of public policy, malpractice law serves not only to compensate victims of another person's negligence, but also to deter negligent conduct, insofar as that is possible.[89] But civil courts have been reluctant to recognize that the pharmacist is a professional whose judgment must be utilized for the patient's benefit. The effect of deterring negligent conduct, which the recognition of the expanded pharmacist liability might cause, will not be fully achievable in a system that allows for judgment only by physicians.

Two cases that are over a half century old contain language suggesting that, under certain circumstances, a pharmacist should second-guess a physician's medical judgment, and should substitute a different medical view by refusing to fill a prescription. In *Jones v. Walgreen Co.*,[90] the court said of the defendant pharmacist, "As a chemist he may know that the physician has erred in his prescription and that to fill it might cause death or serious injury to the patient."[91] In *People's Service Drug Stores v. Somerville*,[92] the court phrased the all-important question as: "Under what circumstances should a pharmacist set up his judgment against that of a licensed physician?"[93] The court observed that a pharmacist who was negligent in filling a prescription could not escape liability because the doctor who wrote the pre-

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88. Professor King recognizes that "the facts of a case often speak louder than the words of the court's opinion." *Id.* at 709. His message is that a court may indicate a pharmacist is liable for a simple misfilling error, when the reality is that the error would not have occurred, or would have been quickly rectified, if the pharmacist had been doing a better job of taking care of the patient. Therefore, liability that appears to be based on misfeasance, may in reality be based on the failure to act in a way that would prevent harm. For example, a pharmacist who counsels patients on correct drug use will learn if a prescription has been misinterpreted and the wrong drug dispensed, or if the patient is a child (not the mother who has presented the prescription) and the dose is too large. In this regard, patient counseling is a liability reducing factor, because it enables a pharmacist to detect and correct misfilling errors, while the failure to counsel correspondingly increases liability for routine mistakes that go undetected. Professor King continues by noting that "[n]ot many courts are bold enough to impose an increased measure of responsibility in clearcut language until the principle is rather thoroughly established by new meaning given to old terms." *Id.*

89. In Troppi v. Scarf, 31 Mich. App. 240, 187 N.W.2d 511 (1971), the court considered the purpose of pharmacist civil liability and concluded as follows:

> In theory at least, the imposition of civil liability encourages potential tortfeasors to exercise more care in the performance of their duties, and hence, to avoid liability-producing negligent acts. Applying this theory to the case before us, public policy favors a tort scheme which encourages pharmacists to exercise great care in filling prescriptions. To absolve defendant of all liability here would be to remove one deterrent against the negligent dispensing of drugs.

Id. at ____, 187 N.W.2d at 517.

90. Jones v. Walgreen Co., 265 Ill. App. 308 (1932).

91. *Id.* at 320.

92. People's Serv. Drug Stores v. Somerville, 161 Md. 662, 158 A. 12 (1932).

93. *Id.* at ____, 158 A. at 13.

scription was also liable.[94] Nevertheless, the court said that it would be a dangerous principle to establish that a pharmacist cannot safely fill a prescription merely because it was out of the ordinary.[95] If that were done, many patients might die from being denied unusual remedies in extreme cases.[96] The pharmacist's duty, according to the court, was to contradict a physician only when medication orders were obviously fatal, and to simply make inquiry of the physician when an order appeared to be nonlife threatening but unusual.[97]

More recent cases have confirmed that a pharmacist has no duty to act when the pharmacist is unaware of a specific and avoidable substantial risk to the patient.[98] Courts have not required that pharmacists challenge a physician's judgment by refusing to fill a potentially harmful but nonlethal prescription in order to avoid liability for malpractice.

The earliest pharmacist malpractice case to consider the pharmacist's duty to counsel patients was *Fuhs v. Barber*,[99] a 1934 Kansas case. The court's opinion syllabus contains language hinting at the existence of a common law duty for pharmacists to counsel patients.[100] The facts of the case show that the defendant pharmacist told the plaintiff to discontinue use of a poison ivy ointment a physician prescribed, and to use a nonprescription ointment the pharmacist recommended instead. Allegedly, the pharmacist neglected to counsel the patient that the two products could interact, and to wash from the skin the residue of the old product before using the new product.[101]

When the two products interacted and caused harm to the plaintiff's skin, she returned to the pharmacist, who advised her to continue using the nonprescription product. This erroneous advice only caused exacerbation of the condition.[102] In determining that the pharmacist had a duty to counsel about the potential interaction, the court reacted in large part to the ex-

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94. *Id.*
95. *Id.*
96. *Id.*
97. *Id.* at ____, 158 A. at 14.
98. *See, e.g.*, Jones v. Irvin, 602 F. Supp. 399 (S.D. Ill. 1985); Pysz v. Henry's Drug Store, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984).
99. Fuhs v. Barber, 140 Kan. 373, 36 P.2d 962 (1934).
100. *Id.* at ____, 36 P.2d at 962. The syllabus of the court states:

> [R]egistered pharmacist and druggist selling drugs, poisons, medicines and compounds of the same, should always exercise great care, and where a drug, harmless in itself, is to be mixed or used in connection with another, which would then have an injurious effect, and the purchaser has no knowledge of this effect, he should exercise a high degree of care in advising the purchaser of this injurious effect and of the combination. A failure to exercise such care will make him liable for the consequences.

Id.
101. *Id.* at ____, 36 P.2d at 964.
102. *Id.* at ____, 36 P.2d at 963.

treme misconduct of the pharmacist in contradicting the physician's prescription, and in giving poor advice after the injury had occurred.[103] Because of the extreme facts, one should not rely on *Fuhs* as establishing a general duty for pharmacists to counsel patients. The language of the case suggests liability for nonfeasance, whereas the facts show acts of misfeasance.

The only other pre-1980s appellate opinion to squarely consider the issue of the pharmacist's duty to warn was an even more factually bizarre case, *Krueger v. Knutson*.[104] The plaintiff in *Krueger* was a sixteen-year-old boy who purchased a quantity of potassium chlorate from the defendant pharmacist, and used it in combination with other chemicals to make fuel for a toy rocket. When the rocket exploded, injuring the plaintiff, the lawsuit ensued, alleging negligent failure to warn of the explosive nature of potassium chlorate.[105] A verdict for the plaintiff was upheld on appeal. The court relied on the rationale expressed in *Fuhs*, and on a previous case ruling that retailers generally have a duty to warn of the dangerous propensities of goods they distribute.[106] As was the case with *Fuhs*, the broad language of *Krueger* is difficult to extend beyond the narrow confines of its nontraditional facts.

Through the 1970s, pharmacist malpractice litigation continued to be based almost entirely on alleged errors of misfeasance, and the key legal issue was causation, once the occurrence of a dispensing error was established.[107] The unprecedented increase in allegations of nonfeasance through

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103. *Id.* at ____, 36 P.2d at 964.

104. Krueger v. Knutson, 261 Minn. 144, 111 N.W.2d 526 (1961).

105. *Id.* at ____, 111 N.W.2d at 528-29.

106. *Id.* at ____, 111 N.W.2d at 532. The court cited Benes v. Campion, 186 Minn. 578, ____, 244 N.W. 72, 73 (1932) for the proposition that "a maker or dealer who puts out an article which is poisonous or dangerous to use, when used as intended, without giving notice of its dangerous qualities, is liable not only to the buyer, but to any person who suffers injury by the use thereof, such injury being one that might reasonably be anticipated."

107. There is a line of cases from the years before 1980 that appears to deal with liability for nonfeasance, but in reality is nothing more than a series of drug product liability cases in which the drug manufacturer is the real defendant, and the pharmacist is simply joined as a codefendant. The parallel arguments that the manufacturer provided an inadequate warning, and that the pharmacist also failed to warn, suffer from the inconsistency that if the manufacturer's warning was inadequate, then the pharmacist had no way to know of the adverse effect, and could not have provided a warning. *See infra* notes 142-43 and accompanying text. The first case in this line of cases is McLeod v. W. S. Merrell Co., 174 So. 2d 736 (Fla. 1965). This case deals with a claim by the plaintiff that he was harmed by the drug MER/29, and that the manufacturer and pharmacist failed to adequately warn of potential risks of drug use. The second case is Batiste v. American Home Products Corp., 32 N.C. App. 1, 231 S.E.2d 269 (1977). The plaintiff alleged in this case that the pharmacist failed to warn of "the numerous risks, hazards, contraindications, harmful side effects and dangerous adverse reactions, including clotting of the blood, and severe strokes, inherent in the use and consumption of said oral contraceptive drug." *Id.* at ____, 231 S.E.2d at 273. The case was dismissed against the pharmacist. In Bichler v. Willing, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1977), the court dismissed the complaint against the pharmacist and acknowledged that at the time of the sale there was no

failure to counsel that began in the early 1980s has met with predictable concern and criticism. The legal issue of duty owed is intimidating to pharmacists in discussions of duty-to-counsel litigation, just as it is intimidating to physicians in discussions of informed-consent litigation. Concern that expanded legal duties for pharmacists will not be appropriately limited in scope has led to considerable conjecture about the potential adverse consequences of such an expansion.[108]

One frequently expressed concern is a duty for pharmacists to counsel patients would require that pharmacists impart to all patients all known information about every drug.[109] Because such "full disclosure" is impossible, the argument suggests that pharmacists would be liable any time a drug harms a patient and the patient can successfully assert that the harm would not have occurred (because the drug would not have been taken) if the information had been provided. This is a "straw man" argument, because courts have not consistently imposed such overly burdensome disclosure requirements on physicians. Therefore, there is no reason to believe that a requirement applicable to pharmacists would be of such an unlimited character. Courts are accustomed to setting limits on legal responsibilities. A sound theoretical basis for limited pharmacist nonfeasance liability, accompanied by several well-reasoned judicial opinions, would suffice to avoid automatic exposure to malpractice for failing to tell all patients all known information about every drug.

A second criticism of plaintiffs' attempts to establish a pharmacist's duty to counsel (and any judicial move to recognize such a duty) is the "slippery slope" argument. This argument reasons that recognition of a limited duty inevitably would lead to unlimited expansion into new areas of liability. Therefore, the argument suggests the first step should not be taken, be-

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recognized risk that called for a warning. The court noted that a seller is only required to warn of a risk of which the seller knows or should know. *Id.* at ____, 397 N.Y.S.2d at 59. Under this rationale, any case alleging that both the manufacturer and the pharmacist failed to warn suffers from a conceptual flaw, because it is from the manufacturer that warnings come to a pharmacist.

108. *See, e.g.*, Duckworth, *supra* note 10.

109. One example of this argument is the opinion in Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985). In describing the plaintiff's contention, the court stated, "His complaint alleges Hook's negligently failed to warn him of side effects associated with Valium, including dizziness, drowsiness, and syncope, failed to advise him to avoid working near machinery, and failed to add these warnings to the label on the drug." *Id.* at 883. At the end of the opinion, the court stated, "Ingram's position would require a pharmacist filling a prescription for Valium to give the entire list of side effects and cautionary statements. Such a voluminous warning would only confuse the normal customer and be of dubious value." *Id.* at 887 n.4. In reality, the plaintiff's position was not nearly so broad. He contended that he should have been given the single most obvious piece of risk management information about Valium: that it may cause drowsiness. Giving this one piece of information is not as likely to cause confusion or be lacking in value as is a list of all side effects and cautions. By mischaracterizing the plaintiff's argument, the court facilitates its own criticism, but it fails to respond to the actual allegations.

cause it would necessarily begin a judicial race toward a legal duty by pharmacists to perform functions for which they are not qualified, and for which they have no authority.[110] The refutation of this criticism is that the judiciary is by no means so undisciplined as to permit unwarranted expansion into new areas of liability, and to the extent that pharmacy practice patterns actually do change, the judiciary should recognize those changes through expanded legal expectations.

The final commonly heard criticism of recognizing expanded pharmacist responsibilities is a "fall back" argument based on pragmatic concerns. This argument concedes that a limited duty to counsel is possible, and that the judiciary can be trusted not to unjustifiably expand it. However, those who make this argument contend that pharmacists do not have the time to counsel, do not have the physical setting within which to correctly perform counseling tasks, and do not receive adequate compensation to justify establishing a legal duty to counsel.[111] This point is well taken. To the extent that the expansion of patient-oriented responsibilities is prevented by circumstances and environmental factors beyond a pharmacist's control, conditions of practice should be recognized as relevant to an analysis of expanded judicial expectations of pharmacists. Nevertheless, if circumstances and environment can be changed without undue hardship, then it is not inappropriate to attach only minor significance to these factors in evaluating the potential nonfeasance liability of pharmacists.

VI. Evaluating Drug Risks

The drug distribution system, while rigid in some respects, is sufficiently flexible to accommodate risk evaluation at several levels. It is possible to view the system as having three levels at which to evaluate risk. The first level is a negotiated process that occurs between the Food and Drug Administration ("FDA") and a new drug's industrial sponsor.[112] In deciding whether to approve a new drug, and how that new drug will be labeled if approved for marketing, a scientific assessment of risk is made, based on knowledge of general population characteristics. At this first level, individ-

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110. *See, e.g.*, Duckworth, *supra* note 10, at 12.

111. The burden on pharmacists of imposing a duty to warn would not be a complete barrier to the recognition of a duty, but it is a factor to balance against benefits to be expected. *See, e.g.*, Leesley v. West, 165 Ill. App. 3d 135, 518 N.E.2d 758 (1988).

112. "New Drugs" are those drugs that are "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1) (1986). No person may introduce a new drug into interstate commerce unless the FDA has approved a new drug application ("NDA") for that drug. 21 U.S.C. § 355 (1986). A drug is approved by the FDA as safe and effective, not because it is harmless and always works, but because its benefits outweigh its detriments. *See* Kennedy, *A Calm Look At Drug Lag*, 239 J. Am. Med. A. 423 (1978); *see also* McMahon, *How Safe Should Drugs Be?*, 249 J. Am. Med. A. 481 (1983).

ual patient characteristics are not considered, because future drug users are unknown and unknowable.

A second level of risk evaluation occurs after the drug becomes available, when a physician tries to determine for an individual patient whether the benefit of the drug exceeds its detriment.[113] The physician makes a clinical assessment of risk, based on knowledge of the particular patient's medical history and diagnosis. Even if a drug is generally recognized as safe and effective, it may cause adverse effects that do not relate to a characteristic of the drug itself, but to a patient's particular susceptibility to an effect. Only by having a physician consider each patient's physiologic idiosyncrasies can an evaluation of risk be reasonably accurate.

The third level of risk evaluation occurs every time a patient self-administers a medication.[114] A personal assessment of risk is made by the patient, based on the patient's circumstances and attitudes at that moment. Patients may choose to avoid a risk by not using a drug, or to manage a risk by modifying their lifestyle in a way that will decrease the probability that an adverse effect will occur. Pharmacists can assure through patient counseling that decisions made at the third level of risk evaluation are as informed and as careful as those made earlier.

The system's ability to assess and manage risk depends on the free flow of accurate information from those more knowledgeable to those less knowledgeable. Scientific, clinical, and personal decisions are all of better quality when responsibilities for the provision of information are met.

A. *The Pharmaceutical Manufacturer's Responsibility*

Drug product liability litigation has addressed the issue of the adequacy of warnings pharmaceutical manufacturers provide to physicians.[115] Under the "learned intermediary" doctrine, the manufacturer's responsibility is to

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113. Physicians hold the key to the medicine chest for those drugs that are available only through a prescription. A prescription drug is a "drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 12 U.S.C. § 353(b)(1)(B) (1986). The prescription requirement has been criticized in recent years as being overly broad in its current form, sometimes serving as a disincentive for patients to acquire information necessary to make a decision about their own treatment. *See* Mitchell, *Deregulating Mandatory Medical Prescriptions*, 12 Am. J. Law & Med. 207 (1987).

114. Decisions patients make concerning the use or nonuse of prescribed medications can be viewed as self-regulation. The only difference between this type of regulation and the regulation that occurs at the manufacturer or physician level, is that it is viewed as outside the system, and therefore aberrant. There have been suggestions that decisions made by patients should be included within the system, and that doing this would result in those decisions being made more carefully. *See* Conrad, *supra* note 60.

115. For a discussion of the warning defect theory of drug product liability, see Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 St. Louis U.L.J. 633 (1986).

warn the physician of risks it knew about or should have known about when the drug was manufactured or distributed, given the state of the art at that time.[116] As the best expert on its own product, a manufacturer is under a continuing duty to warn physicians of newly discovered risks.[117] The breadth of the warning required has been described this way:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it . . . ; and 5. the means to convey the warning must be adequate.[118]

In practice, the warning requirement imposed on manufacturers is usually met by using appropriate language in a leaflet known as the "package insert," which accompanies the drug product and details the uses, contraindications, and toxicities of the medication.[119]

Physicians seldom see this package insert, but the *Physician's Desk Reference* (*"PDR"*) reprints all information contained in the package insert, if a manufacturer opts to have its product included in the *PDR*, giving the physician ready access to knowledge concerning drug warnings and risks. If newly discovered information is too critical to wait for the next update of the *PDR*, then the manufacturer may be required to send "Dear Doctor" letters to individual physicians to advise them of the new information.[120]

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116. The phrase "learned intermediary" first appeared in a judicial opinion in the case of Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). Without extensive discussion, the court distinguished between prescription drugs, for which a warning to the physician will suffice, and other products, for which a warning directed to the consumer is required. The rationale underlying the doctrine was developed in subsequent cases, including Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), in which the court stated:

> As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patients. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Id. at 1276.

117. *See* Schenebeck v. Sterling Drug, Inc., 423 F.2d 919 (8th Cir. 1970).

118. Richards v. Upjohn Co., 95 N.M. 675, 625 P.2d 1192, 1196 (Ct. App. 1980).

119. The "package insert" should not be confused with the "patient package insert," which is required for very few drugs. While the latter is written in lay language, the former is written in technical language and is intended to be used by health care providers. Package inserts are included with the drug product and are distributed with it to pharmacists, not to physicians. Unless the manufacturer chooses to voluntarily reprint the package insert in the *PDR*, or have a medical sales representative provide a package insert to a physician, the only way a physician is likely to see the insert is in an advertisement in a medical journal. The warnings manufacturers provide to physicians through the package insert are not necessarily received by all physicians, but are received by all pharmacists.

120. *See, e.g.*, Lawson v. G. D. Searle & Co., 64 Ill. 2d 543, 356 N.E.2d 779 (1976).

Because not all physicians regularly read "Dear Doctor" letters or consult the *PDR*, a manufacturer may be required to utilize medical service representatives (formerly known as detail men) when a particularly threatening risk is discovered.[121]

When the distribution or administration of a pharmaceutical product does not entail a physician's active involvement in the chain of distribution, courts have been reluctant to hold that the learned intermediary doctrine is applicable.[122] For example, if a manufacturer knows or should know that its prescription vaccine will be administered in a mass immunization program or a public health clinic, under circumstances in which there is no physician present to weigh the risk versus the benefit of a particular patient using the vaccine, then the manufacturer must directly provide the patient with adequate information so that the patient may do his own balancing of the risks and benefits of using the drug.[123] Under such circumstances "[a] duty to warn depends on superior knowledge and is said to exist when one may reasonably foresee danger of injury or damage to one less knowledgeable unless adequate warning of danger is given."[124] This two-step trigger for recognition of a duty owed—superior knowledge and reasonable foreseeability of harm—sets the standard for requiring disclosure by a manufacturer directly to a patient, and it sets the stage for a parallel requirement of pharmacists.

B. *The Physician's Responsibility*

The physician's duty to warn patients of risks before prescribing a drug may be considered a corollary to the learned intermediary doctrine.[125] If the manufacturer of pharmaceuticals has a duty to warn only the physician, then the physician has a duty to reconvey pertinent warnings to the patient. The physician must act with reasonable care based on a manufacturer's adequate warning. If this does not occur, then the physician's negligence is the intervening, independent, and sole proximate cause of the plaintiff's injuries, thus relieving the manufacturer of liability.[126]

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121. *See, e.g.*, Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 980 (8th Cir. 1969).

122. *See*, Brushwood & Simonsmeier, *Drug Information for Patients: Duties of the Manufacturer, Pharmacist, Physician, and Hospital*, 7 J. LEGAL MED. 279, 288 (1986).

123. *See, e.g.*, Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 131 (9th Cir. 1968) (patient was given polio vaccine in a mass immunization clinic); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974) (patient received polio vaccine at a county health clinic).

124. Petty v. United States, 740 F.2d 1428, 1434 (8th Cir. 1984)(quoting Lakatosh v. Diamond Alkali Co., 208 N.W.2d 910, 913 (Iowa 1973)).

125. *See, e.g.*, Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099 (1976); Klink v. G. D. Searle & Co., 26 Wash. App. 951, 614 P.2d 701 (1980). For a discussion of the physician's role in interpreting for the patient the warnings that are provided by the manufacturer for the physician, see Saber, *The DES Problem: Fashioning a Physician's Duty to Warn*, 5 J. LEGAL MED. 25 (Mar. 1977).

126. *See, e.g.*, Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966); Formella v. Ciba-Geigy Corp., 100 Mich. App. 649, ___, 300 N.W.2d 356, 358 (1980); *see also* Paul, *The*

The law of informed consent has clarified the physician's disclosure responsibility.[127] Informed consent cases alleging failure to disclose risks of drug treatment have had to overcome the absence of a "touching." Under the traditional view that informed consent is a defense to the intentional tort of battery, a surgical touching usually triggered the duty to warn.[128] While at least one jurisdiction continues to view informed consent as inapplicable to drug cases because there is no touching,[129] the overwhelming majority view is to recognize a physician's duty to disclose drug risks based on negligence principles.[130]

Like cases involving surgery and other nondrug medical treatments, informed consent in drug cases is based on the disclosure standard expressed in the landmark case of *Canterbury v. Spence*.[131] A physician is required to disclose material risks. A risk is "material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[132]

The materiality of a risk in informed consent cases relating to drug therapy is a function not only of the severity of the potential injury, but also the likelihood that the injury will occur.[133] Thus, risk is the multiplicative product of the magnitude and the probability of an adverse effect.[134] For every approved drug, there are scores of documented potential adverse effects, some of which are of miniscule significance.[135] The law recognizes that self-determination "is an important value worthy of society's protection, but

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Pill—A Legal and Social Dilemma, 45 TEMP. L.Q. 484 (1972).

127. For a discussion of the law of informed consent and prescription drugs, see Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367 (1986).

128. *See, e.g.*, P. APPELBAUM, T. LIDZ, & A. MEISEL, INFORMED CONSENT: LEGAL THEORY & CLINICAL PRACTICE 114-18 (1987).

129. Malloy v. Shanahan, 280 Pa. Super. 440, ____, 421 A.2d 803, 804 (1980); Boyer v. Smith, 345 Pa. Super. 66, ____, 497 A.2d 646, 646-49 (1985).

130. *See, e.g.*, Trogun v. Fruchtman, 58 Wis. 2d 596, 207 N.W.2d 297 (1973) (rejecting battery theory in favor of negligence).

131. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

132. *Id.* at 787.

133. *See, e.g.*, Precourt v. Frederick, 395 Mass. 689, 481 N.E.2d 1144 (1985) (patient suffered damage to hip bones as the result of taking a steroid drug). The court said:

> The materiality of information about a potential injury is a function not only of the severity of the injury, but also of the likelihood that it will occur. Regardless of the severity of a potential injury, if the probability that the injury will occur is so small as to be practically nonexistent, then the possibility of that injury occurring cannot be considered a material factor in a rational assessment of whether to engage in the activity that exposes one to the potential injury.

Id. at ____, 481 N.E.2d at 1148.

134. *See* COUCH & WILSON, RISK/BENEFIT ANALYSIS 9-11 (1982).

135. *See* MATTHEWS, SCHNEIWEISS & CERSOSIMO, A CLINICAL MANUAL OF ADVERSE DRUG REACTIONS (1986).

that there must be a reasonable accommodation between the patient's right to know, fairness to physicians, and society's interest that medicine be practiced" without unrealistic and unnecessary disclosure burdens on practitioners.[136]

Judge Learned Hand once illustrated the same principle in a famous case involving injury resulting from the breaking loose of a vessel from its pier.[137] Liability depended on whether B>PL, where P=the probability that the vessel would break away, L=the gravity of the injury, and B=the burden of adequate precautions.[138] The standard for physician disclosure of drug-related risks requires that the physician evaluate each patient, and determine for that patient whether a specific adverse effect is of sufficient probability and magnitude to warrant disclosure. The adequacy of a physician's disclosure of drug risks to a patient is also measured by considering the burden to the physician that a disclosure requirement would impose.

C. *The Pharmacist's Responsibility*

The risk disclosure responsibilities of the pharmacist are not nearly as well defined in the law as those of the physician and the pharmaceutical manufacturer. Recent litigation suggests that the pharmacist has a limited disclosure responsibility, but the polarized environment of litigation does not lend itself to line drawing. The extreme positions that advocates present to courts give scant guidance on striking a balance between overly broad and overly narrow expectations of pharmacists. Through a decade of litigation, courts have begun to distinguish between circumstances in which pharmacists have no legal duty to warn and circumstances in which they do have such a duty, based on the difference between types of information given to patients by physicians and pharmacists.[139] According to this rationale, the existence of a duty to warn by pharmacists depends on what type of information the patient wanted but was not given. If the patient wanted risk assessment information, but was given none, then the pharmacist is not an appropriate defendant. If the patient wanted risk management information, but was given none, then the pharmacist is an appropriate defendant.

Risk assessment information is provided to a patient who is making a drug choice decision. Specific patient-related medical knowledge is required to convey risk assessment information, and the risk avoidance behavior of the patient who acts on the information is nonuse of the drug. Risk management information is provided to a patient who is making a drug use decision. General drug-related pharmaceutical knowledge is required to convey

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136. Precourt v. Frederick, 395 Mass. at ____, 481 N.E.2d at 1149.

137. United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

138. *Id.*

139. Empirical data suggest that patients expect different information about drugs from physicians and pharmacists. *See, e.g.*, Morris, *supra* note 25; Cosler, *supra* note 15.

risk management information, and the risk avoidance behavior of the patient who acts on the information is lifestyle modification.

In a medical sense, risk assessment information is judgmental, because it requires a decision concerning the materiality of risk based on a specific patient's medical condition, but risk management information is nonjudgmental, because it relates to the drug and may be given to all patients who receive that drug.[140] A legal requirement that pharmacists provide risk assessment information would be inconsistent with their professional role, but a legal requirement that pharmacists provide risk management information would not be inconsistent with that role.

To illustrate the distinction between risk assessment and risk management information, consider the following hypothetical. A pregnant woman visits her physician complaining of nervousness. The physician determines that the nervousness is detrimental to the woman and to the fetus, and prescribes a medication that effectively treats this condition. The medication has been associated with a low incidence of birth defects in rodents. The medication also has a high probability of causing drowsiness. The physician does not tell the patient about either risk. The patient's pharmacist correctly fills the prescription, but does not tell the patient anything about the drug.

If the woman bears a child with birth defects and sues for failure to warn, essentially her argument is that she should have been given a piece of information that would have caused her to choose not to use the drug. This is risk assessment information. If the same woman bears a healthy child, but she falls asleep at the wheel of her automobile and has a wreck due to the sedative effect of the drug, her failure-to-warn argument is essentially that she should have been given a piece of information that would have caused her to change her lifestyle (by not driving) while continuing to use the drug. This is risk management information. An allegation that the pharmacist should have provided her with information about birth defects would be inappropriate, but an allegation that the pharmacist should have warned about drowsiness would be more in keeping with the pharmacist's established role.

The distinction between risk assessment information and risk manage-

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140. The judgmental/nonjudgmental distinction was first made in Kirk v. Michael Reese Hospital & Medical Center, 136 Ill. App. 3d, 945, ____, 483 N.E.2d 906, 911 (1985), *rev'd on other grounds*, 117 Ill. 2d 507, 513 N.E.2d 387 (1987). The patient had not been told that certain drugs administered and prescribed within the hospital would cause drowsiness and impair the ability to drive an automobile. The hospital asserted that the expertise and judgment of a physician is required to provide such information. The court said:

> The duty which is involved here simply requires a warning, not control or prevention. In this regard, we point out that the duty to warn would arise only if the doctors, hospitals or drug manufacturers know or should know of the adverse effects of a drug. The duty is plainly nonjudgmental.

Id. at ____, 483 N.E.2d at 912.

ment information is not nearly so obvious in actual litigation as it is in the hypothetical above. Yet, it is a distinction that pharmacists are making as they act through their regulatory agencies to promulgate regulations that require patient counseling on drug use.[141] It is a distinction that accounts for the differences between physicians and pharmacists. This distinction also accounts for the character of decisions made at well-defined points on the drug distribution chain. Finally, it is a distinction that judges have recognized in determining the limits of a pharmacist's expanded responsibilities.

VII. Significant Pharmacist Duty-to-Warn Cases of the 1980s

Case law in the area of the pharmacist's duty to warn is far from fully developed, but a number of well-reasoned appellate opinions from the past

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141. The following states have a board of pharmacy regulation requiring some sort of counseling by pharmacists: California, Colorado, Delaware, District of Columbia, Florida, Illinois, Kansas, Maine, Massachusetts, New Jersey, New York, North Dakota, Oregon, Texas, Utah, Washington, West Virginia, and Wisconsin. J. Keller-Teplitz (Ed.), 1989-1990 Survey of Pharmacy Law 40 (1989).

While these regulations vary greatly, the following regulation from the state of Washington is typical:

> Patient information required. Except in those cases when the prescriber has advised that the patient is not to receive specified information regarding the medication:
>
> (1) In order to assure the proper utilization of the medication or device prescribed, with each new prescription dispensed by the pharmacist, in addition to labeling the prescription in accordance with the requirements of RCW 18.64.245 and WAC 360-16-255, the pharmacist must:
>
> (a) Orally explain to the patient or the patient's agent the directions for use and any additional information, in writing if necessary, for those prescriptions delivered inside the confines of the pharmacy; or
>
> (b) Explain by telephone or in writing for those prescriptions delivered outside the confines of the pharmacy.
>
> (2) In those instances where it is appropriate, when dispensing refill prescriptions, the pharmacist shall communicate with the patient or the patient's agent, by the procedure outlined in subsection (1)(a) or (b) of this section or the patient's physician regarding adverse effects, over or under utilization, or drug interaction with respect to the use of medications.
>
> (3) Subsections (1) and (2) of this section shall not apply to those prescriptions for inpatients in hospitals or institutions where the medication is to be administered by a nurse or other individual authorized to administer medications.
>
> (4) In the place of written statements regarding medications, the pharmacist may use abstracts of the Patient USP DI 1988 edition, or comparable information.

Wash. Admin. Code § 360-16-265 (1989).

The reference in this regulation to the directions for "use" and assurance of proper "utilization" of medication arguably establishes a standard of disclosure that includes risk management (drug use) information, but not risk assessment (drug choice) information.

In an unprecedented move, a national organization of independent pharmacists has recently adopted a policy favoring the establishment of regulations that would mandate patient counseling by pharmacists. The apparent motivation is to elevate the level of practice among pharmacists. *See* Conlan, *NARD Quietly Endorses Mandatory Patient Counseling*, 133 Drug Topics 14 (Dec. 11, 1989).

decade provide insight on contemporary judicial expectations of pharmacists. Most of the significant cases have arisen procedurally from the granting of a motion for summary judgment in favor of the defendant pharmacist. The appellate court has been asked to reverse the lower court's opinion and reinstate the case. Unfortunately, this posture necessarily means that the appellate review is based on an incomplete factual record from the lower court. The customary approach of accepting as true the allegations of the plaintiff still does not provide the factual specificity needed to form the basis of a truly satisfactory legal opinion. Nevertheless, the summaries of five cases that follow give a useful overview of judicial reasoning as applied to varying factual situations in which pharmacists have allegedly caused harm by failing to warn of a drug's potential adverse effects.

Several reported opinions, which on their face appear to be relevant, have been omitted from this discussion, because they do not contribute significantly to an understanding of the pharmacist's duty to warn the patient under ordinary circumstances.[142] Particularly conspicuous by their absence are the opinions from a line of drug product liability cases involving Bendectin.[143] These cases allege that the drug was defective in that the manufacturer's warning was inadequate, and that the pharmacist should be held liable for failing to cure the manufacturer's inadequate warning. The fact that the prescribing physician was not named as a codefendant in any of these cases makes it obvious that there really was never any firmly held belief that anyone other than the manufacturer was at fault.[144] The five case summaries

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142. In several cases there is a significant issue regarding whether the pharmacist had authority from the physician to fill or refill the prescription. Absence of authority to dispense a prescription drug is a legal issue that supercedes the duty-to-warn issue. *See* Javitz v. Slatus, 93 A.D.2d 830, 461 N.Y.S.2d 44 (1983); Stafford v. Nipp, 502 So. 2d 702 (Ala. 1987); Bickowicz v. Nedco Pharmacy, 130 A.D.2d 89, 517 N.Y.S.2d 829 (1987). In other cases, it is clear that causation is the dispositive issue, and that the discussion of duty owed is irrelevant. *See* Stebbins v. Concord Wrigley Drugs, Inc., 164 Mich. App. 204, 416 N.W.2d 381 (1987); *see also* Kinney v. Hutchinson, 449 So. 2d 696 (La. Ct. App. 1984) (pharmacist had no duty to warn consumers directly of adverse effects of the prescribed drugs). Finally, there is one otherwise pertinent case in which the pharmacist's duty to warn the physician is addressed, but there is no allegation that the pharmacist failed to warn the patient, so the case is not directly relevant to this discussion. Eldridge v. Eli Lilly & Co., 138 Ill. App. 3d 124, 485 N.E.2d 551 (1985).

143. Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85 (E.D. Pa. 1986); Raynor v. Richardson-Merrell, Inc., 643 F. Supp. 238 (D.D.C. 1986); Coyle v. Richardson-Merrell, Inc., 372 Pa. Super. 118, 538 A.2d 1379 (1988), *appeal granted*, 520 Pa. 588, 551 A.2d 215 (1988); Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 361 Pa. Super. 589, 523 A.2d 374 (1987); Ealy v. Richardson-Merrell, Inc., Prod. Liab. Rep. (CCH) ¶ 11,236 (D.D.C. 1987). The idea that ten years ago a pharmacist should have warned of the propensity of Bendectin to cause birth defects is preposterous given that even today there is no solid scientific evidence of this adverse effect. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir. 1989) (reversal of jury verdict for plaintiff due to lack of conclusive epidemiological proof that Bendectin causes birth defects), *modified*, 884 F.2d 166 (5th Cir. 1989).

144. Often a pharmacist is named as a defendant simply as a ruse to achieve some broader goal, with no genuine belief that the pharmacist actually is at fault. This might happen

that follow all focus primarily on the pharmacist's role as a health care provider, not on the pharmacist as a safety net when the manufacturer has not met its responsibilities.

A. Hand v. Krakowski[145]

The appellate opinion in this 1982 New York case was the first to review a set of facts involving a pharmacist who correctly dispensed a prescribed medication to a patient, but who did not warn the patient of possible adverse effects, and to conclude that the pharmacist may be liable for the failure to warn.[146] Beginning in the mid-1970s, there were several widely publicized trial level verdicts and settlements on this issue,[147] which led to a widely held belief that the duty to warn was becoming a recognized legal standard for pharmacists.[148] The opinion in *Hand* appeared to validate that belief.[149]

The plaintiff in *Hand* was the executrix of the estate of the deceased patient.[150] The patient allegedly died from the adverse effects of alcohol combined with prescribed drugs the defendant pharmacist dispensed.[151] In reversing summary judgment for the pharmacist, the court said:

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when the plaintiff sues an in-state pharmacist, along with an out-of-state manufacturer, to destroy complete diversity of citizenship, in the belief that a state court will be more sympathetic to the plaintiff. *See* McFeggan v. Merrell Dow Pharmaceuticals, Inc., No. 87C70, slip op. (N.D. Ill. Apr. 7, 1987) (denying fraudulent joinder claim by defendant pharmacist in drug product liability case), *reprinted in* D. BRUSHWOOD, MEDICAL MALPRACTICE PHARMACY LAW app. N (Supp. 1989). It might also occur when the manufacturer has not been identified, and the pharmacist is the only potential party known to the plaintiff. *See* Murphy v. E. R. Squibb & Sons, 40 Cal. 3d 672, 710 P.2d 247, 221 Cal. Rptr. 447 (1985). Or the plaintiff's philosophy could be to sue everybody remotely associated with the adverse drug incident, hoping that the defendants will implicate each other to protect themselves, thus building the plaintiff's case at the expense of the defendants collectively.

145. Hand v. Krakowski, 89 A.D.2d 650, 453 N.Y.S.2d 121 (1982).

146. *Id.*

147. A pharmacist contributed to a $350,000 settlement in Mahaffey v. Sandoz, No. C-20275 (Sedgwick County, Colo., Dist. Ct. May 1974). The claim was that the patient had not been counseled concerning the hazards of prolonged use of the drug methylsergide. A pharmacist who put his own label over a manufacturer's label on a package of methoxalen, was liable to the patient for $7,500, because the patient received no warning about exposure to sunlight. Tonneson v. Paul B. Elder Co., No. 286258 (Santa Clara County, Cal., Superior Ct. Mar. 8, 1974). In another case, a $50,000 settlement was entered into by a pharmacist as the result of injuries sustained by an automobile operator who blacked out while driving, and had not been told of the sedating nature of Valium. Kaiser v. Fred Meyer, Inc., No. 79-054275 (King County, Wash., Dist. Ct. Jan. 1982).

148. *See, e.g.*, Salisbury, *The Pharmacist's Duty to Warn the Patient of Side Effects of Drugs*, 17 J. AM. PHARM. A. 97 (1977); Fink, *The Legal Duty to Consult With Patients*, 1 J. CONT. EDUC. PHARM. 65 (1977).

149. *See* Brushwood, *The Informed Intermediary Doctrine and The Pharmacist's Duty to Warn*, 4 J. LEGAL MED. 349 (1983).

150. Hand v. Krakowski, 89 A.D.2d 650, ___, 453 N.Y.S.2d 121, 122 (1982).

151. *Id.* at ___, 453 N.Y.S.2d at 123.

> Here Condo knew that the decedent was alcoholic and knew, or should have known, that the prescribed drugs were contra indicated and, therefore, extremely dangerous to the well-being of its customer. Clearly, under these circumstances, the dispensing druggist may have had a duty to warn decedent of the grave danger involved and to inquire of the prescribing doctors if such drugs should not be discontinued.[152]

Remanding the case to the trial court, the appellate division noted that the failure-to-warn claim might eventually be justified by the facts, because the "interrelationship between prescribing physicians and pharmacists is highly professional and rests upon a comprehension of the intricate compounds that make up a narcotic drug."[153] Thus, the case was not appropriate for summary judgment without further exploring those facts. The court's opinion rested entirely on the pharmacist's actual knowledge of the patient's alcoholism, and the fact that the dispensed drugs were, in the court's view, "contraindicated with the use of alcohol."[154]

The narrow factual scenario in the *Hand* opinion has caused other courts to shy away from the rationale that court developed. In the absence of a pharmacist's actual knowledge of a patient's condition, and if the drugs are not strictly contraindicated, courts usually will not follow the rationale of *Hand*.[155] Yet, on closer analysis, the "contraindicated" language appears untrue as regards the drugs prescribed for the patient in *Hand*. While not disclosed in the opinion,[156] appellant's brief revealed that the drugs prescribed were haloperidol, amitriptyline, and diazepam.[157] The package insert for these drugs (reprinted in the 1982 *PDR*) listed the potential for the drugs to interact with alcohol under "warnings," not "contraindications."[158]

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152. *Id.*

153. *Id.*

154. *Id.* The court cited Baker v. St. Agnes Hosp., 70 A.D.2d 400, 421 N.Y.S.2d 81 (1979) for the proposition that "a 'contraindication' refers to a circumstance under which the drug must never be given. It is absolute and admits of no exceptions." *Id.*

155. *See* Jones v. Irvin, 602 F. Supp. 399, 402 (S.D. Ill. 1985); Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 886 n.3 (Ind. Ct. App. 1985); Stebbins v. Concord Wrigley Drugs, Inc., 164 Mich. App. 204, ____, 416 N.W.2d 381, 387 (1987).

156. In its opinion, the court does not identify the drugs dispensed, but states that the pharmacist dispensed "psychotropic drugs knowing that such opiates are contraindicated with the use of alcohol." Hand v. Krakowski, 89 A.D.2d at ____, 453 N.Y.S.2d at 123. This statement is perplexing because psychotropic drugs are not opiates. As it turns out, of the three drugs dispensed, only one is a psychotropic drug (haloperidol), and none is an opiate. *See supra* note 107.

157. The brief purports to list five drugs, but one listed drug, "Saurevtpam," is not identifiable as any drug ever marketed, and another listed drug, "Hydrochloride," is not a drug at all but a chemical form in which many drugs are prepared. This is an example of the type of factual problem appellate courts must deal with when ruling on the appropriateness of an early dismissal.

158. The *PDR* entry for amitriptyline (listed on page 1245 under the trade name "Elavil") is typical. It states, "Elavil may enhance the response to alcohol and the effects of barbiturates and other CNS depressants. In patients who may use alcohol excessively, it should be borne in

The significance is that although contraindications are descriptions of situations under which drugs absolutely should not be used, warnings refer to potential safety hazards and to steps that should be taken if certain adverse effects materialize while the patient is using the drug.[159] The characterization of the drugs dispensed by the defendant pharmacist in *Hand* as "contraindicated" was, therefore, in error. The court apparently recognized the possibility that a pharmacist had a duty to warn in these circumstances, but did so under the mistaken impression that the drugs were contraindicated, when in fact they were not.

It is possible that the court understood that the drugs prescribed actually required a warning but were not contraindicated. If this is true, then other courts deciding cases concerning warnings rather than contraindications should not be so reluctant to follow *Hand*. Nevertheless, it would be difficult to argue persuasively for the application of the *Hand* rationale to the actual facts of the case (warnings necessary but drugs not contraindicated), rather than to the much narrower facts that the court appears to have mistakenly believed.

The *Hand* opinion is significant because it recognizes that there are circumstances under which a pharmacist may be required to provide a warning to a patient, and other circumstances under which no warning is required. The information at issue here (the potential interaction between drugs and alcohol) is generally considered to be risk management information. Therefore, the warning would be a responsibility of the pharmacist, because the patient may avoid the adverse effect by modifying her lifestyle, that is, by not using alcohol while continuing to use the drug.[160] The incomplete facts of this case confound that analysis, however, because the patient was an alcoholic and perhaps not capable of discontinuing the use of alcohol. Because the facts are not fully developed, and because of the ambiguous mismatch of fact and logic in the opinion, the *Hand* case is not as significant as it might have been in defining the pharmacist's legal duty to warn.

B. Pysz v. Henry's Drug Store[161]

To the extent that the opinion in *Hand v. Krakowski* appeared to open

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mind that the potentiation may increase the danger inherent in any suicide attempt or over dosage." The entry for haloperidol (listed on page 1159 under the trade name "Haldol") is stronger. It says, "The use of alcohol with this drug should be avoided due to possible additive effects and hypotension." For diazepam (listed on page 1625 under the trade name "Valium"), the *PDR* says, "Since Valium has a central nervous system effect, patients should be advised against the simultaneous ingestion of alcohol and other CNS-depressant drugs during Valium therapy." All of these statements are listed under warnings rather than under contraindications.

159. 21 C.F.R. § 201.57(d)(e) (1982).

160. *See supra* note 67 and accompanying text.

161. Pysz v. Henry's Drug Store, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984).

the door to pharmacist liability for failure to warn, that door was swiftly shut in *Pysz v. Henry's Drug Store*, a Florida case decided in 1984. The opinion in this case (as usual, the review of dismissal of the defendant pharmacist by the trial court), answers the following two questions:

> Whether a licensed pharmacist has a duty not only to properly fill a prescription but also to warn the customer of the dangerous propensities of the prescription drug and whether a licensed pharmacist who has actual or constructive knowledge of a customer's dependency and addiction to a prescription drug has a duty to warn the customer's treating physician of this fact.[162]

The court stated, "The facts alleged in appellant's complaint require us to answer each of these questions in the negative."[163] The facts involved the defendant pharmacist's dispensing of the drug Quaalude for nine years without informing the patient or the doctor that the drug would subject the patient to physical and psychological dependence and addiction.[164]

The court relied on a previous case from the same jurisdiction that had defined the pharmacist's responsibilities in narrow terms twenty years earlier.[165] In rejecting the plaintiff's argument that the pharmacist's legal duty is broader than correct prescription filling, the court noted that the plaintiff had cited no prior case law in which a pharmacist had been held liable in spite of having properly filled a lawful prescription.[166] While acknowledging that a pharmacist may have greater knowledge than a physician of the propensity of drugs, the court stated that the physician had the duty to know the drug he is prescribing and to properly monitor the patient.[167] In deferring to the physician as the person who was responsible for providing drug warnings, the court excluded the pharmacist from that responsibility.

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162. *Id.* at 562.

163. *Id.*

164. *Id.* at 561.

165. In McLeod v. W. S. Merrell Co., 174 So. 2d 736 (Fla. 1965), the court stated:

> a druggist who sells a prescription warrants that (1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug has not been infected with some adulterating substance.

Id. at 739. The obsolescence of this definition is obvious from its reliance on warranty as a theory of recovery and from its several references to compounding (which rarely occurs anymore).

166. The plaintiff's failure to direct the court's attention to the *Hand* case, which is the kind of authority the court said did not exist, appears to have been an oversight. Even though that case had been published two years earlier, the *Pysz* court made no effort to distinguish it, and apparently was not aware of it.

167. The plaintiff argued that the practice of pharmacy had changed drastically in the past twenty years, and that the court should take a new look at the duty of the pharmacist. Pysz v. Henry's Drug Store, 457 So. 2d at 562. The court admitted that the pharmacist's level of knowledge had changed, but felt that the pharmacist's duty had not changed. *Id.*

In one very important respect, the opinion in *Pysz* is consistent with the opinion in *Hand*. Both opinions recognize that the pharmacist's responsibilities vary with the circumstances. The *Pysz* opinion stated, "We limit our affirmance to the facts of this case since we recognize that a factual situation could exist which would support an action for negligence against a druggist who has lawfully filled a prescription issued by a licensed physician."[168] The court was clearly saying that the correct filling of a prescription was not an insurance policy against liability.

That statement has been misinterpreted by at least one subsequent court, which took it to mean that "a pharmacist will not be found liable for lawfully filling a prescription issued by a licensed physician."[169] The *Pysz* opinion did not say that. The judicial language in the later case provided insurance against liability—insurance that the *Pysz* court specifically withheld. *Pysz* was a narrow opinion, pointedly limited to its facts. Expansions of the *Pysz* rationale, under different fact situations, would be contrary to the admonitions of that court, and should be resisted by courts considering factually distinguishable cases.

C. Riff v. Morgan Pharmacy[170]

This 1986 Pennsylvania case affirmed a jury verdict against a pharmacist, and held that a pharmacist may be liable to a patient for negligence in filling a prescription, even if the pharmacist correctly filled the prescription as written by the physician.[171] The rationale underlying *Riff* was that each member of the health care team "has a duty to be, to a limited extent, his brother's keeper."[172] The court boldly justified this position by noting:

> Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team.[173]

The duty Morgan Pharmacy was found to have breached was a duty to warn the patient or to notify the prescribing physician of the obvious inadequacies appearing on the face of the prescription, creating a substantial risk of serious harm to the patient.[174] This is a narrow duty since, fortunately, situ-

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168. *Id.*
169. Adkins v. Mong, 168 Mich. App. 726, ___, 425 N.W.2d 151, 153 (1988).
170. Riff v. Morgan Pharmacy, 353 Pa. Super. 21, 508 A.2d 1247 (1986).
171. *Id.* at ___, 508 A.2d at 1253.
172. *Id.*
173. *Id.*
174. *Id.* at ___, 508 A.2d at 1252.

ations presenting such a substantial risk of serious harm occur infrequently in prescribing. There is no duty under *Riff* either to countermand a physician's order or to assume control of a patient's drug therapy. Thus, as noted above, the pharmacist's duty to be his brother's keeper is a limited one.

The plaintiff in *Riff* was given a prescription for Cafergot suppositories to treat her migraine headaches.[175] The prescription for twelve suppositories instructed that one suppository be inserted every four hours for headache.[176] Neither the prescribing physician nor the pharmacist warned the patient that no more than two suppositories should be used per headache and that no more than five should be used per week.[177] The plaintiff used the suppositories as directed, but being unaware of the limitation she overused them and suffered toxic effects.[178] The court confirmed that failure by a pharmacist to warn under such circumstances breached the pharmacist's standard of care, noting: "If the consensus of the medical community is that a safety net of overlapping responsibilities is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man's human frailty."[179] The result was affirmance of a jury verdict that held the pharmacist liable for a greater percentage of the patient's damages than the percentage attributed to the physician.[180]

The decision in *Riff* was a watershed in American pharmacist malpractice litigation. It established a standard that required something more than correct prescription filling.[181] *Riff* fits nicely into the risk assessment/risk management analysis.[182] The plaintiff was not asserting that if she was given information, she would have decided not to use the drug at all. Rather, her contention was that she should have been warned of the harm that excessive drug use might cause, so that she could use the drug safely. This is the type of information that a pharmacist can provide to a patient without interfering with the physician-patient relationship.

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175. *Id.* at ____, 508 A.2d at 1249.

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.* at ____, 508 A.2d at 1253-54.

180. The jury awarded the plaintiff a total verdict of $185,000.00. D. BRUSHWOOD, MEDICAL MALPRACTICE PHARMACY LAW 394, app. I (1986). The jury determined that the defendant physician was responsible for 35% of the plaintiff's injury and the defendant pharmacy was responsible for 65% of the injury. *See id.*

181. Riff v. Morgan Pharmacy, 353 Pa. Super. 21, 508 A.2d 1247 (1986). A strikingly similar British case from three years earlier anticipated the outcome of *Riff*. *See* Dwight v. Rodrick, Court of Appeal, Nov. 3, 1983, *reprinted in* 52 MEDICO-LEGAL J. 64 (1984). In the British case, capsules of Migril were prescribed for the plaintiff, with neither the physician nor the pharmacist instructing the patient about the maximum safe dosage. Ergotamine tartrate is the toxic component of both Cafergot and Migril. The appellate opinion affirmed a judgment against the pharmacist, "who failed in the task of safety-net and overseer." *Id.* at 64.

182. *See supra* note 67 and accompanying text.

The opinion rested heavily on the absence, on the face of the prescription, of an instruction concerning excessive use. Other cases since *Riff* have been factually distinguishable, and have refused to follow its logic, due to the lack of any irregularity on the face of the prescription.[183] These cases may be missing the point that it was an omission on the prescription, and the pharmacist's failure to cognitively react to the omission, that created the duty in *Riff*.[184] Refusing to follow *Riff* because no inaccuracy appears on the face of a prescription is too narrow a view of that case. *Riff* requires that a pharmacist apply knowledge about drugs to the facts of a situation, and act for the patient's benefit by providing a warning, when a drug has been prescribed in a way that presents a substantial risk of serious harm.

D. Ferguson v. Williams[185]

In keeping with prior cases, but with scant reference to them, *Ferguson*, a 1988 North Carolina opinion, recognized that a pharmacist may be liable to a patient even if the prescription was filled correctly, and in addition that a pharmacist's responsibilities to the patient depend on circumstances as well as theories.[186] In a brief opinion, the appellate court reversed dismissal in favor of the pharmacist.[187] The factual basis for the reversal was, of course, the allegations of the plaintiff. Because the patient died due to the effects of the dispensed medication,[188] and the plaintiff was the wife bringing suit as the administratrix of her husband's estate,[189] the allegations regarding what was said and done when the prescription was dispensed are necessarily based in part on conjecture.[190]

The pertinent facts are that the patient took a prescription for Indocin[191] to the defendant pharmacy and, prior to having it filled, told the pharmacist that he was allergic to Percodan.[192] The patient asked the pharmacist whether it was safe to use Indocin, given the fact that he was allergic

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183. Stebbins v. Concord Wrigley Drugs, Inc., 164 Mich. App. 204, ____, 416 N.W.2d 381, 387 (1987); Forish v. Paul, No. 5453-A-1982, slip op. at 4 (Erie County, Pa., Ct. Common Pleas Feb. 13, 1989).

184. There is nothing about the prescription in *Riff* that would have caused an untrained person to have any questions about it. It is a pharmacist to whom the inadequacy would be obvious. The test is not limited to what the prescription says, but extends also to how a reasonable and prudent pharmacist should react to what is on the face of the prescription.

185. Ferguson v. Williams, 92 N.C. App. 336, 374 S.E.2d 438 (1988).

186. *Id.* at ____, 374 S.E.2d at 440.

187. *Id.*

188. *Id.* at ____, 374 S.E.2d at 438.

189. *Id.*

190. *Id.* at ____, 374 S.E.2d at 439.

191. Indocin is the trade name for the drug indomethacin, which is a nonsteroidal anti-inflammatory drug.

192. Ferguson v. Williams, 92 N.C. App. at ____, 374 S.E.2d at 439. Percodan is a combination analgesic that contains aspirin and the narcotic drug oxycodone (in two forms).

to Percodan.[193] The pharmacist advised "that it was safe to take Indocin, even though the medical literature specified that the use of the drug Indocin is contraindicated[194] in those who suffer aspirin allergies or aspirin sensitivities."[195] The next day, the patient took one of the capsules, which caused him to have an anaphylactic reaction resulting in his death.[196]

Distinguishing an earlier case in which the court held that the defendant pharmacist had no duty to act beyond correct prescription filling,[197] the court said:

> While a pharmacist has only a duty to act with due, ordinary care and diligence, this duty, like all others, expands and contracts with the circumstances. Here, it is alleged that defendant Williams undertook to dispense not only drugs, but advice also. While a pharmacist has no duty to advise absent knowledge of the circumstances, . . . once a pharmacist is alerted to the specific facts and he or she undertakes to advise a customer, the pharmacist then has a duty to advise correctly.[198]

The court clearly believed that a warning regarding the cross-sensitivity of aspirin and Indocin would not have been required of the pharmacist, had the question not been asked by the patient.[199] But the questioning by the patient triggered a duty to warn.[200]

The information that the plaintiff in *Ferguson* alleged the patient failed to receive was risk assessment information, because it related to a decision whether to use or not use the drug. Therefore, it was arguably beyond the scope of the pharmacist's responsibilities.[201] Yet, the rationale for distinguishing between risk assessment and risk management information is based in large part on the pharmacist's knowledge. Pharmacists usually do not know idiosyncratic characteristics of an individual patient, but they do know peculiar characteristics of a particular drug. Therefore, it makes sense

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193. *Id.*

194. The 1987 *PDR* entry for Indocin stated under contraindications, "Indocin should not be used in . . . patients in whom acute asthmatic attacks, urticaria, or rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs."

195. Ferguson v. Williams, 92 N.C. App. at ___, 374 S.E.2d at 439.

196. *Id.* at ___, 374 S.E.2d at 438.

197. Batiste v. American Home Prods. Corp., 32 N.C. App. 1, 231 S.E.2d 269 (1977).

198. Ferguson v. Williams, 92 N.C. App. at ___, 374 S.E.2d at 440.

199. *Id.*

200. *Id.* The opinion could be read to say that it was the pharmacist's undertaking to answer the question that triggered the duty to warn. Yet it is inconceivable that the pharmacist could have avoided liability by not saying anything to the patient once the question was asked. Perhaps the court is suggesting that if the pharmacist had not answered the question, but had referred the patient back to the physician, then there would have been no liability. The trigger for recognition of a duty is more logically the asking of the question rather than pharmacist undertaking to answer it. It is probably safe to assume that once a patient asks a pharmacist a question about drug risks, and the pharmacist knows that the risk exists, the pharmacist must do something other than remain quiet and fill the prescription.

201. *See supra* note 67 and accompanying text.

to require that pharmacists give warnings regarding drug-specific information, but it does not make sense to require that pharmacists give warnings regarding patient-specific information.

The warning that allegedly was not provided in *Ferguson* was such patient-specific information. Yet, the pharmacist was not lacking in such knowledge, because the patient disclosed it to the pharmacist. The court indicated that with this information, a pharmacist had a duty to act. But under the same circumstances, without affirmative disclosure by the patient, there would have been no duty to warn.

E. McKee v. American Home Products Corp.[202]

The facts and legal analysis from this case were reviewed earlier,[203] but the implications of *McKee* are so potentially significant that they warrant several summary comments. The pharmacist duty-to-warn cases that preceded *McKee* can be seen as brief experiments with the issue.[204] The *McKee* opinion is far more thorough, lengthier, and heavily referenced than its predecessors.[205] Because of its outward appearance, the *McKee* opinion may seem decisive (or as decisive as any 5-to-4 split opinion can be). Yet, that appearance disguises a failure to address and resolve three critical questions.

The first unaddressed question was whether there is a meaningful difference between a case in which there has been a prescribing error, and one in which there has been an inadequate warning by the prescriber. The *McKee* majority adopted a very narrow interpretation of *Hand*[206] and *Riff*,[207] indicating that "both of these cases involved obvious or known errors in the prescription."[208] The court's argument apparently was that in those two cases, something within the prescription should have alerted the pharmacist that the physician had erred in prescribing, and that those courts required corrective action because of the prescribing error.[209]

In reality, those two cases did not involve errors in the sense that anything appearing on the prescription was incorrect. They involved omissions from the prescription that should have been obvious to the pharmacist and that the pharmacist could have rectified by warning the patient.[210] There-

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202. McKee v. American Home Prods. Corp., 113 Wash. 2d 701, 782 P.2d 1045 (1989).

203. *See supra* notes 33-54 and accompanying text.

204. *McKee* is one of only two state supreme court opinions on the issue. The rest of the opinions are from trial courts or intermediate state appellate courts.

205. There were two amicus curiae briefs filed: one by the Washington State Trial Lawyers Association, and one by the Washington State Pharmacists' Association. Thus, there was no lack of legal argument put forth to the court.

206. *See supra* notes 145-60 and accompanying text.

207. *See supra* notes 170-84 and accompanying text.

208. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1053.

209. *See id.*

210. The prescriptions in *Hand* and *Riff* were complete prescriptions, not lacking in any information concerning the identity of the drug prescribed, or the strength, or the directions for

fore, *Hand* and *Riff* cannot be factually distinguished from *McKee*, in which the allegation likewise was that a warning was omitted, not that a mistake was made. The majority in *McKee* should not have so hastily disposed of those two cases by mischaracterizing them as "failure to detect error" cases, rather than "failure to warn" cases.

A second unresolved problem in *McKee* was the meaning of the Washington administrative regulation that requires patient consultation by a pharmacist.[211] In a footnote, the *McKee* majority explained that this regulation applied to nonjudgmental information,[212] such as "whether to take the drug on an empty or full stomach, substances to avoid while using the drug, or not to drive or use heavy machinery while taking the drug."[213] But the majority did not explain why the information withheld from the plaintiff in *McKee* was judgmental,[214] and the court refused to decide whether a pharmacist's failure to give a patient nonjudgmental information was actionable.[215] The dissenters did not refer to the regulation at all. In a case involving a matter of first impression in a state's highest court, brief footnoted reference to a major conceptual distinction and to a relevant administrative mandate is not satisfactory.

Perhaps the most troubling of the questions omitted from the *McKee* opinion was whether prescribing expertise was necessary to monitor drug therapy properly. Citing its own previous opinion in *Young v. Key Pharmaceuticals, Inc.*,[216] the *McKee* majority made the not-so-startling observation that "pharmacists are not doctors and are not licensed to prescribe medication."[217] Did this restatement of the obvious have any relevance to the facts of the case? One could argue that it did not, because it was through monitoring rather than initiating a drug order that the risk of harm to the plaintiff in *McKee* would have become obvious.[218] Pharmacists are

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use. They did not contain warnings about risk, just as the prescriptions in the *McKee* case contained no warnings. There is simply no basis for factually distinguishing these cases based on the face of the prescription.

211. *See supra* note 141.

212. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1052 n.7.

213. *Id.*

214. This was an opportunity to make the risk assessment/risk management distinction, but the court chose not to do so.

215. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1051. The meaning of the Washington Board of Pharmacy "Patient Counseling Required" regulation will have to be determined as the result of an administrative action. The *McKee* opinion defers to the legislative process as being more appropriate to "reconcile the interests of all persons concerned with the imposition of such a duty." *Id.* at ____, 782 P.2d at 1055. Yet, if the regulation is within the scope of the Board's enabling legislation, then that has already been done.

216. Young v. Key Pharmaceuticals, Inc., 112 Wash. 2d 216, 770 P.2d 182 (1989).

217. McKee v. American Home Prods. Corp., 113 Wash. 2d at ____, 782 P.2d at 1051.

218. There is no allegation that the plaintiff in *McKee* should not have used the drug at all. The allegation is that prolonged use posed an unacceptable risk. *Id.* at ____, 782 P.2d at 1047.

not only qualified to monitor drug therapy, but that function is also specifically included within the definition of pharmacy practice in Washington.[219]

VIII. Major Issues in Pharmacist Duty-to-Warn Litigation

Throughout the 1980s, as the judiciary grappled with allegations of expanded responsibilities for pharmacists, the same issues recurred with consistency. Potential harm to the physician-patient relationship seems to have been an overriding concern to courts faced with arguments favoring expanded pharmacist responsibilities. A separate question was whether the duty to warn should be considered as one aspect of the general duty of care owed by a pharmacist, or instead be considered a separate duty. Significant attention was also paid to the pharmacist's level of knowledge at the time a drug was dispensed. In addition, circumstances surrounding the dispensing of medication could be considered sufficient to make it foreseeable to a pharmacist that harm would result to a patient if a warning were not provided.

The discussion of issues that follows summarizes the major considerations that courts addressed as they evaluated the arguments regarding the pharmacist's failure to warn. While there is some overlap, these four issues present separate and distinct challenges to the development of a theoretical basis for a pharmacist's duty to counsel.

A. *The Relationship Issue*

There are certain types of drug risk warnings that, if provided by a pharmacist to a patient, could cause the patient to lose confidence in the physician for having prescribed the drug.[220] The possibility that the physician-patient relationship may be harmed has been used as justification for refusing to recognize that a pharmacist has a duty to warn a patient of drug risks.[221] Implicit in this view is the notion that pharmacist warnings are redundant and unnecessary, because the physician has a recognized warning responsibility. Therefore, if any possibility exists of a pharmacist's warning causing harm (mistrust of the physician or a decision not to use the drug), then the unnecessary warning should not be given. It assumes that physician responsibilities and pharmacist responsibilities are mutually exclusive—that if a physician has a duty to warn, then a pharmacist necessarily has no such

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219. Wash. Rev. Code § 18.64.011(11) (1989).

220. It would be improper for a pharmacist to consult with a patient in a manner that disparages the patient's physician. Usually risk-related information can be conveyed in a manner that does not cast aspersions on anyone. Pharmacists recognize that relative risk information can cause loss of confidence in physicians. However, it is necessary to also recognize that if truthful information about risk, presented in a proper manner by a pharmacist, causes the patient to question why the physician prescribed the drug or did not warn of the risk, this is not so bad as having the risk materialize for an unsuspecting and unconsenting patient.

221. *See supra* notes 48, 167 and accompanying text.

duty.[222] Adopting this posture may overemphasize the physician-patient relationship and undervalue the pharmacist-patient relationship, without recognizing the importance of pharmacist warning responsibilities that do not disparage the prescriber. It may also fail to recognize a physician-pharmacist relationship within which there is an expectation that the pharmacist will add value to the drug therapy process by monitoring drug therapy and by supplementing warnings provided by the physician.

Illustrative of this point is the opinion in the case of *Jones v. Irvin*.[223] In this case, the court held that a pharmacist has no duty to warn that "a drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer."[224] The court reasoned that it is the physician's duty to properly prescribe drugs and warn the patient of any dangers associated with taking a drug.[225] Placing a duty to warn on the pharmacist would, according to the court, compel the pharmacist to second-guess every prescription a doctor orders in an attempt to escape liability.[226] Yet, the plaintiff's allegation was that the physician had failed to meet his duty, and that the pharmacist knew or should have known of this failure.[227] An otherwise redundant warning may become essential when the physician's duty has not been met.[228]

Empirical studies suggest that physicians do not provide patients with adequate warnings of adverse drug effects.[229] Therefore, the presumption

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222. The analogy to this argument would be that if a real estate agent has a duty to draft an adequate contract for the sale of land, then a lawyer representing the buyer or seller has no duty to do the same. Or if an accountant has a duty to correctly use generally accepted accounting principles, then a lawyer representing the same client has no duty to do the same. The point is that the duties of these people overlap, although some may be primary and some secondary. The *Riff* case recognizes this point by referring to the "health care team" and "overlapping responsibilities." Riff v. Morgan Pharmacy, 353 Pa. Super. at ____, 508 A.2d at 1253. This is not a suggestion that a pharmacist or anyone else should take turf away from physicians, but that physicians might share their turf, to the extent that patients will benefit.

223. Jones v. Irvin, 602 F. Supp. 399 (S.D. Ill. 1985).

224. *Id.* at 402.

225. *Id.*

226. *Id.*

227. *Id.* at 400.

228. Reliance on the physician as the person who is required to warn of risks seems a weak argument when the fact is that the physician has not warned and the pharmacist knows it.

229. Pharmacists do not always provide adequate warnings either. Relevant to this issue, the FDA has said:

> Although both the physician and the pharmacist have an opportunity to provide information to the patient about a prescribed drug product, studies show that patients are not exposed to information about prescription drug products. In a national telephone survey of patients, 48 percent of the respondents said that their physician did not talk to them about their most recent prescription and 88 percent said the pharmacist did not talk to them about the prescription. In a study of patients at a clinic

that a patient has been adequately warned when a prescription is presented to a pharmacist may be more pretense than reality. There is also evidence that certain types of information may be more effectively communicated by a pharmacist than by a physician.[230] This evidence indicates that patients are more attentive to information about medications when they are at the pharmacy, rather than at the doctor's office, where their attention is on their complaints, diagnosis, and prognosis.[231]

On those infrequent occasions when a physician has omitted significant warning information during the patient's visit to the office, and the patient's attitude toward the physician changes after the pharmacist provides a warning, perhaps the outcome can be viewed as positive. It is positive if an adverse drug effect is avoided, and if the patient assumes greater responsibility for decisions about drug therapy. Emphasis on the physician-patient relationship, to the exclusion of the pharmacist-patient relationship, may deny patients the opportunity to make their own decisions about risk and to avoid adverse outcomes. The "health care team" referred to in *Riff*[232] stresses shared responsibility and a relationship of mutual trust between members of the team.[233] If the team approach to patient case is appropriate, then the idea that professional responsibilities cannot overlap is mistaken.

B. *The Duty/No Duty Issue*

Rather than closely examining the pharmacist-patient relationship to determine how far the pharmacist's general duty of care extends, several opinions have considered whether a pharmacist owes a patient a separate, extra duty to warn of potential adverse drug effects.[234] The result has usu-

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> that allowed direct observation of the physician's instructions, one author found that the prescriber discussed the length of therapy in only 10 percent of the cases and the dosage frequency in only 17 percent of the cases. In 17 percent of the cases the drug was never discussed at all. Other studies that have observed pharmacists' interactions with patients also suggest that pharmacists infrequently provide information to patients about prescription drug products, even when the pharmacist is required to do so by State regulations.

44 Fed. Reg. 40,020 (1979).

230. The FDA indicates that patients remember only about half of the information a physician tells them about their treatment, and in one study only 63 percent of the patients could remember the name of the drug prescribed for them although a tape recording revealed that they had been told the drug's name. 44 Fed. Reg. 40,020 (1979).

231. *Id.* at 40,033.

232. *See supra* note 9.

233. The concept of the health care team is by no means avant garde. *See* Willig, *Physicians, Pharmacists, Pharmaceutical Manufacturers: Partners in Patient Care, Partners in Litigation?*, 37 MERCER L. REV. 755 (1986).

234. *See, e.g.*, Ingram v. Hooks Drugs, Inc., 476 N.E.2d 881, 883 (Ind. Ct. App. 1985). ("The duty to exercise care for the safety of another arises as a matter of law out of some relation existing between the parties, and it is the province of the court to determine whether such a relation gives rise to such a duty.").

ally been that the pharmacist-patient relationship has been viewed as being of such a character that it establishes a duty to follow doctor's orders, correctly but no further duty. The procedural impact of this approach is to permit the court to determine, as a matter of law, whether a specific duty to warn exists, and to prevent consideration of the matter by a jury if there is no pharmacist duty to warn.[235] The substantive impact is that the pharmacist's activities are divided into an endless series of details of conduct, with some details being considered a duty and others not.[236]

The concept of "duty" was addressed a different way in *Docken v. Ciba-Geigy*.[237] Three defendants, a physician, a pharmacy, and a drug manufacturer, allegedly failed to warn of a drug's potential adverse effects.[238] The appellate court, reversing summary judgment for all three defendants, referred to prior Oregon case law, and noted that the existence of a duty depends on foreseeability of harm.[239] The court also held that the existence of a legal duty is a question of law rather than a question of fact.[240] The court stated, "We cannot say as a matter of law that the harm was not foreseeable or that the complaint fails to allege facts from which a jury could find defendants negligent."[241]

Rather than focusing on the character of the pharmacist-patient relationship, a task that is complicated by deference to the virtually sacrosanct physician-patient relationship, this approach to defining duty considered what steps the pharmacist reasonably could have taken, in light of the apparent risk.[242] This is an expansive view of duty, which was later scaled-back in a subsequent opinion from the same case.[243]

The pharmacist's traditional function of purveying a product, serving merely as a conduit between the physician and patient, makes it difficult for a court to recognize as a matter of law that a new duty exists.[244] While phar-

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235. The jury considers custom and practice only after the law has imposed a duty of care. Ingram v. Hooks Drugs, Inc., 476 N.E.2d at 884 n.1 (citing Roberts v. Indiana Gas & Water Co., 140 Ind. App. 405, 218 N.E.2d 556 (1966)).

236. Some are critical of this approach, suggesting that 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." W. KEETON, *supra* note 55, at 356.

237. Docken v. Ciba-Geigy, 86 Or. App. 277, 739 P.2d 591 (1987).

238. *Id.* at ___, 739 P.2d at 592-93.

239. *Id.* at ___, 739 P.2d at 593.

240. *Id.* This court's holding that the existence of a legal duty is a question of law, not fact, was generally accepted. However, this court set itself apart by thoroughly analyzing the facts of the case rather than the status of the pharmacist.

241. *Id.*

242. Recognition of a duty following this approach uses foreseeability of harm as a limiting factor, not physician preeminence.

243. Docken v. Ciba-Geigy, 101 Or. App. 252, 790 P.2d 45 (1990).

244. In partial justification of its position that pharmacists have no duty to warn, the court in Leesley v. West, 165 Ill. App. 3d 135, 518 N.E.2d 758 (1988) said, "We believe that this

macists might like to divorce themselves from terms such as "suppliers of chattels" or "retailers," the practice of pharmacy still includes the distribution of a product, even though associated nondistributive functions are becoming more important.[245] One might surmise that a significant barrier to finding a legal duty to warn on the part of a pharmacist is identification with product distribution, rather than the provision of a service. Yet, courts have seemingly chosen to avoid recognition of the liability associated with this function as well.[246]

The resolution of the duty/no duty issue has depended in large part on the willingness of a court to examine microscopically current pharmacy practice patterns that incrementally expand on the traditional scope of pharmacy practice. Shifting the focus of analysis from limits on the pharmacist-patient relationship to prevention of harm may facilitate reasoning that more broadly considers all relevant factors in determining the existence of a legal duty. The pharmacist actively participates in the distribution of a potentially harmful product. Recognizing a duty to assist in protecting patients against an unreasonable risk of harm would be consistent with that active participation. A limiting factor in this expansion would be that no duty is breached unless the professional standard of care has not been met.

C. *The Knowledge Issue*

A recurrent theme through the pharmacist failure-to-warn litigation of the 1980s has been the pharmacist's level of knowledge, and an understandable judicial hesitancy to require that a pharmacist affirmatively act to warn a patient of an adverse effect of which the pharmacist did not know, and could not have known.[247] "One of the most difficult questions in connection

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position is most consistent with this State's legislative policy against expanding the liability risks of health professionals." *Id.* at ____, 518 N.E.2d at 763. Stung by a decade of criticism that the tort system is out of control, courts are understandably reluctant to expand liability.

245. *See supra* notes 66-67 and accompanying text.

246. The RESTATEMENT (SECOND) OF TORTS § 401 (1965) provides a legal principle that could establish liability for a pharmacist as a person who supplies chattels for the use of others:

> A seller of chattel manufactured by a third person who knows or has reason to know that the chattel is, or is likely to be, dangerous when used by a person to whom it is delivered or for whose use it is supplied, or to others whom the seller should expect to share in or be endangered by its use, is subject to liability for bodily harm caused thereby to them if he fails to exercise reasonable care to inform them of the danger or otherwise to protect them against it.

Id. This section has never been used to hold a pharmacist liable, and might not be applicable if the pharmacist did not know of the harm that could occur.

247. It is impossible to know that an adverse drug effect will occur. Physicians cannot know this, and neither can pharmacists. Yet it is possible to know that an adverse effect may occur. Knowing that an adverse effect is possible can help patients make decisions about risk. When a possibility turns into a strong probability or a virtual certainty, and less risky alternatives are available, the issue is not one of warning but of proper treatment. This is certainly the physician's domain, and will not even be an issue for the pharmacist under ordinary circum-

with negligence is that of what the actor may be required to know."[248] For pharmacists, as with other professional persons, the knowledge question relates not to a minimal standard, but to a level of knowledge, skill, or intelligence superior to that of the ordinary person.[249] A body of law dealing with the pharmacist's responsibility to assure that narcotic prescriptions are issued for a legitimate medical purpose has firmly established that a pharmacist may not remain oblivious to circumstances suggesting a nonmedical use, fill a prescription that is technically valid but suspicious, and then assert lack of knowledge as a defense.[250] This approach may have some value in the failure-to-warn context, in which the relevant question seems to be what the pharmacist can be expected to know given the circumstances.

The decision in *Leesley v. West*[251] indicated that pharmacists have no duty to warn of drug hazards because there are two kinds of knowledge that a pharmacist generally lacks: (1) knowledge of a patient's medical condition and history; and (2) knowledge that the physician has not given relevant warnings.[252] Other cases have justified a finding that there is no pharmacist duty to warn, because a pharmacist lacks the knowledge necessary to conduct a medical examination and to take a medical history.[253] While it is certainly true that pharmacists are not trained or qualified to assess patient characteristics, pharmacists do have knowledge of drug characteristics, and there are many drug-specific warnings that pharmacists without medical expertise can provide to patients.[254] These warnings may be given to a patient irrespective of whether the physician has also provided warnings. They are

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stances, because a prescription will not be issued. In those rare circumstances when a prescription is issued for a medication that a patient obviously should not use, a warning by the pharmacist may lead to the avoidance of harm. The pharmacist's responsibility, however, generally would not extend beyond a warning. There is no duty to refuse to fill a prescription for a medication that a physician has determined is appropriate, and that a patient has knowingly consented to use. *See* Brushwood & Lively, *Refusal to Dispense a Prescription: What Is The Law?*, 29 AM. PHARMACY 645 (1989). Only if a prescribed medication presents grave risks to the patient's immediate physical condition, and the physician and patient do not seem to know what each wants, should the pharmacist even consider refusing to dispense a medication on grounds that the risk to the patient is too great.

248. W. KEETON, *supra* note 55, at 182.

249. *Id.* at 185.

250. *See, e.g.*, United States v. Hayes, 595 F.2d 258 (5th Cir. 1979); Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy, 125 Cal. App. 3d 19, 177 Cal. Rptr. 807 (1981).

251. Leesley v. West, 165 Ill. App. 3d 135, 518 N.E.2d 758 (1988).

252. *Id.* at ____, 518 N.E.2d at 762.

253. *See, e.g.*, Ingram v. Hooks Drugs, Inc., 476 N.E.2d 881, 886-87 (Ind. Ct. App. 1985); Stebbins v. Concord Wrigley Drugs, Inc., 164 Mich. App. 204, ____, 416 N.W.2d 381, 387 (1987).

254. Most pharmacists would not be sufficiently knowledgeable to examine patients, diagnose illnesses, and select appropriate medications from all those available. Yet providing accurate information about drug risks to patients for whom all of this has already been done by the physician does not require a high level of diagnostic expertise. Knowledge about drugs is sufficient for this exercise; knowledge about patients is not a prerequisite.

warnings that supplement the physician's prescribing and monitoring of drug therapy, without conflicting with the physician. These warnings are accurate and helpful to patients no matter who the patient is and no matter what the physician has told the patient.

Objective evaluation of the knowledge issue, focusing on what a pharmacist should have known rather than on what the pharmacist actually knew, must include recognition that pharmacists have general knowledge of drug characteristics. This type of knowledge limits the warnings that a pharmacist can be expected to provide, because peculiar characteristics of individual patients cannot be accounted for. However, the lack of medical knowledge relating to specific patient characteristics cannot justify a blanket exemption for pharmacists from all warning requirements. Virtually every pharmacist duty-to-warn opinion points out that pharmacists are not doctors.[255] Yet, this abundantly obvious fact does not compel the conclusion that pharmacists are totally lacking in knowledge regarding drug characteristics. By paying closer attention to the knowledge pharmacists do possess, rather than to the knowledge they admittedly lack, judges considering the scope of a pharmacist's duties could use the knowledge issue to clarify the limits on reasonable expectations of pharmacists.

D. *The Foreseeability Issue*

Action can be taken to warn of avoidable harm only if the actor recognizes potential danger at the time a warning can be given.[256] The foreseeability issue, as a determinant of liability, requires not simply that the actor should have had knowledge of existing facts, but also that the actor should have formed a reasonable belief that harm would occur in the absence of a warning.[257] The foreseeability issue contextualizes the knowledge issue.[258] The question of foreseeability of harm may arise not only with regard to the duty owed, but also as a component of the causation analysis.[259]

A surprisingly large number of pharmacist malpractice cases have alleged a pharmacist's failure to prevent a patient's suicide with drugs the pharmacist dispensed.[260] The legal question in these cases is whether the

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255. The *McKee* opinion notes that " 'pharmacists are not doctors and are not licensed to prescribe medication because they lack the physician's rigorous training in diagnosis and treatment.' " McKee v. American Home Prods. Corp., 113 Wash. 2d 701, ____, 782 P.2d 1045, 1051 (1989) (quoting Young v. Key Pharmaceuticals Inc., 112 Wash. 2d 216, 230, 770 P.2d 182, 190 (1989)). Yet, the point of the *McKee* case is not whether pharmacists are qualified to prescribe medication; it is whether pharmacists are qualified to provide information to patients about the potential hazards of drug use. *Id.* at ____, 782 P.2d at 1055-56.

256. W. KEETON, *supra* note 55, § 31, at 170.

257. *Id.*

258. *Id.*

259. *Id.* § 43.

260. The most recent of these cases is Moss v. Meyer, 117 Ill. App. 3d 862, 454 N.E.2d 48 (1983), in which the plaintiffs were a young girl and her parents. The facts of the case show

patient's intentional act of ingesting an overdose of medication was foreseeable to the pharmacist when the medication was dispensed. If it was, then this act did not operate as a superceding intervening cause, and the pharmacist may be liable.[261] The numerous reported opinions uniformly hold that an intentional overdose is unnatural, and therefore unforeseeable, so the chain of causation is cut off, leaving the pharmacist without exposure to liability.[262] The determination of unforeseeability relates to the misuse of the medication, not to the type of harm. When the intentional act of medication misuse is something other than attempted suicide, courts may be less willing to conclude that the act is unnatural and, therefore, unforeseeable as a matter of law.[263]

Within the legal analysis of duty to warn litigation, the emphasis of the foreseeability test is on adverse effects that may occur even if the drug is used correctly, according to the physician's directions.[264] There is no expectation that a pharmacist will foresee an intentional act of medication misuse. The danger that the pharmacist must be able to recognize pertains to the characteristics of the drug when used correctly, not to the nature of the patient's conduct in using the drug.

The foreseeability issue was addressed in *Kirk v. Michael Reese Hospi-*

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that on November 10, 1977, the defendant pharmacy received a telephone call requesting delivery of 100 capsules of Placidyl (a sleeping pill) purportedly for the girl's father. *Id.* at ____, 454 N.E.2d at 49. The order was a refill request that was actually placed by the young girl for her own use. *Id.* The pharmacy filled the prescription, and delivered it to the plaintiff's home by leaving it on the front doorstep. *Id.* A sibling retrieved the medication for the girl, and that night she wrote a suicide note and ingested 35 capsules. *Id.* She was in a coma for four days and spent an additional one and one-half months in the hospital. *Id.* The major issue in the case was causation. *Id.* at ____, 454 N.E.2d at 50. The court had to choose between the "but for" test and the "intervening cause" test. *Id.* The court held that the "intervening cause" test was more appropriate, because it would be unfair to hold the pharmacy responsible for all consequences of its conduct. *Id.* at ____, 454 N.E.2d at 51; *see also* Riesbeck Drug Co. v. Wray, 111 Ind. App. 467, 39 N.E.2d 776 (1942); Runyon v. Reid, 510 P.2d 943, 949 (Okla. 1973); Scott v. Greenville Pharmacy, Inc., 212 S.C. 485, 48 S.E.2d 324 (1948); Eckerd's, Inc. v. McGhee, 19 Tenn. App. 277, 86 S.W.2d 570 (1935).

261. In Speer v. United States, 512 F. Supp. 670 (N.D. Tex. 1981), *aff'd* 675 F.2d 100 (5th Cir. 1982), the court did an extensive analysis of superceding intervening cause. It concluded that the mere sale of a toxic substance does not give the pharmacist sufficient information to foresee suicide. *Id.* at 679-80. But the court left open the possibility that more extensive knowledge would lead to foreseeability. *Id.*

262. *See supra* note 260.

263. The unusual case of Quinn v. Memorial Medical Center, 764 S.W.2d 915 (Tex. Ct. App. 1989) contains the allegation that a pharmacist should have foreseen that the plaintiff's boyfriend was prescribing an abortifacient drug improperly, and could have prevented harm caused to the plaintiff from use of that drug. The court concludes, "[A] fact issue exists concerning whether appellees should have anticipated that the failure to take reasonable precautions in dispensing this hormone could result in its wrongful use and danger to others." *Id.* at 918.

264. Foreseeable misuse is an entirely separate issue. It focuses on the foreseeability of actions taken by patients rather than on the foreseeability of harm.

tal and Medical Center,[265] in which the plaintiff alleged that the defendant hospital failed to warn a patient that medications administered and prescribed in the hospital immediately before discharge might cause drowsiness and impair the ability to drive an automobile.[266] The court noted that the existence of a legal duty does not depend on foreseeability alone, but rather, on whether the harm was reasonably foreseeable.[267] This standard of reasonable foreseeability was applied to the defendant's conduct in determining the foreseeability of harm to the plaintiff, who was a passenger in the patient's car.[268] The court held that the plaintiff's injury caused by the effects of medication on the plaintiff could not be considered reasonably foreseeable.[269] One commentator has suggested that the court erred in holding that the injury the plaintiff suffered was not reasonably foreseeable, because the injury was specifically mentioned in warnings found in reference materials available to hospital employees.[270]

Consideration of the foreseeability issue adds to a discussion of the pharmacists duty to warn, because it places a reasonableness limitation on the knowledge issue. When knowledge is defined to include both actual and constructive knowledge, there is a danger that the fictional concept of what a pharmacist should have known will be viewed too expansively. By requiring that knowledge be used only when potential harm is recognizable, pharmacists are protected from expectations that are unreasonable within the

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265. Kirk v. Michael Reese Hosp. & Medical Center, 117 Ill. 2d 507, 513 N.E.2d 387 (1987).

266. *Id.* at ____, 513 N.E.2d at 391.

267. *Id.* at ____, 513 N.E.2d at 396.

268. *Id.*

269. *Id.* In discussing the issue of foreseeability, the court refers to the nature of the relationship between the defendant hospital and the plaintiff who was not the patient. *Id.* at ____, 513 N.E.2d at 397. This discussion queries whether the relationship with the patient was sufficient to impose a duty to protect unidentifiable, unknown third parties whom a patient endangers. The foreseeability issue is inextricably interwoven with the third party issue. *Id.* at ____, 513 N.E.2d at 397-99.

270. Note, *Kirk v. Michael Reese Hospital: A Hospital's Liability as a Health Care Producer*, 19 Loy. U. Chi. L.J. 1261, 1276-77 (1988). The commentator states:

> The pharmacist, as a professional hospital employee, failed to apply his knowledge and training about pharmaceuticals to provide the required warning to McCarthy. The drug distribution system provides a built-in method of communication between the drug manufacturers and pharmacists by giving the pharmacist access both to drug inserts and to the Physicians' Desk Reference. The availability of these reference materials so establishes that the pharmacist employed by Michael Reese Hospital knew or should have known of the adverse effects that the psychotropic drugs would have on McCarthy's ability to safely operate his car when combined with the consumption of alcohol. The court erred in holding that the injury suffered by Kirk was not reasonably foreseeable to the hospital pharmacist, as a hospital employee, because the injury suffered by Kirk was of the exact nature of the warning found in the reference materials available to hospital employees.

Id. at 1278-79.

context of their actual knowledge.

IX. Theoretical Models of Pharmacist Duty

Any line of cases addressing an issue that is usually a matter of first impression in each state is bound to have a number of seemingly contrary, if not actually contradictory, conclusions. The search for consistency within such a line of cases requires analysis of theories that form the basis for the opinions, and criticism of the advantages and disadvantages of each theory. Analysis of competing theories attempts to show how one can consistently determine what is correct conduct, by providing frameworks of analysis that are persuasive to unbiased judges, whose only interest is the fair and uniform application of the force of law. While it may not be possible to achieve universal recognition that a single theory transcends all others, the exercise of theory development and selection can help clarify issues and can lead to an understanding of why some judicial opinions are better reasoned than others in terms of scope and rationale justification.

An evaluation of the theories that militate for or against a pharmacist duty to warn can greatly assist with setting limits on expanded expectations of pharmacists. At a threshold level, no pharmacist should be expected to act in a way that benefits a patient unless there is both a factual and theoretical basis for requiring action. Legal analysis based on fact and theory assures the accounting of both practice trends and legal tradition.

A. *The Policy Analysis Model*

Efficiency is an appealing concept, because it weighs costs and benefits, yielding a result that semiscientifically demonstrates which of several possible choices has the greatest utility. The risk disclosure requirement of physicians can be evaluated by summing the benefits of disclosure, the costs of disclosure, and the results, to observe whether the total is positive or negative.[271] This same approach may be useful in evaluating the risk disclosure requirement for pharmacists.

An approach similar to that used for physicians was used in a case involving a pharmacist, *Leesley v. West*.[272] The approach taken in *Leesley* was heavily oriented toward policy impact, because the context was the adoption of a new legal duty, rather than the interpretation of an existing duty. The court identified the following primary factors for considering whether a pharmacist has a legal duty to warn a patient of a drug's dangerous side effects:

> (1) the foreseeability of injury to the plaintiff as a result of defendant's actions or inactions; (2) the magnitude of the burden to the defendant of

271. *See supra* note 137 and accompanying text.

272. Leesley v. West, 165 Ill. App. 3d 135, 518 N.E.2d 758 (1988).

> guarding against the injury and the consequences of placing that burden on the defendant; and (3) the currently prevailing public policies and social attitudes of the community.[273]

The court discussed each of these factors, incorporating by reference much of the rationale of the decision in *Kirk*,[274] and concluded that it would be poor policy to require a warning by pharmacists.[275]

The policy analysis approach has not been frequently used in pharmacist duty-to-warn litigation. Although easily completed once values have been attached to the factors considered, giving those factors a value in the first place is difficult. In an efficient market, the pharmacist's supply of risk-related information and the patient's demand for this information should reach equilibrium. Overall one should account for societal costs by reflecting, in the prices pharmacists charge for their risk-avoidance services, an amount that at least matches the cost of the avoided risk had it materialized due to the failure to provide the service. Simulating such a fictional market (and inviting its development through litigation) requires speculation at a level that most judges prefer to avoid.[276]

A separate problem with the policy analysis model is that it balances the individual patient's right of bodily integrity and self-determination against fair treatment of pharmacists. This places a traditional common law right in opposition with an interest that has no similar common law basis. A pharmacist certainly has a right to be paid for professional services rendered, but there is no right to withhold information from patients (although there may be a sound legal basis for not compelling disclosure). This apparent deference to the pharmacist seems in reality to reflect judicial inability to determine what a pharmacist knows and how that knowledge can be used for the patient's benefit.[277] Fairness to pharmacists is weak justification for failing to recognize a basic right of patients.

As a theoretical model, the policy analysis goal of efficiency does little to assist with setting limits that are well defined and conducive to consistent application of the law. The task of fine-tuning narrow areas of responsibility within a well recognized legal duty, establishing a new duty, or expanding an existing duty into new areas, may require a theoretical approach that does not oversimplify issues by merely balancing costs and benefits.

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273. *Id.* at ____, 518 N.E.2d at 762.

274. *See supra* notes 265-70 and accompanying text.

275. Leesley v. West, 165 Ill. App. 3d at ____, 518 N.E.2d at 763.

276. The *Leesley* opinion is typical. The court assumes that imposing a duty to warn would be burdensome to pharmacists because they would bear the additional costs of reproducing the material they receive from the manufacturer. *Id.* The idea that the pharmacist might pass on this cost to the consumer, and that the consumer might gladly pay an additional small amount of money for a duplicated warning leaflet is never addressed.

277. The idea of fairness may also incorporate concern about the realities of contemporary pharmacy practice and the barriers to expanded practice. *See supra* note 106 and accompanying text.

B. *The Professional Standards Model*

A judiciary searching for an appropriate theory on which to base the recognition of expanded legal responsibilities for pharmacists could turn toward the pharmacy profession and ask what the profession expects of itself. This approach has rarely been used in pharmacist malpractice litigation, but it is not unheard of. The plaintiff in *Adkins v. Mong*[278] attempted to show that the defendant pharmacy had a legal duty to monitor drug usage, by referring to the standards of practice adopted by the American Pharmaceutical Association, and an article published in a pharmacy professional periodical.[279] The court was not persuaded by what it referred to as "nonlegal authorities,"[280] in light of the many previous cases that had rejected such a duty as a matter of law. The same court refused to consider a body of case law that established exposure to criminal liability, or authorized administrative action against a pharmacist's license, for failing to detect fraudulent prescriptions.[281] Standards set by the professional organization and by the administrative agency were not considered relevant to the issue of legal duty.[282]

Reliance on professional standards as the precursor to legal standards has a certain appeal. It is difficult to argue that anyone knows pharmacists better than pharmacists themselves. There is an ethic within pharmacy that focuses on professional values, and suggests that pharmacists do things because it gives value to the profession.[283] Pharmacy is undeniably expanding its practice frontiers.[284] Incremental advances in legal duties that conform to incremental advances in professional practice (or perhaps lag slightly behind) would accurately reflect both societal expectations of pharmacists, and pharmacists' expectations of themselves.

Yet, the problems with this outwardly attractive approach are significant. What purports to be a practice standard may not be a standard at all, but a goal toward which the pharmacy profession aspires.[285] Recognizing such purported standards as legal duties would be both unfair and a disin-

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278. Adkins v. Mong, 168 Mich. App. 726, 425 N.W.2d 151 (1988).

279. *Id.* at ____, 425 N.W.2d at 153.

280. *Id.*

281. *Id.* The court suggests that the expectations of a pharmacist by a state licensing agency and a court reviewing allegations of civil liability do not relate to each other, but there is no explanation as to why this is the case. *See id.* Perhaps it is because a state licensing agency establishes only minimal standards, and failure to comply with them does not mean that a higher standard of civil liability has not been met.

282. *Id.*

283. *See, e.g.*, Buerki & Vottero, *Ethics*, in A. WERTHEIMER & M. SMITH, PHARMACY PRACTICE: SOCIAL AND BEHAVIORAL ASPECTS (1989); Hepler, *The Third Wave in Pharmaceutical Education: The Clinical Movement*, 51 AM. J. PHARM. EDUC. 374-75 (1987).

284. *See supra* notes 76-77 and accompanying text.

285. *See supra* note 77 and accompanying text.

centive to further development of goals.[286] In addition, to the extent that advances in practice might lead to greater exercise of professional judgment by pharmacists, adoption of those advances as legal duties should include the protection from legal liability that the exercise of judgment offers. This protective aspect of professional discretion would not necessarily be obvious within the standards of the profession, and might be overlooked.

A more fundamental problem with adopting a theoretical model of pharmacist duty that borrows heavily from the professional standard is that it would be at odds with the law of informed consent, which focuses on patient's rights rather than caregiver values. Following the lead of *Canterbury v. Spence*,[287] one could argue that prevailing practice has evidentiary value in determining what the specific criteria measuring challenged professional conduct are, and whether they have been met, but it does not itself define the standard.[288] Permitting professional people to set their own standards could lead to collusive avoidance of liability by conspiring to keep standards so poorly defined that they are unenforceable. The goal of theory development is to recognize expanded responsibilities, while at the same time placing realistic limits on those responsibilities. This goal cannot be met by converting professional standards into legal duties.

C. *The Consumer Expectation Model*

The opinion in *Canterbury* states, "The patient's right of self-decision shapes the boundaries of the duty to reveal."[289] This being the case, the pharmacist's duty to warn might be based on consumer expectations of pharmacists in relation to disclosure about risk. If patients expect no more than to have a prescription filled correctly, then the pharmacist's legal duty would go no farther than that. If consumer expectations are somewhat higher, then the legal duty would expand. In keeping with *Canterbury*, the scope of the duty would be objective, and the pharmacist's duty to warn would include risk-related information that a reasonable person, in what the pharmacist knows or should know to be the patient's position, would expect the pharmacist to disclose, given the circumstances.[290]

A consumer expectation model for pharmacist disclosure of risks assumes that patients rely on the pharmacist's expertise, and that this reliance is justified.[291] It is contractually based, with mutual pledges—the patient

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286. *See supra* note 10 and accompanying text.

287. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

288. The *Canterbury* opinion states that "prevailing medical practice must be given its just due." *Id.* at 785. Precisely what that means is difficult to determine.

289. *Id.* at 786.

290. *Id.* at 787.

291. The consumer's reliance is seldom discussed in pharmacist malpractice cases, except within the framework of reliance on the physician. For example, the court in the *McKee* case states, "In deciding whether to use a prescription drug, the patient relies primarily on the ex-

pledging payment and the pharmacist pledging services, including information about risk. Beyond that, the model is also based on a covenant between the patient and the pharmacist. The pharmacist's promises, either explicit or implicit, induce the patient to engage the pharmacist to fill the patient's prescriptions, and the patient has the right to expect that this will be done to the best of the pharmacist's ability.

It seems platitudinous and unnecessary to say that patients have the right to make decisions about risks to themselves, and to suggest that this right creates a duty by pharmacists to warn of the risks of drug therapy. As obvious as the principle of autonomy may seem within this context, the reality is that patient's rights have not been addressed in pharmacist litigation. The opinion in *Riff*, which imposed a duty on the pharmacist, based that duty on professional standards stating: "It is for the medical community to decide what degree of vigilance is required in this respect."[292] In contrast, the dissenting opinion in *McKee* justified the conclusion that a pharmacist has a duty of due care by noting that "[t]he question is what the *public* would expect a reasonably prudent practitioner to do, not what his peers would expect."[293] Beyond that initial statement, however, the *McKee* dissenting opinion made no further reference to consumer expectations. Instead, it became bogged down in discussion of the expert witness issue,[294] which clearly focused on the medical establishment rather than on patient's rights.

There may be a good reason for the absence of lengthy discussion of consumer expectations in judicial analyses of pharmacist duty-to-counsel claims. Empirical data suggest that, when asked what is the most important reason for patronizing a particular drug store, only 2.5% of respondents indicated their reason was the pharmacist carefully explains how to take the medication.[295] When asked to give other reasons for patronizing a particular pharmacy (not the most important reason), only 9.6% mentioned counseling by the pharmacist.[296] On the other hand, when given a list of drug store characteristics and asked to assign an importance to them, 92.4% of respondents indicated that having a pharmacist available for personal consultation was important.[297] Studies have shown that when asked whether they would

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pertise and judgment of the physician." McKee v. American Home Prods. Corp., 113 Wash. 2d 701, ___, 782 P.2d 1045, 1051 (1989). This language seems to imply that the patient relies secondarily on someone, but the balance of the opinion clarifies that this someone must not be the pharmacist.

292. Riff v. Morgan Pharmacy, 353 Pa. Super. 21, ___, 508 A.2d 1247, 1253 (1986).

293. McKee v. American Home Prods. Corp., 113 Wash. 2d at ___, 782 P.2d at 1057 (citing Harris v. Groth, 99 Wash. 2d 438, 663 P.2d 113 (1983)).

294. *Id.* at ___, 782 P.2d at 1058-62.

295. NATIONAL PRESCRIPTION BUYERS SURVEY, Market Facts, Inc. 25 (1983).

296. *Id.* at 27.

297. Joyce & Hubbard, *Consumer Patronage for Pharmaceutical Services: A Comparative Analysis of Upper Income Households in Urban Areas*, 3(1) J. PHARM. MARKETING &

willingly pay for consultation services provided by a pharmacist, a majority of respondents say that they would.[298] These data suggest that consumers of medications have only modest expectations of pharmacists until they are told that it is permissible to expect something more.

Consumer expectations may serve as the basis for a model of pharmacist duty at some time in the future, but at present consumers are too unsure of what to expect of a pharmacist to rely on their wants and needs to define that duty. Patient's rights, which play such a significant role in defining the disclosure responsibility of the physician, are seldom referred to in pharmacist malpractice litigation. The consumer expectation model of pharmacist duty does not provide the consistent ability to set limits that is needed in a theory.

D. *The Power Model*

At common law there traditionally has been a reluctance to require people to come to the aid of others to prevent an injury, no matter how strong a moral duty might exist.[299] Fairness seems to be the rationale for a newly developing approach that recognizes a duty of affirmative action to a plaintiff who is vulnerable and dependent on a defendant who, correspondingly, holds considerable power over the plaintiff's welfare.[300] Within the context of pharmacy, it has been suggested that because consumers know very little about drugs, the pharmacist's expertise about drug effects is a strong argument for liability.[301] The power model of professional responsibility is knowledge based, requiring that pharmacists use their knowledge for the benefit of others, not solely for their own benefit.[302]

Sociologists have developed several theories that focus on power as the basis of a duty.[303] These theories generally assert that without knowledge, there is uncertainty. Uncertainty leads to dependence, and dependence gives rise to a duty. A similar theological approach is to recognize that based on the principle of stewardship, one's personal knowledge and abilities are not one's own, but are God-given. Therefore, no person has the right to determine how their own skills are used; they must be used altruistically for the benefit of others.

The pharmacist's knowledge is invariably an issue in pharmacist duty-

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MGMT. 3, 11 (1988).

298. Spaulding, Rappaport, Das & Dunn, *Fee-for-Service Pharmacist Consulting: A Consumer Marketing Survey*, 3(4) J. PHARM. MARKETING & MGMT. 73, 77 (1989).

299. W. KEETON, *supra* note 55, at 373.

300. *Id.* at 374. "Fairness in such cases thus may require the defendant to use his power to help the plaintiff, based upon the plaintiff's expectation of protection, which itself may be based upon the defendant's expectation of financial gain." *Id.*

301. Vandall, *Applying Strict Liability to Pharmacists*, 18 U. TOL. L. REV. 1, 20 (1986).

302. P. STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982).

303. *Id.*

to-warn cases.[304] If a court holds that a duty to warn exists, then it is because the pharmacist had knowledge of the risk of harm to the patient. If a court holds that a duty to warn does not exist, then it is because the pharmacist had no knowledge of the risk. This approach is consistent with the *Restatement (Second) of Torts*, which imposes liability on suppliers of chattels when they know of a dangerous character of the chattel, have no reason to believe that those to whom it is supplied know of the danger, and fail to exercise reasonable care to inform them of the danger.[305] The *Restatement* does not refer to pharmacists, but it does use the following relevant illustration:

> A is a guest in B's house. A is taken suddenly ill. B gives him a drug which B knows can only be safely used if taken in certain doses and under certain conditions. B gives the drug to A, but forgets to instruct him as to the manner in which it is to be used. A takes it in a larger dose than is proper, or fails to take the precautions which are necessary to make it safe. In consequence A's illness is increased. B is subject to liability to A.[306]

Following this logic, a pharmacist should have a responsibility to warn a patient of risks, when the pharmacist knows or should know of the risk, and when the pharmacist knows or should know that the patient does not know of the risk.

There are two significant factors that would operate to limit the recognition of a duty to warn under this knowledge-based power analysis. The first is that pharmacists generally have knowledge of drug characteristics, but do not have knowledge of patient characteristics. For example, the fact that a drug may cause drowsiness will always be known,[307] but the fact that a prescribed medication is similar to a medication to which the patient is allergic will not always be known.[308] Whether the patient is unaware of ei-

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304. *See supra* notes 216-23 and accompanying text.

305. RESTATEMENT (SECOND) OF TORTS § 388 (1965) states:

Chattel Known to be Dangerous for Intended Use

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

306. *Id.* at comment g, illustration 2.

307. This is drug-specific information, which can be given to every patient without knowing anything about the patient.

308. This is patient-specific information, which the pharmacist would ordinarily not know

ther of these two pieces of information will also not always be known to the pharmacist.

An approach that is consistent with the nature of the relationship between pharmacists and patients is to assume that the patient *does not* know drug characteristics, and to require disclosure of this information by the pharmacist, unless there is good reason to believe that the patient already knows it. It is also consistent with the nature of the relationship to assume that the patient *does* know patient characteristics (because it is the physician's job to consider these before prescribing), and not to require disclosure of this information unless there is good reason to believe that the patient does not know it. Always assuming that the physician has provided a warning, and that the patient is knowledgeable, is unacceptable. But the pharmacist can assume that physicians do their job (with risk assessment but not necessarily risk management), in the absence of contrary evidence.

A second liability-limiting factor of the power model is foreseeability of harm, which includes a consideration of the circumstances under which the pharmacist is being asked to fill a prescription.[309] A young child or an adult who is bedridden does not require a warning that a drug may impair the ability to drive an automobile, because this is not a foreseeable risk. A drug that may cause a severe rash if there is exposure to ultraviolet radiation while the drug is being taken requires a warning if the patient is a young person on the coast in the summer, but not if the patient is an older person in the upper midwest during winter. The foreseeability of harm test imposes a reasonableness limitation on the requirement that knowledge be used for the benefit of others.

The power model as the basis for a pharmacist duty to warn has a solid foundation in the litigation of the 1980s. It permits setting limits that protect patients and are fair to pharmacists. By focusing on the knowledge that a pharmacist possessed or should have possessed, a court can consistently distinguish those circumstances in which a pharmacist had no duty to warn from those circumstances in which there was a duty.

X. Conclusion

As pharmacy practice evolves, the law of pharmacist malpractice will evolve also, and changes in both will occur. The pharmacist's traditional link with the drug product is a limitation on practice and on malpractice. The evaluation of risks at the dispensing level relates primarily to risk management based on the knowledge of drugs. Only secondarily is risk assessment a factor at the dispensing level, when a pharmacist acquires knowledge about a patient of a type that a pharmacist usually would not be expected to know. Risk assessment is primarily within the physician's domain. Perhaps

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unless told by the physician or patient.

309. *See supra* notes 256-70 and accompanying text.

some day in the not too distant future, advocacy pharmacists will practice in a way that is not limited by physician predominance. But that day has not yet arrived.

There is a sound theoretical basis for recognizing a limited duty for pharmacists to warn patients of certain drug risks, when the facts also militate for such a duty. Yet, the judiciary has been slow to recognize the duty. This judicial reticence must in part be due to general respect for traditional authority, and respect for physicians in particular. It may also be that judges do not value pharmacists services, because judges are assertive, disinclined to leave the doctor's office without a thorough explanation of the risks of drug therapy, and accustomed to making decisions themselves. Perhaps judges permit their personal views and experiences with pharmacists to influence their interpretation of the law.[310]

The growing pervasiveness of drug use in our society requires that traditions be challenged. No good would come from damaging the physician-patient relationship, but the belief that a pharmacist who provides warnings to patients will destroy that relationship shows a lack of understanding of the health care system. Physicians usually know what is best for their patients, but not always, and patients themselves have a right to be involved in decisions about risk. Physicians do not currently tell patients all they need to know. A warning by a pharmacist complements recognized responsibilities of others in the drug distribution chain. The duty to warn is an esoteric body of law that establishes responsibilities and sets limits by using concepts such as superior knowledge and reasonable foreseeability of harm. Yet, in spite of (or perhaps because of) its elusiveness, it is a means by which the judiciary can recognize the dynamic nature of professional responsibilities. Pharmacists will continue to respond to the quality mandate they have been given by virtue of their role as health care providers, and they can expect the law to carefully measure that response, developing new approaches to the recognition of legal duty.

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310. One interesting example of this is the reference in the *McKee* opinion to an administrative regulation that deals with "Monitoring of drug therapy by pharmacists." McKee v. American Home Prods. Corp., 113 Wash. 2d 701, ____, 782 P.2d 1045, 1052 n.6 (1989) (quoting WASH. ADMIN. CODE § 360-12-150 (1989)). The regulation states, "Monitoring of drug therapy shall include, but not be limited to: (1) Collecting and reviewing patient drug use histories." The court then states, "We are unaware of any practice wherein pharmacists must collect and review patient drug use histories." *Id.* at ____, 782 P.2d at 1052 n.6. Because the author of the opinion has never seen it, he assumes the regulation away. *See also* Sely, *Pharmacists As Alternative Sources of Medical Care: The Case of Cincinnati*, 26 SOC. SCI. & MED. 409, 412 (1988) (customers in poor areas express greater need for pharmacist's advice than do customers in wealthy areas).