THE PROFESSIONAL CAPABILITIES AND LEGAL RESPONSIBILITIES OF PHARMACISTS: SHOULD "CAN" IMPLY "OUGHT"?

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I. INTRODUCTION

A. *Problems Associated with Drug Therapy*

Patients who seek medical treatment today can expect drug therapy to provide both relief of symptoms and outright cures that were impossible to imagine as recently as two decades ago. For the most part, modern drug therapy works well. Usually, patients are prescribed an appropriate medication, the medication is administered by a nurse in a hospital or nursing home, or by the patient or patient's caregiver at home, and the patient's response to the drug is monitored for safety and efficacy.[1]

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1. Drug-related litigation does not seem to contribute greatly to the overall volume of malpractice litigation, but data regarding the incidence of medication-related malpractice varies considerably. One insurance company reported 30% of the claims against its insured hospitals are based on the administration of drugs, while another insurance company reported 5.7% of the claims made against its physicians were medication related. Joseph L. Fink III, *Liability Claims Based on Drug Use*, 17 DRUG INTELLIGENCE & CLINICAL PHARMACY 667, 667 (1983). A study in Ohio reported 9.2% of the state's medical malpractice claims arose out of problems with medications. *See* Peter J. Mikolaj, *Hospital Association Determines Nature of Closed Claims in State*, 52 HOSPITALS 53, 54 (1978). For an in-depth discussion of malpractice related to medications, see Michael J. Farrell, *Medication Malpractice: Claims, Culprits and Defenses*, 16 AM. J. TRIAL ADVOC. 65 (1992).

Problems do arise, however, with drug therapy.[2] Approval by the Food and Drug Administration (FDA) does not mean a drug is problem free.[3] Likewise, proper diagnosis of a patient's condition, followed by the appropriate selection of a patient's medication, will not ensure a successful outcome from drug therapy.[4] Toxicities and therapeutic failures can occur from either the chemistry of a drug, the chemistry of a patient, or both.[5] These problems are of such significance that they have generated a body of case law. If a patient is dissatisfied over a bad outcome from drug therapy, the legal system will seek to discover who or what is responsible for the harm done to the patient.[6]

B. *Assigning Responsibility for Drug-Related Problems*

Responsibility for problems with drug therapy can be ascribed in two ways: "thing responsibility" and "agent responsibility."[7] Thing responsibility is a backward-looking assessment.[8] It singles out the decisive factor—a drug or a patient's physiologic anomaly—that was in effect when the problem occurred.[9] Ascribing thing responsibility is equivalent to identifying the cause of the problem.[10] The traditional approach to evaluating problems with drug therapy involves application of thing responsibility—identifying problem drugs—and either eliminating them from the market or significantly restricting their distribution.[11]

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2. *See* Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy, Part 1*, 46 AM. J. HOSP. PHARMACY 929, 929-31 (1989); *see id. Part 2*, at 1149.

3. Richard A. Merrill, *Regulation of Drugs and Devices: An Evolution*, 13 HEALTH AFF. 47, 50-51 (1994).

4. Those who evaluate the quality of health care no longer focus on structure and process alone, but examine outcomes as well. It is not necessarily the case that good outcomes result from good structure and good process. Avedis Donabedian, *The Quality of Care: How Can It Be Assessed?*, 260 JAMA 1743, 1745 (1988).

5. *See* Linda M. Strand et al., *Drug-Related Problems: Their Structure and Function*, 24 DRUG INTELLIGENCE & CLINICAL PHARMACY 1093, 1094 (1990). Strand identified eight categories of drug-related problems: (1) the patient does not receive a needed drug; (2) the patient receives the wrong drug; (3) the patient receives too little of the correct drug; (4) the patient receives too much of the correct drug; (5) the patient has adverse drug reactions; (6) the patient has drug-drug or drug-food interactions; (7) the patient has a medical condition that is a result of not receiving a prescribed drug; and (8) the patient has a medical condition that is a result of taking an unnecessary drug. *Id.*

6. *See infra* part II.

7. Kurt Baier, *Moral and Legal Responsibility*, *in* MEDICAL INNOVATION AND BAD OUTCOMES: LEGAL, SOCIAL AND ETHICAL RESPONSES 101, 102 (Mark Seigler ed., 1987).

8. *Id.* at 103.

9. *See id.*

10. *Id.*

11. John H. Krause, *Accutane: Has Drug Regulation in the United States Reached Its Limits?*, 6 J.L. & HEALTH 1, 14-15 (1991).

Agent responsibility differs from thing responsibility because it is both backward looking and forward looking.[12] Problems with drug therapy may be caused not only by drugs, but by the drug-use process. The process of drug use—prescribing, dispensing, administration, monitoring, and evaluation—is complicated by the presence of human agents.[13] Unlike things, human beings can be blamed and found blameworthy; they can have faults and can also be at fault.[14] While it can be said that a drug *was* responsible for a patient's problem, it is equally appropriate to say that a person *is* responsible for the patient's welfare.[15] Agent responsibility focuses on the individuals involved in the drug therapy process.

The health care community recognizes that problems with drug therapy are not simply the result of unavoidable adverse effects caused by drugs that are risky but otherwise valuable because their benefit outweighs their risk.[16] Some problems with drug therapy may be avoidable, and may be the fault of human beings who control the drug-use process. Physicians, nurses, pharmacists, and others work together to create and operate systems of drug use.[17] Among health care providers, pharmacists are uniquely qualified and situated to oversee the drug-use process.[18]

The education of pharmacists has evolved over the past several decades from an emphasis on the drug product to an emphasis on drug therapy.[19] Empirical studies show pharmacists can and do perform drug-use review functions beyond the act of order processing.[20] Furthermore, expanded responsibilities for pharmacists are cost effective because they increase the overall quality of patient care, and reduce the overall cost.[21] For example, through the establishment of drug-use review requirements for drugs dispensed by pharmacists under the Medicaid program, federal law recognizes the potential for pharmacists to increase the quality of health care and reduce its cost.[22]

There are several reasons to turn to pharmacists as a primary solution to drug therapy problems. First, because patients tend to obtain services from

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12. Baier, *supra* note 7, at 104.
13. *Id.* at 103.
14. *Id.*
15. *Id.* at 104 (emphasis added).
16. Strand et al., *supra* note 5, at 1093.
17. *See id.*
18. *Id.*
19. Richard P. Penna, *Pharmaceutical Care: Pharmacy's Mission for the 1990s*, 47 AM. J. HOSP. PHARMACY 543, 544 (1990).
20. Hind T. Hatoum & Kasem Akhras, *1993 Bibliography: A 32-Year Literature Review on the Value and Acceptance of Ambulatory Care Provided by Pharmacists*, 27 ANNALS PHARMACOTHERAPY 1106, 1109-10 (1993).
21. AMERICAN ASS'N OF COLLEGES OF PHARMACY, REPORT OF THE TASK FORCE ON THE COST-EFFECTIVENESS OF PHARMACEUTICAL PRODUCTS AND PHARMACY SERVICES 36-40 (1989).
22. *See* Kenneth R. Baker, *The OBRA 90 Mandate and Its Developing Impact on the Pharmacist's Standard of Care*, 44 DRAKE L. REV. 503 (1996); *see generally* 42 U.S.C. §§ 1396-1396v (1994) (providing grants to states for medical assistance programs and conditions for receiving such grants).

multiple physicians, but only from a single pharmacy, the pharmacy is likely to be the only place where an accurate record exists of all medications a patient has received.[23] Second, because refills of prescriptions are frequently obtained between visits to the physician, pharmacists are the only health care professionals who know that a patient requesting a refill of a medication has experienced a side effect, or that a pattern of potentially dangerous drug use exists. For example, the frequency of requests to refill a prescription may differ significantly from the way in which the drug was prescribed. Third, pharmacists are accessible within a community. They are usually located in heavily trafficked geographic areas, they do not require an appointment, and they are open for business during both morning and evening hours. Fourth, pharmacists are held in high regard by the public.[24]

Even though pharmacists can prevent or resolve problems with drug therapy by performing functions beyond the traditional role of dispensing medication, courts are reluctant to require pharmacists to do so.[25] Some

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23. The Superior Court of New Jersey recognized this important drug review function as early as 1966, stating:

> Though the primary responsibility for drug prescription rests with the physician, the pharmacist plays an ancillary but important role in insuring that the proper drug and dosage are provided. Accordingly, the pharmacist is required to maintain records of all prescriptions. . . . Thus, if a customer frequents one pharmacy for all of his prescription needs, that pharmacist is in a position to check his records and thereby determine if a prescription is in any way antagonistic or contra-indicated by his previous prescription record.

Supermarkets Gen. Corp. v. Sills, 225 A.2d 728, 736 (N.J. Super. Ct. Ch. Div. 1966).

24. Leslie McAneny, *Pharmacists Retain Wide Lead as Most Honorable Profession*, THE GALLUP POLL MONTHLY, July 1993, at 37-39 (noting Americans rate pharmacists highest for ethics and honesty). Research reveals that the reason behind the pharmacists' high rating has less to do with the perception of professional expertise than a general feeling that pharmacists are good people. *See* Leon E. Cosler et al., *Consumer Preference for Personal Drug Information Source: Relationship to Perceived Importance of Drug Class*, 20 DRUG INTELLIGENCE & CLINICAL PHARMACY 138, 141 (1986).

25. *See, e.g.*, Jones v. Irvin, 602 F. Supp. 399, 402-03 (S.D. Ill. 1985) (recognizing pharmacists' high duty of "prudence, thoughtfulness, and diligence," but claiming they have no duty "to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being overmedicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customers"); Walker v. Jack Eckerd Corp., 434 S.E.2d 63, 67-69 (Ga. Ct. App. 1993) (finding that the imposition of a duty to warn on pharmacists "would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability"); Frye v. Medicare-Glaser Corp., 605 N.E.2d 557, 560-61 (Ill. 1992) (holding that it is the physician's duty to warn patients of the dangers of medication, not the pharmacist's duty); Nichols v. Central Merchandise, Inc., 817 P.2d 1131, 1132-33 (Kan. Ct. App. 1991) (noting that "a duty to warn the pharmacist would intrude on the doctor-patient relationship and force the pharmacist to practice medicine without a license"); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387-88 (Mich. Ct. App. 1987) (holding that there is no duty to warn a patient of "possible side effects of a prescribed medication when the prescription is proper on its face and neither the physician nor the manufacturer has required that any warning be given to the patient by the pharmacist"); Kampe v. Howard Stark Professional Pharmacy, Inc., 841 S.W.2d 223, 225-27 (Mo. Ct. App. 1992)

courts have even held pharmacists should not perform these functions.[26] The purpose of this Article is to supplement the discussion of expanded legal responsibilities for pharmacists by suggesting that pharmacists should provide information to their patients regarding medications because it is morally right to do so. This moral imperative is entirely consistent with the knowledge and activities of modern pharmacists and with the developing body of law expanding the responsibilities of pharmacists.

The basic premise of this Article is that responsible individuals ought to do what they can for those to whom they are responsible; this individual responsibility is based on capacity. It is appropriate to ought to do what they can for patients because pharmacists are moral agents. Moral agency implies that pharmacists understand they have defined responsibilities which must be met. The moral imperative requires an individual to have the capacity to understand guidelines for action, be able to act on them, and understand that one ought to do so.[27] In this sense, agent responsibility is actually capacity responsibility because it is the result of a person's basic abilities.[28] Responsibility arises because one possesses the ability to respond when confronted with a preventable problem.[29] Because pharmacists' abilities have increased, expanding pharmacists' responsibility and liability is justified as an application of the principle of capacity responsibility.

II. THE TREND TOWARD EXPANDED PHARMACIST RESPONSIBILITY

A. *Traditional Basis of Pharmacist Liability*

Pharmacists have always been responsible for the accurate processing of prescription orders to assure that patients receive the correct drug, in the correct dosage, with the correct directions. This responsibility for technical accuracy is so well established that a pharmacist who errs in processing a

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(holding that a pharmacist has no duty beyond "properly filling legal prescriptions that contain[] no apparent discrepancies on their face"); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1385-88 (Pa. 1991) (declining to apply strict liability to pharmacists because physicians act as "exclusive intermediaries").

26. *See, e.g.*, McKee v. American Home Prods., Corp., 782 P.2d 1045 (Wash. 1989). In *McKee*, the court recognized the ability of pharmacists to provide information to patients about potential medication-related problems: "As a legend drug, the pharmacists may have given McKee information about the therapeutic values of plegine, however, they were not required to do so." *Id.* at 1054. In other words, pharmacists may provide information. However, in other sections of its opinion, the court explained that pharmacists should not provide information to patients because to do so would "interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment;" it would "not only place an undue burden on pharmacists, but would likely create antagonistic relations between pharmacists and physicians." *Id.* at 1051-53; *see generally* David B. Brushwood, *The Pharmacist's Drug Information Responsibility After* McKee v. American Home Prods., 48 FOOD & DRUG L.J. 377 (1993) (discussing the responsibilities of physicians and pharmacists in dispensing drugs to patients) [hereinafter *Drug Information*].

27. Baier, *supra* note 7, at 104.

28. *Id.* at 107-08.

29. *Id.* at 108.

physician's prescription order may be held negligent as a matter of law, no matter how careful or attentive the pharmacist may have been to detail.[30] The fact of the error speaks for itself.[31]

An unforgiving, "no mistakes allowed" approach to pharmacy law reflects the technical and nonjudgmental nature of the pharmacist's traditional role and recognizes that an honest error in judgment cannot occur when a pharmacist does not use judgment.[32] In contrast, traditionally pharmacists have not been found liable if the prescription was correctly filled.[33] Until recently, courts have nearly unanimously rejected pharmacist liability for problems caused by drugs the pharmacist correctly dispensed.[34] Thus, the absence of error in the processing of an order has immunized pharmacists from liability.[35]

B. *Increasing Pharmacist Liability*

Over the past decade, the tradition of granting immunity to pharmacists who correctly process prescriptions has eroded.[36] While pharmacists are still required to be error free in the technical act of prescription processing, they also have a duty to recognize potential prescription drug abuse and act to prevent future abuse.[37] Pharmacists have been required, under some limited

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30. *See, e.g.*, DeCordova v. State, 878 P.2d 73, 76 (Colo. Ct. App. 1994).

31. *Id.*

32. Consider the hypothetical situation in which a patient suffers from a disease that can be treated with one of two drugs. A slight majority of physicians would choose Drug A, but a respected minority of physicians would choose Drug B. The patient's physician elects to prescribe Drug B because in the physician's experience, this drug has proved most successful with similar patients. The drug is, however, unsuccessful in treating the condition. With the benefit of hindsight, it becomes obvious that although Drug B was a bad choice, the outcome was not foreseeable when the drug was prescribed. Therefore, the physician has not been negligent. At best this is an unpreventable, though regrettable, bad outcome. At worst it is an honest error in judgment that can be legally forgiven because Drug B was not a clearly inappropriate therapy at the time it was prescribed.

If, for the same patient, a pharmacist mistakenly dispenses Drug B when Drug A has been prescribed, and the negative outcome occurs, the pharmacist was negligent. This is viewed as a preventable error and the pharmacist cannot use the rationale that Drug B was reasonable at the time because the pharmacist did not dispense Drug B for that reason. *See Drug Information*, *supra* note 26.

33. Adkins v. Mong, 425 N.W.2d 151, 154 (Mich. 1988) (holding that a pharmacist will not be liable for lawfully filling a prescription issued by a licensed physician).

34. *See* McKee v. American Home Prods., Corp., 782 P.2d 1045, 1049 (Wash. 1989).

35. Leesley v. West, 518 N.E.2d 758, 760 (Ill. 1988) (applying the learned intermediary doctrine to pharmacists); Batiste v. American Home Prods., Corp., 231 S.E.2d 269, 274 (N.C. Ct. App. 1977) (holding that absent an allegation the product was different than the drug prescribed, the pharmacist will not be found liable); Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978) (adopting the learned intermediary doctrine which limits a prescription drug manufacturer's duty to warn the physician—it is the physician's duty to warn the ultimate consumer).

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

37. *See, e.g.*, Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d at 519 (requiring a

circumstances, to provide patients with appropriate warnings regarding the potential adverse consequences of drug use.[38]

The so-called "duty to warn" cases of the past decade are generally criticized for their failure to establish a firm precedent recognizing an expanded duty for pharmacists.[39] Expressing reluctance to interfere with the physician-patient relationship or to overburden pharmacists, courts have examined the functions that pharmacist must, may, or may not perform.[40] Judicial opinions from the 1980s and early 1990s yielded confusion regarding the scope of pharmacists' duties.[41] Several courts noted, however, specific factual situations justifying an exception to the general rule that a duty to warn exists for pharmacists.[42]

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pharmacist to cease refilling the prescription when a pharmacy customer is having a prescription for a dangerous drug refilled at a rate faster than the one prescribed).

38. *See, e.g.*, Pittman v. Upjohn Co., 890 S.W.2d at 435.

39. A sampling of pertinent commentaries reflects criticism of judicial reluctance to expand pharmacists' duties to include a duty to warn. *See, e.g.*, Sally Apter, Recent Decision, 30 DUQ. L. REV. 181, 201 (1991) ("Because of his special knowledge and expertise, the pharmacist is in the best position to effectively reduce the risk of injury caused by adverse reactions to the drugs he sells. This can best be accomplished by the pharmacist providing warnings directly to the consumer. . . . Imposing strict liability on pharmacists may prove to be an incentive to safety, contrary to the rationale adopted by the courts."); Monica C. Berry, Casenote, 19 LOY. U. CHI. L.J. 1261, 1279 (1988) ("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."); Terrence C. Green, Casenote, 24 CREIGHTON L. REV. 1449, 1450 (1991) ("This Note concludes that the court in *McKee* misinterpreted the Washington statute and regulations in declaring that the pharmacists have no duty to warn. This Note also concludes that the present allocation of duties upon the pharmacist, as expressed by the Washington Supreme Court, does not fully enable the patient to make an informed choice; thus, pharmacists should have a duty to warn."); Louis P. Milot, Casenote, 13 S. ILL. U. L.J. 1003, 1018 (1989) ("The court should not have automatically presumed that pharmacists have no duty to warn customers without considering surrounding circumstances.").

40. *See supra* notes 25-26 and accompanying text.

41. *See* David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 8-11 (1991).

42. *See, e.g.*, Hand v. Krakowski, 453 N.Y.S.2d 121, 123 (App. Div. 1982) (holding that a pharmacist breaches the duty of care by knowingly ignoring the danger and consequences of an identified alcoholic's ingestion of prescription drugs commonly recognized as taken without regard to prescription); Ferguson v. Williams, 399 S.E.2d 389, 393 (N.C. Ct. App. 1991) (holding that when a pharmacist undertakes the duty to advise a client concerning medication, the pharmacist is bound to advise correctly); Riff v. Morgan Pharmacy, 508 A.2d 1247, 1250-52 (Pa. Super. Ct. 1986) (requiring pharmacist to warn patient of the maximum dosage limitations of a dangerous and toxic drug, the adverse side effects of which were well known in the pharmaceutical community); Dooley v. Everett, 805 S.W.2d 380, 382, 386 (Tenn. Ct. App. 1991) (holding that pharmacists may be liable for failing to warn of the possible dangers associated with the interaction of Erythromycin and Theophylline, which can cause cerebral seizures in patients).

In *Lasley v. Shrake's Country Club Pharmacy, Inc.*,[43] the Arizona Court of Appeals ventured beyond prior decisions in favor of a pharmacist's duty to warn. In *Lasley*, the court did not carve out a narrow, fact-based exception to a general rule limiting a pharmacist's duty.[44] Instead, the *Lasley* court rejected outright the no-duty argument and ruled that the trial court, in granting summary judgment for the defendant pharmacy, confused the concept of duty with that of the standard of care.[45] The court demonstrated a refreshing understanding of the basic principles of tort law, stating:

> It is better to reserve "duty" for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal standard of what is required to meet the obligation. In other words, "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 [if it exists] is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.[46]

The *Lasley* court held that the pharmacy owed the patient a duty of reasonable care and the trial court erred in holding as a matter of law that the pharmacy owed no duty to warn.[47]

The *Lasley* opinion is grounded in the solid traditions of tort law. It stands for the premise that a pharmacist's duty is dependent upon the professional character of the relationship between the pharmacist and patient.[48] A pharmacist's duty is not determined by examining a list of functions the pharmacist should or should not perform.[49] The nature of the pharmacist-patient relationship requires pharmacists to fulfill their duty of due care to patients because pharmacists are under an obligation to minimize the risk of the pharmaceutical products they dispense.[50] An examination of specific tasks a pharmacist may perform in reducing the risks of drug therapy is appropriate in analyzing the requisite standard of care and whether the pharmacist has met the standard as a matter of fact.[51] A pharmacist owes, however, a duty as a matter of law to those who seek pharmaceutical products and services.[52]

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43. Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994).
44. *Id.*
45. *Id.* at 1132.
46. *Id.* (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53, at 356 (5th ed. 1984)).
47. *Id.* at 1130.
48. *Id.* at 1132-33.
49. *Id.* at 1131-32.
50. *Id.* at 1132.
51. *Id.* at 1134.
52. *Id.* at 1132.

The expansion of legal responsibilities will certainly continue. The time to litigate claims against pharmacists based on incidents occurring subsequent to the adoption of federal standards is rapidly approaching.[53] As a condition of participation in the state administered, but partially federally funded Medicaid pharmaceutical benefits program, the Congress required states to adopt rules mandating prescription screening, patient counseling, and extensive documentation by pharmacists.[54] Although the law required states to adopt expanded standards of practice only for Medicaid recipients, most states adopted rules making the standards applicable to all pharmacists.[55] The new standards became effective January 1, 1993.[56] Due to the time between the occurrence of a negligent act and the litigation of claims based on that occurrence, federally inspired state rules expanding pharmacy standards has yet to fully impact the courts. Early indications suggest the impact will be significant.[57]

Preliminary drafts of the Restatement (Third) of Torts mandate the trend toward expanded legal responsibilities.[58] A proposed section of the document states:

> A retail seller of a prescription drug or medical device is subject to liability only if, at the time of sale:
> (1) The drug or medical device contained a manufacturing defect as defined in Section 2(a); or
> (2) The retail seller failed to exercise reasonable care in preparing, packaging, labeling, instructing, or warning about the drug or medical device.[59]

Subsection (1) imposes strict liability on pharmacists for manufacturing defects.[60] Subsection (2) indicates that the standard of reasonable care for a

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53. Faced with allegations that a pharmacist failed to monitor drug therapy or counsel patients about medications, state courts have examined state statutes for guidance regarding the scope of a pharmacist's legal duty. *See* Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 518 (Ind. 1994); Gassen v. East Jefferson General Hospital, 628 So. 2d 256 (La. Ct. App. 1993). The absence of a statute or regulation clearly requiring expanded functions led some courts to rule that no such requirement exists as a matter of law. *See* Kinney v. Hutchinson, 449 So. 2d 696 (La. Ct. App. 1984). As the state statutes and regulations change, based on the federal mandate, this same process of legal analysis will expand a pharmacist's legal duties.

54. *See* Baker, *supra* note 22, at 503.

55. *Id.* at 503.

56. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395 (1994).

57. *See* Huggins v. Longs Drug Stores Cal., Inc., 862 P.2d 148, 153 (Cal. 1993) (describing the responsibilities of pharmacists under the expanded standards and holding that a pharmacist is not liable to parents of a child to whom improperly labeled medication was dispensed); Walker v. Jack Eckerd Corp., 434 S.E.2d 63, 69 (Ga. Ct. App. 1993) (holding that a pharmacist had no duty to warn about the prolonged effects of an eyedrop, but cautioning such a ruling should not be considered precedent for cases decided after the effective date of recently passed regulations expanding pharmacy practice standards).

58. RESTATEMENT (THIRD) OF TORTS § 4 (Tentative Draft No. 1, 1994).

59. *Id.* § 4(c)(1)-(2).

60. The obvious implication of this proposed section is contradicted by a subsequently

pharmacist includes instructing as well as warning patients.[61] The influence of the proposed Restatement on the development of the common law will undoubtedly produce judicial opinions reflecting the new legal standards.

Obviously the legal responsibility of pharmacists has increased over the past decade.[62] The duty to the patient now extends beyond technical accuracy in prescription processing and includes protecting the patient from certain harms caused by medication.[63] The existence of the duty is noncontroversial.[64] The scope of the duty is not, however, well defined.

Capacity based responsibility is a sensible way to define the scope of a pharmacist's duty. Pharmacists ought to do whatever is reasonably possible to protect patients from harm caused by a medication. This approach takes advantage of the pharmacist's ability and knowledge, without unfairly burdening pharmacists with duties that cannot be fulfilled. The new duty reflects patients' reasonable expectations that the risks of drug therapy will be minimized whenever possible. It also reflects the character of the caring relationship pharmacists share with their patients. Pharmacists cannot assure patients that outcomes from drug therapy will be positive. Pharmacists should, however, assure patients they will utilize their professional abilities and knowledge to increase the likelihood of a positive therapeutic outcome.

III. THEORETICAL UNDERPINNINGS OF THE PHARMACIST'S DUTIES

The development of pharmacist malpractice law can be viewed as an attempt to require pharmacists to accept duties related to two basic areas of moral concern—freedom and power. To ask what pharmacists ought to do for patients to whom they provide pharmaceutical products and services is to pose a moral question, because pharmacists are capable of acting for both voluntary and conscious reasons to protect and promote the interests of others. Prescription medications are not only risk-reducing, they are also risk-producing. State governments would not grant pharmacists an exclusive right to distribute medications to patients were it not for the potential risks that medications pose for patients and the need to identify a person whose expertise can protect patients from risks associated with medication.

To ask what pharmacists ought to do in any given situation is also a legal question. In exchange for the exclusive right to distribute medications, legal authorities impose duties upon pharmacists. What pharmacists should legally do and what pharmacists should morally do, are of course, interrelated. The normative structure of pharmacists' legal duties can be explained

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proposed comment which states that, "[r]etailers of prescription drugs and medical devices are liable for harm caused by such products only if the retailers are negligent." *Id.* § 4 cmt. h.

61. The duty to instruct and the duty to warn are separate and distinct. *Id.* § 2 cmt. f. "Instructions inform users how to use products safely. Warnings alert users to the existence and nature of product risks so that they can, by appropriate conduct, avoid injury." *Id.*

62. *See supra* Part I.

63. *See* RESTATEMENT (THIRD) OF TORTS § 4 (Tentative Draft No. 1, 1994).

64. *Id.*

through moral theory.[65] Basic moral principles are recognized and enforced in pharmacist malpractice law.[66]

A. *Duties Related to Freedom*

Freedom is perhaps the most valued moral and legal principle. Freedom demands the respect of each individual's autonomous right to make evaluations and choices when the individual's own interests are at stake. Each individual is an independent agent with his or her own unique approach to life. Individuals differ, however, in their values, interests, attitudes, and beliefs. It would be disrespectful of individuals, as autonomous agents, to reject their considered judgments or deny them the freedom to act on those judgments. Autonomous individuals have the freedom to perform whatever actions they wish, as long as the freedoms of others are not infringed.[67]

The use of medication in American society is reflective of a paternalistic process that does not afford patients a high level of freedom.[68] Traditionally, physicians have made decisions about drug therapy *for* patients rather than *with* patients.[69] Pharmacists and physicians have recognized a responsibility to avoid discussing drug therapy with patients as opposed to including patients in their decisions.[70] This approach to patient care is paternalistic because it may be contrary to the patient's immediate desires and clearly limits the patient's freedom to choose.

The paternalism inherent in the drug use process is a reflection of the rules for drug regulation, which evolved during the 20th century. In 1906, the Pure Food and Drug Act required, among other things, accuracy in the labeling of ingredients on drug containers.[71] This approach was one of "indirect regulation" because the purpose was to assist patients in making decisions for themselves based on accurate information, rather than to make decisions for patients.

"Direct regulation" began in 1938 when the Food, Drug, and Cosmetic Act denied patients the freedom to use certain drugs because these drugs could not be placed in interstate commerce until they had been declared safe

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65. For an overview of the moral imperative arguments, see LON L. FULLER, THE MORALITY OF LAW (rev. ed. 1969).

66. *See generally* David B. Brushwood & Charles D. Hepler, *Redefining Pharmacists' Professional Responsibilities*, *in* PHARMACEUTICAL CARE 195 (Calvin H. Knowlton & Richard P. Penna eds., 1995).

67. There are, of course, many views of autonomy and freedom. For a concise and pertinent review, see RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 235 (1986).

68. *See* JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 16-25 (1984) (discussing the relationship between doctor and patient in the context of the promulgation of the AMA's first code of ethics).

69. *Id.*

70. *See* ROBERT A. BUERKI & LOUIS D. VOTTERO, ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE 92-93 (1994).

71. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

for use.[72] In 1951, the Durham-Humphrey Amendment further restricted patients' choices about drug use by imposing a prescription requirement for certain classifications of drugs.[73] The Kefauver-Harris Amendments introduced additional direct regulation through an efficacy requirement—patients could not use a safe medication their physicians were willing to prescribe because the medication was not proven effective.[74]

State paternalism—as reflected in this approach to regulation of the discovery, development, and marketing of new drugs—is easily justified. Generally, society believes sick people must be protected from quacks, charlatans, and those who raise false hopes and take advantage of human suffering. State paternalism limits, however, the range of choices in drug therapy to those considered legitimate and scientific. The result is generally accepted for most therapies. People seeking treatment for cancer or AIDS question, however, such paternalism and, as a result, modifications were created by carving out narrow exceptions to general rules.[75] Apart from these narrow exceptions, state paternalism provides solid conceptual support for a tradition of governmental decision making on behalf of people who use medications.

Decisions made during the medication-use process, rather than the medication research and development process, are less centralized and more focused on the special needs of each patient rather than the general characteristics of drugs.[76] The medication-use process considers the risks of a drug product at the end of a chain of events including research, development, production, marketing, and distribution. Even in a society placing a high value on individual freedom, state paternalism by the drug manufacturer and the FDA is prevalent and even welcomed. Unfortunately, personal paternalism by the physician and pharmacist may appear to be the next logical step beyond state paternalism; it often becomes a central characteristic of medication-use at the end of the chain. Whereas state paternalism is characterized by a governmental body exerting control over particular kinds of practices, personal paternalism involves an individual deciding what is best for another person based on personal principles and values.

Personal paternalism results from the patient's dependent relationship on the physician and pharmacist. In this dependent relationship, the patient surrenders autonomy to the care provider, who accepts responsibility for the patient's care. The surrender of autonomy conflicts, however, with the principle that rational individuals enjoy the right to personally make intimate decisions about their well-being.

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72. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395 (1994).

73. Durham-Humphrey Amendment, 21 U.S.C. § 353(b) (1994).

74. Kefauver-Harris Amendments, 21 U.S.C. §§ 301-381 (1994).

75. *See* Ellen C. Cooper, *Changes in Normal Drug Approval Process in Response to the AIDS Crisis*, 45 FOOD DRUG COSM. L.J. 329, 331 (1990).

76. Michael J. Holleran, *The Pharmaceutical Access and Prudent Purchasing Act of 1990: Federal Law Shifts the Duty to Warn from the Physician to the Pharmacist*, 26 AKRON L. REV. 77, 86 (1992).

Perhaps this is why the most recent major federal legislation concerning drug use focuses on patients as the decision makers rather than physicians, manufacturers, or government.[77] This legislation marks a backward shift toward indirect regulation. It also emphasizes the need to educate and empower patients by incorporating them into the medication-use process as providers of self-care. Furthermore, it enlists the pharmacist as the primary agent within this new approach to shared responsibility.[78]

Patients do not always strictly follow doctors' orders.[79] Instead, some patients receive advice and subsequently develop their own routine concerning medication use. This action by patients was previously viewed as aberrant and labeled as "noncompliance."[80] However, the practice of having patients depend on themselves rather than on others is now fully recognized as a legitimate part of the drug-use system and carves out a responsibility for pharmacists to assure that patients make informed and careful decisions.[81]

Many negative results in drug therapy, both therapeutic failures and toxicities, are manageable by patients through adjustments in habits and lifestyle. Certain negative outcomes are, however, not manageable by the patient alone, yet they can be anticipated by an alert patient who detects a warning sign and contacts the prescriber before complications arise. Some medication-related problems cannot be prevented by even the most responsible decision at the moment when the medication is prescribed. By self-monitoring and developing a plan for drug use consistent with the personal goals, patients can increase the likelihood of a positive outcome from carefully prescribed medications.

Effective medication use promotes the autonomy of patients who are otherwise sick, disabled, or in some other position of dependence. Although medications used properly can relieve human suffering, medications used improperly can increase human suffering. This poses a problem for pharmacists attempting to carry out their legal responsibilities. When patients suffer a preventable injury from medication use, their autonomy may be restricted in a variety of ways.

The fact that a preventable medication-related injury occurred is no reason to punish the pharmacist or require the pharmacist to compensate the patient. Pharmacists' liability must rest on wrongful conduct. From an autonomy perspective, pharmacists should be held morally accountable for

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77. 42 U.S.C. § 1396r-8(g)(2)(A)(i)(I) (1994) (requiring states to establish standards for drug review by pharmacists).

78. *See* Holleran, *supra* note 76, at 86.

79. Jenny L. Donovan & David R. Blake, *Patient Non-Compliance: Deviance or Reasoned Decision-Making?*, 34 SOC. SCI. MED. 507, 507 (1992).

80. *Id.* It is possible to view patients' use of medications differing from the way the medications were prescribed as "self-regulation"; this is an appropriate and necessary factor in the drug regulatory process. *See* Peter Conrad, *The Meaning of Medications: Another Look at Compliance*, 20 SOC. SCI. MED. 29 (1985). The fact that patients may have good reasons for using medications differently from the way they were prescribed is now well recognized. *See* Donovan & Blake, *supra* note 79, at 507.

81. Donovan & Blake, *supra* note 79, at 508.

harm to patients only if they could have known that a medication would cause unwarranted harm.

The freedom-based analysis of duty is necessary, but not sufficient to fully describe the pharmacist's relationship with patients. A discussion of the pharmacist's duty may begin with a focus on freedom, but it must also consider the patient's rights relating to power. Power analysis is important because one must posses the ability to bring one's chosen goals to fruition in order to control one's destiny and achieve freedom.

B. *Duties Related to Power*

Power is a second area of moral concern related to the issue of a pharmacist's obligation to patients. The pharmacist's power and the duty that arises from it are based on the imbalance of information which permits providers of health care to assist—and sometimes exploit—patients. The imbalance of knowledge between a health care provider and patient creates uncertainty. Uncertainty leads to dependence; dependence gives rise to a duty.

Professional expertise enhances the quality of decisions about a medication's risks and benefits. Generally, consumer goods and services can be divided into three categories, with the classification of a good dependent on the ordinary user's ability to make risk-benefit decisions about it and, in turn, assess the value of the product.[82] Pre-experience goods—also known as search goods—can be evaluated prior to their purchase, either through inspection or by examining a description of specifications for the goods.[83] Experience goods must be consumed for the user to ascertain their qualities.[84] Post-experience goods—also known as credence goods—are distinct because their qualities can only be determined some time after using them.[85] Medications are post-experience goods because without the benefit of professional knowledge and expertise, one cannot know whether the product will be either effective or safe until long after consumption.[86]

The most accurate and predictable decisions are those made for pre-experience goods because decisions about pre-experience goods are prospective.[87] The purchaser of pre-experience products need not squander funds on goods or services of low value, or suffer unsatisfactory results to discover their deficiencies.[88] Prior to purchase, consumers of pre-experience goods determine the products upon which money will be spent and the risks involved. Product users want all their decisions to be as accurate and certain

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82. The economic analysis in this section is based on the diagnosis of the market failure known as "information asymmetry" presented in DAVID L. WEIMER & AIDAN R. VINING, POLICY ANALYSIS CONCEPTS AND PRACTICE 69 (1989).

83. *Id.*

84. *Id.* at 71.

85. *Id.* at 69.

86. *Id.* at 74.

87. *Id.* at 75.

88. *Id.* at 71.

as decisions made for pre-experience goods.[89] Through education, training, and professional practice, an authority on post-experience goods can gain the knowledge necessary to make prospective decisions approaching the level of certainty and accuracy which otherwise applies only to decisions concerning pre-experience goods.[90] In effect, the influence of the knowledgeable person can decrease the uncertainty involved in decisions regarding post-experience goods.

Power is the ability to use knowledge for the benefit or detriment of others. The failure to use one's ability to benefit others may be considered an abuse of power. Pharmacists possess the ability to use knowledge to improve the certainty of patients' decisions about medications. Pharmacists' increased knowledge provides justification for a rule of law requiring pharmacists to help patients reduce risks through improved decision making. Whether it is appropriate to require pharmacists to act to prevent harm to patients turns on whether a pharmacist has the requisite knowledge and can use that knowledge to prevent the harm.

Medication-related problems would not occur if: (1) the pharmacist, physician, and patient were familiar with the medication's characteristics; (2) the patient had the ability to self-administer the medication; and (3) the pharmacist could accurately anticipate the patient's reaction to the medication.[91] Of course, perfect knowledge is impossible. Patients have expectations, however, which may or may not reflect the reality of actual knowledge.[92] These expectations are relevant to assigning accountability for medication-related problems.

Statements affirmatively creating false expectations of medication safety or efficacy impair the autonomy of patients.[93] This is a case of misrepresentation, and when it occurs, the pharmacist should compensate the patient for harm caused by the incorrect assertion. This form of pharmacist liability should apply whether the untruthful information is provided intentionally or negligently.[94]

Whether pharmacists are morally obligated to avoid liability for non-feasance by acting affirmatively to protect patients from medication-related problems—by monitoring drug therapy, warning of medication-related dangers, and instructing on medication use—is a question that depends on the availability of information to both pharmacists and patients.[95] If the information is obvious to the patient—for example, that sleeping pills cause drowsiness or that ear drops should not be used in the eye—then there is no reason for a pharmacist to intervene for the patient's benefit. The

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89. *See id.* at 72.
90. *Id.*
91. *See* Frank J. Vandall, *Applying Strict Liability to Pharmacists*, 18 U. TOL. L. REV. 1, 21 (1986).
92. *Id.*
93. *Id.* at 21-22.
94. *Id.* at 22.
95. *Id.* at 21.

pharmacist's duty to protect arises only if the hazard is not obvious to the patient.[96]

Arguably, pharmacists should act affirmatively to protect patients from medication-related problems, which are inherent in the product and could occur in any patient using the product.[97] Pharmacists possess a great deal of information about drugs. Sometimes knowing nothing about a patient's condition, but a great deal about a drug, is sufficient to enable a pharmacist to anticipate preventable harm. For example, the maximum quantity of a drug that can be used over a period of time, without experiencing toxicity, is well known for many drugs. A pharmacist who provides the drug and recognizes the medication is subject to overuse should be required to instruct the patient about the maximum dose and the potential consequences of overdosing.[98]

In addition, patients believe that pharmacists have a responsibility to discover and resolve foreseeable dangers of drug use. For example, pharmacists presented with a prescription order may not know, but certainly have the ability to learn, that a patient experienced an allergic reaction to a similar medication.[99] While the method by which medication is prescribed poses no actual threat to most patients—as opposed to the drug prescribed which can be overused and toxic to anyone—intervention by the pharmacist is an appropriate and important risk reduction measure when potentially allergic patients are involved.[100]

When a potential problem with medication use is neither known nor reasonably discoverable, the problem of accountability for the resulting harm to patients becomes more difficult. Arguably, a pharmacist who makes an innocent, but untrue statement about a medication's safety should bear no responsibility for the harmful consequences.[101] Strong reasons exist, however, for imposing strict liability for accidental harm to patients resulting from innocent, and even careful, but nevertheless false, assertions by a pharmacist regarding medication safety and efficacy.[102] Safety and efficacy information is important to medication users because it allows them to make better risk-related decisions, which enhance a patient's autonomy.[103] If the objective of law is to promote patient autonomy, the law should rectify the pharmacist's untruthfulness and resulting inequality in the access to information regardless

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96. *See id.*

97. *Id.* at 21-22.

98. *See id.* at 18.

99. John C. West & David E. Smith, *A Prescription For Liability: The Pharmacy Mandate of the Omnibus Budget Reconciliation Act of 1990 and Its Impact upon Pharmacists' Common Law Duties*, 2 J. PHARMACY & L. 127, 137 (1994).

100. *See id.*

101. *See* David B. Brushwood & Richard B. Abood, *Strict Liability in Tort: Appropriateness of the Theory for Retail Pharmacists*, 42 FOOD DRUG COSM. L.J. 269, 287 (1987) (concluding that applying strict liability to pharmacists is unnecessary because plaintiff's interests are fully protected under the existing scheme of liability).

102. *See* Vandall, *supra* note 91, at 20-33.

103. *Id.* at 21-22.

of whether the pharmacist should have known the information to be untruthful.[104]

The strict liability failure-to-warn cases present, however, a different situation than that of the affirmative, but erroneous disclosure.[105] The silent pharmacist causes no harm when facts are neither known nor discussed.[106] Decisions made by the patient, as well as the autonomy of the patient remain unchanged. The pharmacists provide medications believed to be safe and effective. It is unreasonable to hold a pharmacist liable for failing to cure an erroneous impression the pharmacist neither created nor knew existed. Patients who use medications are aware the world's chemistry contains numerous hidden dangers. A patient injured by an unknowable medication-related problem should have no claim against the pharmacist filling the prescription.[107] This rule recognizes the limits of pharmacists' abilities.

IV. THE "CAN" AND "OUGHT" OF PHARMACY PRACTICE

The "can-ought" question presented in the title of this Article is presented inversely from the way that question is ordinarily stated. Usually, the question asked is, "Does ought imply can?"[108] The question arises in the course of deciding whether it is fair to require action to be taken without first determining whether such action is possible.[109] To say that *ought* implies *can* is to say that a duty exists only if the duty is capable of being performed.[110] This duty underlies the principle of corrective justice—a person who injures another person has an obligation to the victim to compensate for the harm caused; likewise, the victim has a corresponding right against the injurer to receive just compensation.[111] If the injurer could not have prevented the victim's injuries, the victim has no right to compensation.[112]

Asking whether *can* implies *ought* shifts the focus to issues of fairness based on policy considerations.[113] This is the ultimate question upon which virtually all legal principles are based. Any controversy involving contracts, property, torts, criminal law, and other legal fields deals essentially with whether certain conduct should be compelled, permitted, or forbidden under

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104. *Id.* at 48-49.

105. *See* Brushwood & Abood, *supra* note 101, at 276. *But see* Vandall, *supra* note 91, at 20-33.

106. *See* Brushwood & Abood, *supra* note 101, at 276.

107. *Id.* at 286.

108. *See, e.g.*, Stephen R. Perry, *The Moral Foundations of Tort Law*, 77 IOWA L. REV. 449, 511 (1992).

109. *Id.*

110. *Id.*

111. *Id.* at 485-91.

112. *Id.*

113. Framing the question in this way avoids the "technological imperative," which advocates using whatever means necessary to do anything that possibly can be done, regardless of the social costs. Instead, the question presented here is whether it is fair to patients, physicians, pharmacists, and others to require pharmacists to prevent problems with drug therapy if it is possible for pharmacists to do so.

the law. Within the context of a pharmacist's legal duty, the question is relevant because courts in the past specifically rejected the argument that pharmacists ought to be responsible for medication-related harm to patients, regardless of whether pharmacists possess the ability to prevent medication-related problems.[114] Courts have ostensibly based their rulings primarily on principles of fairness and other policy considerations. This judicial reasoning warrants re-evaluation because denying a patient's right to protection from preventable medication-related problems can only be justified by strong countervailing interests. A patient's right to be protected from harm should prevail against all but the most compelling rationale.

A. *What Can Pharmacists Do for Patients?*

The pharmacy profession has a long history of service to those who use medications to treat ailments.[115] As early as the second millennium B.C., evidence demonstrates that a group of persons whose job it was to prepare medications existed separately from physicians and other healers.[116] Over the course of many centuries, the pharmacy profession experienced a cycle of advancement and regression. Early 20th century American pharmacy was characterized by professionalization of the scientific art of medication preparation and dispensation, with emphasis on university education, collaboration with physicians, and the availability of scientifically valid expertise.[117]

Contemporary American pharmacy practice is a mature version of this earlier professionalism.[118] Pharmacists have evolved from an early period in which they were primarily compounders, through a phase in which they became primarily product distributors, to their present position in which they assist physicians by evaluating and improving medication use.[119] In the early 1990s, the pharmacy community embraced the concept of "pharmaceutical care" in an effort to meet unmet health care needs. Pharmacists who aspire to practice pharmaceutical care accept responsibility for bad results from drug

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114. *See supra* note 25-26 and accompanying text; *see also* Frye v. Medicare-Glaser Corp., 605 N.E.2d 557, 561 (Ill. 1992) (noting that while the pharmacist's duty to inform was not an issue before the court, two pharmacist organizations filed briefs arguing that the court should place an affirmative duty on pharmacists). "Medicare-Glaser by and through its agent Nightengale undertook to warn Frye that Fiorinal may cause drowsiness. That was the extent of their undertaking, which they were obligated to perform with reasonable care." *Id.* at 561. Nevertheless, the court disapproved of pharmacist warnings as a matter of policy, stating that in their opinion, "consumers should principally look to their prescribing physician to convey the appropriate warnings regarding drugs, and it is the prescribing physician's duty to convey these warnings to patients." *Id.*

115. For a concise review of the history of the pharmacy profession, see GREGORY J. HIGBY, *Evolution of Pharmacy*, *in* REMINGTON'S PHARMACEUTICAL SCIENCES 8, 8-16 (Alfonso R. Gennaro ed., 18th ed. 1990).

116. *Id.* at 9.

117. *Id.* at 14.

118. *Id.* at 15.

119. *Id.* at 16.

therapy by making a commitment to achieve definite outcomes—increasing the quality of patients' lives through improved pharmacotherapy.

Despite widespread recognition that pharmaceutical care is an appropriate and necessary role for pharmacists, some policy makers may remain unconvinced that pharmacists can actually improve pharmacotherapy. For those reluctant to recognize that pharmacists possess abilities beyond the skills necessary for accurate order processing, the question of what pharmacists can do must be analyzed within the historical context of increasing patient-related responsibilities for pharmacists. To acknowledge that pharmacists in the past have been expected to provide products, but not to care for patients, ignores the probability that outcomes from drug therapy would be vastly improved if pharmacists were given greater responsibilities.

One of the insidious costs of maintaining a legally imposed status quo is that innovative services and products are rarely implemented. Society may be unaware that it is paying an unnecessary price for the status quo. In an era of health care reform emphasizing increased quality and reduced costs, expanded legal responsibilities for pharmacists is a logical departure from the status quo. Even for skeptics who dispute its utility, the possibility of relieving human suffering by improving the quality of drug therapy justifies the increased trust and responsibility placed in pharmacists to produce positive results.

Pharmacists have shown they are competent to advise patients on the appropriate use of medications. This "drug use" advisory function includes providing techniques pertaining to drug administration, self-monitoring for safety and efficacy, and avoiding risk-increasing activities—such as using potentially interacting drugs or driving an automobile while sedated.[120] Pharmacists have demonstrated that they can advise patients concerning the choice of drug therapy. In controlled settings, pharmacists have proved as effective as physicians in this "drug choice" function.[121] Additionally, pharmacists can monitor ongoing drug therapy.[122] They can evaluate a patient's progress. Furthermore, they can adjust drug therapy or recommend to patients and physicians steps necessary to enhance the likelihood of benefit and reduce the likelihood of detriment to the patient.[123]

This is not to say that all pharmacists are currently able to effectively initiate drug therapy and monitor medication use. Significant evidence exists, however, pointing to the competence of pharmacists in their expanded roles. The evidence suggests pharmacists would do well in a drug-use system which grants them the authority to perform expanded functions, and attaches liability for failing to perform them correctly. Empirical evidence reflects the ability of groups of specially trained pharmacists to perform with increased responsibility; this evidence can be extrapolated to an entire population of

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120. OFFICE OF INSPECTOR GENERAL, THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST app. IV, at 5-6 (1990).

121. *See id.*

122. *Id.*

123. *See* Michael J. Rupp, *Value of Community Pharmacists' Interventions to Correct Prescribing Errors*, 26 ANNALS PHARMACOTHERAPY 1580, 1583 (1992).

similarly trained pharmacists.[124] The pharmacy profession indicated its willingness to accept expanded responsibilities through the adoption of pharmaceutical care as its mission. Further, individual pharmacists have demonstrated that they are capable of meeting expanded responsibilities. It would be a significant step, but not an unreasonable or unprecedented one, for the judiciary to impose expanded responsibilities upon all pharmacists.

B. *What Should Pharmacists Do for Patients?*

Pharmacists have performed well in their traditional role as distributors of products ordered for patients by physicians. Accuracy in drug distribution is an important commitment, which has enhanced the quality of drug therapy. This commitment will certainly continue. To suggest that pharmacists ought to do more for patients does not belittle the distributive role nor advocate its abandonment. To the contrary, any role for pharmacists seeking to protect the public interest to a greater degree would have to include responsibility for the accurate distribution of drugs as well as responsibility for the results of drug therapy.

Pharmaceutical care—the recognized mission for the pharmacy profession—is formally defined as "[t]he responsible provision of drug therapy, for the purpose of achieving definite outcomes, that are intended to improve a patient's quality of life."[125] With pharmaceutical care, pharmacists are responsible for providing a framework by which competent care is possible and using accepted practices which increase the possibility of a good outcome.[126] Pharmacists are also responsible for the outcomes themselves. When a problem develops with drug therapy, the pharmacist ought to be able to resolve the problem or explain why resolution was not possible.

The notion that a pharmacist is responsible for patient care carries with it the requirement of a mechanism, which not only assures that pharmacists meet certain responsibilities, but also provide appropriate corrective consequences when pharmacists fail to meet their responsibilities.[127] Accountability is related to a pharmacist's responsibility. However, accountability primarily concerns activities undertaken to determine why things have not gone well. Similarly, liability implies the existence of an authority such as a court or professional review board. Liability will exist when answers to accountability-related questions demonstrate a failure to meet a duty of care resulting in a bad outcome.

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124. *See, e.g.*, David R. Gray et al., *Cost Justification of a Clinical Pharmacist-Managed Anticoagulation Clinic*, 19 DRUG INTELLIGENCE & CLINICAL PHARMACY 575, 578-80 (1985); Lisa L. Ioannides-Demos et al., *Impact of a Pharmacokinetic Consultation Service on Clinical Outcomes in an Ambulatory-Care Epilepsy Clinic*, 45 AM. J. HOSP. PHARMACY 1549, 1551 (1988); Ronald A. Jones et al., *Cost-Effective Implementation of Clinical Pharmacy Services in an Ambulatory Care Clinic*, 26 HOSP. PHARMACY 778, 780-82 (1991).

125. Charles P. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 AM. J. HOSP. PHARMACY 533, 539 (1990).

126. *Id.*

127. *See* Brushwood & Hepler, *supra* note 66, at 195-96.

While responsibility relates to individualized patient care, accountability is analogous to Continuous Quality Improvement (CQI). The goal of CQI is to improve health-related outcomes and quality of life for all patients. Accountability requires that pharmacists account for their actions at a particular time if there is reason to believe certain responsibilities were not met. Through an examination of patient records, incident reports, performance data bases, and other information, it is possible to recognize sentinel indicators of suboptimal performance or outcomes. Accountability requires a pharmacist who was responsible for a patient for whom a sentinel indicator is identified to account for his or her actions regarding that patient. For example, if two drugs interact, a pharmacist whose records indicate the drugs were dispensed to the same patient for use at the same time, must explain why the interaction was not avoided.

Pharmacists cannot guarantee good outcomes. Furthermore, the presence of an indicator, standing alone, does not establish anything conclusive regarding a pharmacist's responsibility. An indicator merely presents a rebuttable presumption that the pharmacist failed to meet a responsibility. To be accountable simply means a person must rebut the presumption of an unfulfilled responsibility. Accountability functions retrospectively, requiring a showing that the pharmacist adhered to the standard of care at the time care was provided and prospective responsibility was met. If the care provided is unsatisfactory, then a pharmacist cannot be considered responsible. A pharmacist who cannot explain the therapeutic rationale behind dispensing two interacting drugs to the same patient simultaneously has failed to meet a professional responsibility.

Failure to provide responsible care—as demonstrated by an inability to account for a suboptimal outcome—leads to liability. The principal difference between accountability and liability is legally enforceable sanctions accompany a finding of liability. The purpose of liability is neither to improve the quality of patient care, nor to promote a good outcome for a particular patient. Rather, the purpose is to compensate one party for harm caused by another party by requiring the party who caused harm to make a payment to the party who suffered harm. While imposing liability has a beneficial effect of deterring further improper conduct, thus improving the overall quality of health care, the primary purpose of liability is simply compensation.

In pharmaceutical care, a pharmacist is not responsible for drug products or drug advice alone, but shares the responsibility for the outcomes of drug therapy with the patient and physician. The pharmacist-patient relationship involves three types of responsibilities—technical, judgmental, and normative—necessary for pharmaceutical care.[128] In broad terms, an error is a failure to achieve what should be done, either through ignorance, deficiency, or accident. In other words, an error is the failure to meet a responsibility.

Technical responsibilities involve basic knowledge and skill—knowing the usual dose of a medicine and recognizing an unusual dosage. Most phar-

128. *Id.*

macists are familiar with the major examples of technical responsibility—correct drug, dose, time, and route in the proper patient. An example of a technical responsibility owed to a patient or colleague is providing accurate information about drug therapy.

Judgmental responsibilities involve decisions and other applications of knowledge and skill, including choosing an appropriate dosage for a specific patient. Judgmental responsibility also involves decisions concerning which information to provide to a patient, what to emphasize, how to present and reinforce that information, and how the pharmacist evaluates the patient's comprehension of the information.

Normative responsibilities involve role obligations within relationships. For example, suppose Physician Brown reasonably would expect Pharmacist Jones to warn him if an ordered dosage appeared problematic or a patient's condition worsened. Jones' failure to warn Brown constitutes a normative error—a breach of responsibility created within a relationship.

Normative responsibility to a patient consists of acting in good faith within the given relationship. For example, it would be a normative error if a patient relied upon his pharmacist to review his drug history and to warn him of possible drug interactions or side effects and the pharmacist failed to do so. If the pharmacist warned him of a potential side effect with negligible probability or practical significance to the patient, it would be a judgmental error. If a pharmacist did not know that two medicines could interact significantly, it would be a technical error. As pharmacy practice matures toward pharmaceutical care, one should expect the nature of a pharmacist's relationships with patients and with colleagues to change. Consequently, one should also expect normative responsibilities to change.

Simply stated, pharmacists ought to accept responsibility for the outcomes of drug therapy. They should account for their actions and be held legally liable when reasonably preventable and causally-related harm occurs. Pharmacists should be required to possess general knowledge of drugs and drug therapy. They should also be responsible for acquiring specific knowledge about each individual patient's unique drug therapy history by conducting patient interviews, consulting with the physician, or maintaining an extensive record of patient-related information. To the extent additional information is necessary to fully assess the patient's condition, pharmacists should acquire the information through laboratory tests and other means. Failure in this knowledge-responsibility element should be a technical error, leading to liability for the pharmacist.

Pharmacists ought also to apply their knowledge of drugs, drug therapy, and individual patients to the facts of each therapeutic event. In the process, pharmacists should consider whether harm to the patient, either from direct toxicity or therapeutic failure, is reasonably foreseeable. This analysis requires a consideration of the probabilities, which can be deduced through scientific studies and contextualized by clinical impressions formed through extensive education, training, and practice experience. Failure to detect foreseeable harm to a patient is to commit a judgmental error, resulting in liability for the pharmacist.

Finally, pharmacists ought to use their powers of persuasion with physicians and patients in order to provide accurate information about conditions of treatment and prospects for success or failure. Pharmacists should recommend adjustments in therapy or make adjustments on their own, when legally permissible. On those rare occasions when a physician's care is unreasonable and the patient is placed at risk of death or serious bodily harm, the pharmacist ought to refuse to participate in the patient's drug therapy. To do otherwise would constitute normative error, thereby creating liability for the pharmacist.

V. CONCLUSION

Pharmacists are not mere bystanders in the health care industry. They are active participants, socially commissioned through licensure, to act as gatekeepers in the drug therapy process. When public trust is betrayed by a pharmacist who fails to meet a duty of care, a patient harmed by the pharmacist's omission should have an available remedy at law. The fact that pharmacists actively place medications in commerce and derive profit from them, strengthens the argument that pharmacists should have a legally recognized duty of care to patients.

During the past several decades, the advanced education of pharmacists, their practice achievements, and their potential to relieve human suffering have gone largely unnoticed by a tort system that has often refused to impose expanded legal duties on pharmacists. Perhaps this is because the judiciary, still smarting from criticism that a malpractice crisis was created by an undisciplined tort system, is reluctant to expand liability in any way.

Yet as drug therapy becomes more complex and pharmacy practice expands to fill a need for oversight of personal drug therapy, the justifications for refusing to expand pharmacists' legal responsibilities become less persuasive. Pharmacists have the ability to identity problems with drug therapy, foresee harm to patients, and prevent that harm. Pharmacists can also increase the likelihood of a good result from drug therapy. Pharmacists ought to use their ability to promote good outcomes from drug therapy; this responsibility should be recognized as a legal duty.