


July 2015

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Michael J. Holleran R.PH.

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Recommended Citation

Holleran, Michael J. R.PH. (1993) "The Pharmaceutical Access and Prudent Purchasing Act of 1990: Federal Law Shifts the Duty to Warn from the Physician to the Pharmacist," *Akron Law Review*: Vol. 26 : Iss. 1 , Article 4.
Available at: <http://ideaexchange.uakron.edu/akronlawreview/vol26/iss1/4>

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**THE PHARMACEUTICAL ACCESS AND PRUDENT
PURCHASING ACT OF 1990:
FEDERAL LAW SHIFTS THE DUTY TO WARN
FROM THE PHYSICIAN TO THE PHARMACIST**

by

MICHAEL J. HOLLERAN, R.PH.*

INTRODUCTION

Mr. Jones injured his hand while working at a foundry in the city. He was issued a prescription for a narcotic analgesic by his personal physician, whose office is near the foundry. Two months prior to this injury, this same physician prescribed a mild tranquilizer for Mr. Jones which he continues to take several times a day for the treatment of anxiety. Mr. Jones originally obtained and continues to legally receive his tranquilizers from a pharmacy near his residence in the suburbs. Since Mr. Jones was experiencing significant pain after receiving treatment for his injury, he elected to have his analgesic prescription filled at the pharmacy located in the same building as his physician's office. The pharmacist inspected the prescription to determine that it was in fact a valid prescription. The pharmacist found that the prescription was for an average quantity of a common but potent analgesic, and that the prescription met all legal requirements for dispensing the medication. The prescription was properly filled with the medication requested. Neither the physician nor the pharmacist told Mr. Jones of the potential for drowsiness associated with the analgesic, nor was he told that concomitant use of tranquilizers would potentiate this drowsiness. Upon leaving the pharmacy, Mr. Jones stopped at the drinking fountain near the building's exit and took one of the analgesics as well as a tranquilizer. He then proceeded to drive himself home to recuperate. While on the highway, Mr. Jones was overcome by extreme drowsiness which resulted from the combined effects of the narcotic analgesic and tranquilizer, and soon crashed into a highway barrier. Is the physician or pharmacist likely to be held liable for Mr. Jones' accident-related injuries for failing to warn Mr. Jones of the side effects of the prescribed narcotic analgesic and the dangers of combining narcotic analgesics and tranquilizers?

A recently enacted amendment¹ to Title XIX of the Social Security Act is likely to increase the volume of negligence litigation involving pharmacists and

* B.S. Pharmacy, University of Cincinnati; J.D., Cleveland-Marshall College of Law; Fellow, American Society for Pharmacy Law; Associate, Thompson, Hine and Flory, Cleveland, Ohio.

¹ The Pharmaceutical Access and Prudent Purchasing Act of 1990, 42 U.S.C. § 1396r-8 (1991). [hereinafter Prudent Purchasing Act].

significantly alter the traditional answer to the question posed. As this article will discuss, most jurisdictions would be forced to at least reconsider if not entirely reverse the expected result if this hypothetical case was before a court today. One of the enumerated purposes of the Pharmaceutical Access and Prudent Purchasing Act of 1990 (hereinafter "the Act") is "to enhance the role of pharmacists in providing quality medical care, through a comprehensive drug utilization review program."² However, though the stated purpose is admirable, the Act will likely statutorily shift the duty to inform patients of the potential consequences of pharmaceutically-based medical treatment away from the physician and place this burden upon the pharmacist.³ As a result of the Act, a pharmacist's statutory standard of care will be significantly altered. This leads one to ask whether a pharmacist will be or should be protected by the shorter statute of limitations for medical malpractice⁴ as a pre-emptive move to prevent the cataclysmic increase in health care costs that will likely follow.

This article will first discuss the legislation recently enacted as part of the budget reduction package passed by Congress in late 1990 and how that legislation will affect pharmacists' liability. Second, the article will address the applicable statutes of limitation regarding pharmacists in particular and within the general area of malpractice. Third, the applicable standard of care will be explored as it pertains to pharmacists as well as physicians. Coupled with the standard of care discussion is an overview of the various theories of liability which physicians and pharmacists currently face and how these may change under the Act. Finally, this article will take a closer look at how the Act will specifically affect claims against pharmacists.

PHARMACEUTICAL ACCESS AND PRUDENT PURCHASING ACT OF 1990

The Pharmaceutical Access and Prudent Purchasing Act of 1990⁵ is an Act that is primarily designed to control the cost of providing Medicaid reimbursement for prescription medication.⁶ However, included within this Act is a provision that places a statutory standard of care upon the pharmacist.⁷ According to the text of the Act, these additional responsibilities are designed "to enhance the role of pharmacists in providing quality medical care, through a comprehensive drug

² 136 CONG. REC. S5982-04 (daily ed. May 10, 1990) (statement of Sen. Pryor).

³ Even if the Bill does not entirely shift the duty to advise patients regarding their medicine, it is likely to be shared to a much wider extent than under existing law.

⁴ See, e.g., OHIO REV. CODE ANN. § 2305.11 (Baldwin 1992).

⁵ Prudent Purchasing Act, 42 U.S.C. § 1396r-8 (1991).

⁶ One of the stated purposes is "to provide a mechanism, which states may adopt in their efforts to control the prices of drugs, to stimulate price competition among manufacturers of drugs which are therapeutic alternatives . . ." 136 CONG. REC. 5982-04, *supra* note 2, at (b)(1). A similar measure with virtually identical provisions relating to pharmacists is also pending before the Senate. See The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act, 136 CONG. REC. S12954-01 (daily ed. Sept. 12, 1990).

⁷ Prudent Purchasing Act, U.S.C. § 1396r-8 (1991).

utilization review program."⁸ An additional purpose of the Act is to "control the price of drugs, [and] to preserve physicians' prerogatives to prescribe as they deem medically necessary for their patients."⁹ The Act provides in pertinent part that:

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

...

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

...

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding the individuals receiving benefits under this title:

...

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.¹⁰

Under the terms of the Act, these duties would only be required when dealing with a patient whose prescription medication is provided through a state medicaid program.¹¹ However, once a higher standard of care is established for pharmacists dealing with medicaid patients, others will vigorously argue that it would be inappropriate, unconscionable, and possibly even discriminatory to hold pharmacists to a lower standard of care when dealing with non-medicaid patients.¹² Therefore, this Act will likely impose its statutory duties upon pharmacists when dealing with *all* patients, not just those within the medicaid program.

⁸ *Id.*

⁹ *Id.*

¹⁰ 42 U.S.C. § 1396r-8(g)(2)(A)(ii) (1991).

¹¹ Prudent Purchasing Act, 42 U.S.C. § 1396r-8 (1991).

¹² Although this would not be an immediate result, the preferential treatment afforded this class is not likely to pass constitutional muster particularly since access to health care is involved.

STATUTE OF LIMITATIONS

As it Relates to Pharmacists

Under current law, a pharmacy customer generally has no more than two years to file an action against a pharmacist for injuries resulting from that pharmacist's negligence.¹³ The applicable statute of limitations is generally the same as that applied in ordinary negligence cases¹⁴ and not the shortened medical malpractice one year statute of limitations.¹⁵ For example, in Ohio, a pharmacist and a pharmacist's function are not expressly included within the definition of a medical claim or medical malpractice.¹⁶ However, there is some question as to whether the one year limitation applies.¹⁷ In *Reese v. K-Mart Corp.*,¹⁸ the Franklin County Court of Appeals held that a negligence action against a pharmacist for incorrectly filling a prescription was not barred by the one year statute of limitations because it was not a "medical claim" as defined by the statute.¹⁹ However, in *Boudot v. Schwallie*,²⁰ the Hamilton County Court of Appeals held that the one year statute of limitations was applicable thus barring a claim of pharmacist's negligence.²¹ The court stated that the customer:

comes to the pharmacist, clothed in the doctor-patient relationship, with a prescription; she asks the defendant, as a pharmacist or specialist in his field, to fill the prescription; the very basis of her cause of action is failure on the part of the pharmacist to exercise that degree of reasonable care employed by those called upon by doctors to fill prescriptions for the physical impediments of their patients. . . . The practice of the profession of pharmacy is a part and parcel of the system of practice of modern medicine.²²

¹³ See, e.g., OHIO REV. CODE ANN. § 2305.10 (Baldwin 1992).

¹⁴ *Id.*

¹⁵ See, e.g., OHIO REV. CODE ANN. § 2305.11 (Baldwin 1992) which provides in pertinent part:

(B)(1) Subject to division (B)(2) of this section, an action upon a medical, dental, optometric, or chiropractic claim shall be commenced within one year after the action accrued. . . .

Id.

¹⁶ *Id.*

¹⁷ The confusion does not arise directly from the language of the statute, but rather in the interpretation as to who is the "agent" of the physician.

¹⁸ 443 N.E.2d 1391 (Ohio Ct. App. 1981).

¹⁹ " 'Medical claim' means any claim that is asserted in any civil action against a physician, podiatrist, or hospital, against any employee or agent of a physician, podiatrist, or hospital, or against a registered nurse or physical therapist, and that arises out of the medical diagnosis, care, or treatment of any person." OHIO REV. CODE ANN. § 2305.11(D)(3) (Baldwin 1992).

²⁰ 178 N.E.2d 599 (Ohio Ct. App. 1961).

²¹ *Id.*

²² *Id.* at 599-600. "[T]he duty to warn of hazards associated with prescription drugs is part and parcel of the physician-patient relationship. . . ." *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 886 (Ind. Ct. App. 1985).

Although *Boudot* makes a strong argument for the inclusion of the profession of pharmacy among those professions protected by a one year statute of limitations, *Reese* and the majority of decisions hold that a pharmacist's actions fall within the two year statute of limitations for negligence. It would appear that the latter view is more likely to be followed in Ohio.

Where pharmacists have been granted privileges or duties traditionally reserved for physicians, the legislatures have included pharmacists within the state's malpractice statutes.²³ One such state is Florida, which has granted pharmacists limited prescribing privileges.²⁴ The granting of these prescribing privileges may have prompted the Florida legislature to re-define their "medical malpractice" statute to include "any provider of health care."²⁵ Judicial recognition of pharmacists as "providers of health care" under the statute was seen in *Sheils v. Jack Eckerd Corp.*,²⁶ where the court held that an action against a pharmacist who incorrectly filled a prescription written by a physician was barred by the two year medical malpractice statute of limitations.

Due to the enactment of the amendment to Title XIX of the Social Security Act,²⁷ all pharmacists are likely to stand in a similar position as those pharmacists in Florida. Although the power to prescribe medications is not granted under the Act, another of the traditional duties of physicians will be shifted to pharmacists; namely, the duty to advise patients and to warn of side effects.²⁸ Pharmacists would then be required to provide "professional services" to patients.

Prior to the enactment of the Act, the physician-patient relationship appeared to be the factor that traditionally excluded pharmacists from both the liability associated with failing to inform the patient as well as the need to be included within the definition of medical malpractice. For example, in *Ingram v. Hook's*

²³ This has been seen in California, Florida and Michigan. See CAL. CODE OF CIV. P. § 340.5 (West 1982); FLA. STAT. ANN. § 95.11 (West 1982 and Supp. 1992); MICH. COMP. LAWS ANN. 600.2912 (West 1986).

²⁴ Pharmacists may prescribe certain medications listed in a formulary developed by an appointed committee. FLA. STAT. ANN. § 465.186 (West 1982 and Supp. 1992).

The Committee shall establish a formulary of medicinal drugs which may be made available to the public upon the order of a pharmacist which is issued pursuant to a dispensing procedure established by the committee for each drug contained in such formulary. Dispensing procedures may include matters related to reception of patient, description of his condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. *Id.* at § 465.186(1). . . . A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for each drug in conjunction with its inclusion in the formulary. *Id.* at § 465.186(2).

²⁵ "An 'action for medical malpractice' is defined as a claim in tort or in contract for damages because of the death, injury, or monetary loss to any person arising out of any medical, dental, or surgical diagnosis, treatment, or care by any provider of health care." FLA. STAT. ANN. § 95.11(4)(b) (West 1982 and Supp. 1992).

²⁶ 560 So. 2d 361, 362 (Fla. Dist. Ct. App. 1990).

²⁷ Grants to States for Medical Assistance Programs, 42 U.S.C. § 1396 (1980).

²⁸ 42 U.S.C. § 1396r-8(g)(2).

Drugs, Inc.,²⁹ an Indiana court stated that "the duty to warn of hazards associated with prescription drugs is part and parcel of the physician-patient relationship."³⁰ This same court went on to say that "[t]he injection of a third-party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of ongoing treatment."³¹ Therefore, it appears that not only is the court not "including" the pharmacist into the responsible decision making process regarding patients, but is actually "excluding" the pharmacist from this arena. This exclusion, whether by design or otherwise, has the apparent effect of insulating the pharmacist from some degree of liability.³²

In states where pharmacists are not excluded, they are considered to provide professional services. Michigan has held that "[t]he key to a malpractice claim is whether it is alleged that the negligence occurred within the course of a professional relationship."³³ However, similar to the Florida statute previously discussed, Michigan's malpractice statute of limitations applies to pharmacists as being included with those who hold themselves out "to be a member of a state licensed profession."³⁴ It would appear likely that since pharmacists would be required to provide professional services under the Act, many states may similarly follow the Michigan and Florida examples and include pharmacists within the malpractice statutes.³⁵

For Purposes of "Malpractice"

At common law, "malpractice was restricted to intentional or negligent acts by physicians and lawyers."³⁶ However, since the origin of the common law, legislatures have repeatedly broadened the class of persons and occupations included within the statutory definition of malpractice. The shortened statute of limitations for medical malpractice apparently grew out of the rapid increase in malpractice-related litigation and the accompanying increased cost of malpractice

²⁹ 476 N.E.2d 881 (Ind. Ct. App. 1985).

³⁰ *Id.* at 886.

³¹ *Id.* at 887.

³² A review of the cases indicates that the courts repeatedly excuse pharmacists from liability in duty to warn cases under the banner of physician-patient relationship and the implications associated with this relationship. See generally *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881 (Ind. Ct. App. 1985); *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986); *Ullman v. Grant*, 450 N.Y.S.2d 955 (N.Y. Sup. Ct. 1982); *Kinney v. Hutchison*, 449 So. 2d 696 (La. Ct. App. 1984).

³³ *Becker v. Meyer Rexall Drug Co.*, 367 N.W.2d 424 (Mich. Ct. App. 1985).

³⁴ "A civil action for malpractice may be maintained against any person professing or holding himself out to be a member of a state licensed profession. The rules of common law applicable to actions against members of a state licensed profession, for malpractice, are applicable against any person who holds himself out to be a member of a state licensed profession." MICH. COMP. LAWS ANN. 600.2912(1) (West 1986).

³⁵ It is not merely the provision of services in general that would trigger this need for statutory protection or inclusion within the malpractice statutes, but rather the specific services called for and lengths to which the pharmacist must go in attempting to successfully provide these services. See generally *Prudent Purchasing Act*, 42 U.S.C. § 1396r-8 (1991).

³⁶ *Reese v. K-Mart Corp.*, 443 N.E.2d 1391 (Ohio Ct. App. 1981).

insurance, both of which drive up the cost of health care. The malpractice statutes were broadened in an attempt to address the rapid increase in the cost of health care, which many thought had its genesis in this skyrocketing cost of malpractice insurance.³⁷ However, the courts do not appear to be as anxious to include additional occupations or professions under the umbrella of "malpractice." Many courts strictly construe the applicable statutes so as to exclude those professions not expressly mentioned within the plain language of the statute.³⁸ Therefore, a statutory change must take place before the judiciary is likely to view pharmacists as being included within malpractice statutes. The Pharmaceutical Access and Prudent Purchasing Act of 1990 could easily become the catalyst for such statutory changes.

PHARMACIST'S CURRENT STANDARD OF CARE

The practice of pharmacy has been commonly defined as the "art of preparing, compounding, and dispensing of medicines."³⁹ Former Chief Justice Warren Burger is credited with having once said that a pharmacist "no more renders a true professional service than does a clerk who sells law books."⁴⁰ Others have stated that "[t]he role of the pharmacist, to a great degree, has today been reduced from the careful compounding of prescribed elixirs to interpretation of the doctor's handwriting, counting the requisite number of pills, and typing the directions for use."⁴¹ In contrast however, it has been held that "[t]here can be no serious question that in performing the service of a pharmacist one engages in a profession."⁴² Regardless of whether these statements reflect the actual responsibilities of the modern practice of pharmacy, pharmacists are held to an

³⁷ In passing and amending Ohio's malpractice statute, the Ohio General Assembly stated as its goal, "to stabilize the marketplace for medical, dental, optometric, and chiropractic professional liability insurance in this state, with the concomitant effects of slowing the upward spiral of medical, dental, optometric, and chiropractic care costs in this state. . . ." OHIO REV. CODE ANN. § 2305.11 (Baldwin 1989) (legislative history).

³⁸ See *Reese v. K-Mart Corp.*, 443 N.E.2d 1391 (Ohio Ct. App. 1981).

While it is true that pharmacists are professionals in the health care field, they are not *enumerated* in R.C. 2305.11(A) and do not fall within the common-law definition of malpractice. Therefore, the one year statute of limitations set forth in said statute does not apply to the negligent acts of pharmacists.

Id. at 1392.

³⁹ DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1140 (24th ed. 1965). See also THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 983 (7th ed. 1978) (similarly defining "pharmacy"). The term "druggist" is frequently used interchangeably with "pharmacist" and has been defined as "[a] dealer in drugs; one whose business is to mix, compound, dispense, and sell drugs." B LACK'S LAW DICTIONARY 447 (5th ed. 1979).

⁴⁰ Brushwood, *The Informed Intermediary and the Pharmacist's Duty to Warn*, 4 J. LEGAL MED. 349, 365 (1983) (citing Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976)). However, what Chief Justice Burger actually said was "[a]ttorneys and physicians are engaged primarily in providing services in which professional judgement is a large component, a matter very different from the retail sale of labeled drugs already prepared by others." 425 U.S. at 774.

⁴¹ Haunholter, *Negligence and the Pharmacist*, 2 LEGAL MED. Q. 2 (1978).

⁴² *Lee v. Gaddy*, 183 So. 4, 5 (Fla. 1938). See also *Sashihara v. State Board of Pharmacy*, 46 P.2d 804, 805 (Cal. Ct. App. 1935) (specifically holding the practice of pharmacy is a profession).

elevated standard of care in most jurisdictions.⁴³ For example, in Ohio, a pharmacist has traditionally been held to an "ordinary care" standard. The Ohio Supreme Court in *Taughler v. Ling*⁴⁴ defined ordinary care as "that degree of care in the dispensing of the drugs that persons of ordinary prudence engaged in that business are accustomed to use under the same or similar circumstances."⁴⁵ However, the court further elaborated upon its definition of "ordinary care" as it pertains to pharmacists. The court stated that such care consists of "the highest practicable degree of prudence, thoughtfulness, and vigilance, and the most exact and reliable safeguards consistent with the reasonable conduct of the business, in order that human life may not constantly be exposed to the danger flowing from the substitution of deadly poisons for harmless medicines."⁴⁶ Where a pharmacist dispenses a medication other than that which was prescribed, there exists a breach of the duty which accompanies this standard of care.⁴⁷ If this breach should be found the proximate cause of a customer's injury, the pharmacist will be liable for the proven damages.⁴⁸ Such "duty, breach, causation, and damages" analysis is the simple negligence theory of torts.⁴⁹ However, what are the consequences of a pharmacist's failure to warn a customer of potential side effects of medications properly dispensed under a valid physician's prescription?

It appears to have been almost uniformly held that a pharmacist is not liable for damages arising from prescriptions which are proper on their face and which have been properly filled.⁵⁰ Specifically, it has been held that "[a] pharmacist is not negligent unless he knowingly dispenses a drug that is inferior or defective."⁵¹ This

⁴³ Brushwood, *The Informed Intermediary and the Pharmacist's Duty to Warn*, 4 J. LEGAL MED. 349 (1983).

⁴⁴ 187 N.E. 19 (Ohio 1933) (pharmacist liable for injuries arising from dispensing the wrong medication).

⁴⁵ *Id.*

⁴⁶ *Id.* See also *Kerr v. Clason*, 4 Ohio Dec. Reprint 666 (1862).

⁴⁷ *Taughler*, 187 N.E. at 21.

⁴⁸ See generally *Boudot v. Schwallie*, 178 N.E.2d 599 (Ohio Ct. App. 1961). See also *Reese v. K-Mart Corp.*, 443 N.E.2d 1391 (Ohio Ct. App. 1981). "[A] druggist has the duty to compound the drug prescribed, to use due and proper care in filling the prescription, to use proper methods in the compounding process, and to ensure that the drug is not adulterated with a foreign substance." *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986).

⁴⁹ See generally W. KEETON, PROSSER AND KEETON ON THE LAW OF TORTS (5th Ed. 1984).

⁵⁰ See *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987).

⁵¹ *Ullman v. Grant*, 450 N.Y.S.2d 955, 956 (N.Y. Sup. Ct. 1982) (where pharmacist held not liable for damages resulting from adverse effects of prescription medication dispensed in the form of a generic equivalent with physician's permission) The court specifically held that "[a] pharmacist is not negligent unless he knowingly dispenses a drug that is inferior or defective." *Id.* at 956. However, it is interesting to note that this court required that the pharmacist "knowingly" dispense the wrong drug as opposed to dispensing the drug while exhibiting a level of care that falls short of "that degree of care in the dispensing of the drugs that persons of ordinary prudence engaged in that business are accustomed to use under the same or similar circumstances" as required under *Taughler*, 187 N.E. at 19. Does the element of scienter required under *Ullman v. Grant* intend to lower the standard of care? See also *Bichler v. Willing*, 397 N.Y.S.2d 57 (N.Y. App. Div. 1977) and see *Parker v. State of New York*, 105 N.Y.S.2d 735 (N.Y. Ct. Cl. 1951). But see *Hand v. Krakowski*, 453 N.Y.S.2d 121 (N.Y. App. Div. 1982) (where the pharmacist could be held liable for the death of a customer whom the pharmacist knew was an alcoholic for having failed to warn the decedent of the dangers of drinking alcohol while taking the prescribed medication.)

lack of liability generally exists even where the pharmacist has failed to warn the customer of potential side effects of the medication prescribed.⁵²

It would appear that absent the Act, a pharmacist generally has no duty to warn customers of potentially adverse side effects,⁵³ no duty to refuse to fill an otherwise proper prescription for an addictive drug where the quantity requested is excessive,⁵⁴ no duty to identify addicted customers,⁵⁵ *and*, no duty to inform the prescribing physician of any of these facts.⁵⁶ This absence of specific duties has been upheld, even though many courts recognize that "a pharmacist may have greater knowledge of drug propensities than a physician."⁵⁷ This increased knowledge exists because:

[a]lthough today the pharmacist compounds fewer drugs, he dispenses more (than ever before), both in kind and quantity, and the demands that this tremendous number of products place upon him (whether in the retail or hospital environment) has multiplied the opportunity for error, and has necessitated the expansion of the pharmacist's educational training.⁵⁸

Both pharmacists and physicians are extensively schooled regarding the intricacies of prescription medication. However, despite this similarity in training, it has long been held that "the occupation of a pharmacist and that of a physician are essentially distinct."⁵⁹ This separation of the two professions is demonstrated through the fact that although pharmacists are frequently regarded as having considerably superior expertise regarding the effects and side effects of medications,⁶⁰ pharmacists are not generally considered competent to testify as expert witnesses in medical malpractice cases against physicians.⁶¹ In contrast, however, physicians are permitted to testify as experts in negligence actions against

⁵² See *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987). See also *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985).

⁵³ *Id.* See also *Ullman v. Grant*, 450 N.Y.S.2d 955 (N.Y. Sup. Ct. 1982).

⁵⁴ *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985).

⁵⁵ *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988).

⁵⁶ *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. Ct. App. 1985). However, in Ohio, a pharmacist is required to "participate with practitioners in reviews of drug utilization." OHIO REV. CODE ANN. § 4729.02 (B) (Baldwin 1990). Participation in reviews of drug utilization is defined as maintaining appropriate communication with practitioners to relay certain relevant information concerning a patient in an effort to avoid adverse effects of prescription medication. OHIO ADMIN. CODE § 4729-5-01(F) (1990).

⁵⁷ *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387 (Mich. Ct. App. 1987). See also *Pysz v. Henry's Drug Store*, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984).

⁵⁸ *Haunholter, Negligence and the Pharmacist*, 2 LEG. MED. Q. 2 (1978).

⁵⁹ *Greenfield v. Getman*, 35 N.E. 435, 436 (N.Y. 1893).

⁶⁰ *Haunholter, supra* note 45, at 7. See also *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) and see *Pysz v. Henry's Drug Store*, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984).

⁶¹ See *Bell v. Hart*, 516 So. 2d 562 (Ala. 1987) (Pharmacist held incompetent to testify regarding correct dosage of a prescription medication in a medical malpractice case against a physician).

pharmacists.⁶² This unilateral crossover of competency to testify as an expert would appear to support the theory that physicians are the parties vested with the ultimate authority to supervise the medical therapy of the patient and thereby carry the burden to inform the patient with regard to medications. The conferring of this authority upon the physician may be the basis for generally having eliminated the pharmacist's duty to warn patients regarding medications.

In some jurisdictions however, there have been limitations to this absence of specific duties. In *Hand v. Krakowski*,⁶³ a New York court held that a pharmacist had breached his duty of ordinary care when he dispensed a psychotropic drug⁶⁴ to a customer without any warning concerning the dangerous interaction between the drug and alcohol. The pharmacist's duty to warn arose from the fact that the pharmacist had specific knowledge that the customer was an alcoholic.⁶⁵ Here, the applied standard of ordinary care was similar to that expressed under Ohio law⁶⁶ and defined as "the highest practicable degree of prudence, thoughtfulness and vigilance commensurate with the dangers involved and the consequences which may attend inattention."⁶⁷

Liability for the failure to warn may also arise where the pharmacist has voluntarily created such a duty by advertising patient counseling as one of the services performed by the pharmacist. In *Larabee v. SuperX Drug*,⁶⁸ an Ohio court stated that where "a purveyor of prescription drugs advertises that it will give superior warnings to those to whom they dispense drugs that they have a duty thereafter to give warning in accordance with the reasonable expectations of the ordinary layman in the market place."⁶⁹ However, it would appear that this court would find pharmacist liability for failure to warn a patient of adverse side effects of prescribed medication only where the advertisements expressly create a heightened duty. The court stated that "nothing in the advertisements in this case justify[ed] reasonable purchasers to expect from the druggist a `second medical opinion.'"⁷⁰

⁶² See *Pressler v. Irvine Drugs, Inc.*, 215 Cal. Rptr. 807 (Cal. Ct. App. 1985) (Physician permitted to testify as an expert where a pharmacist dispensed incorrect type of insulin).

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

⁶⁴ "Psychotropic" is defined as "[e]xerting an effect upon the mind; capable of modifying mental activity." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1246 (24th ed. 1965).

⁶⁵ *Hand*, 453 N.Y.S.2d at 123.

⁶⁶ An Ohio pharmacist is held to "that degree of care in the dispensing of the drugs that persons of ordinary prudence engaged in that business are accustomed to use under the same or similar circumstances." *Taughner v. Ling*, 187 N.E. 19 (Ohio 1933).

⁶⁷ *Hand v. Krakowski*, 453 N.Y.S.2d 121, 122 (N.Y. App. Div. 1982).

⁶⁸ No. CA-876, 1987 Ohio App. LEXIS 33026, (Ashland County June 24, 1987).

⁶⁹ *Id.* However, the *Larabee* court found no liability on the part of the pharmacist or the pharmacy because the Plaintiff could not establish a reliance upon the advertisements.

⁷⁰ *Id.* (where the advertisement stated that the pharmacy "would alert their customers to possible dangers associated with the drugs they sell."). *Id.*

A pharmacist's negligence in warning a patient regarding side effects and drug interactions may also give rise to liability. Recently in *Frye v. Medicare-Glaser Corp.*,⁷¹ the Illinois Court of Appeals held a pharmacist liable for failing to inform the customer that combining the drug with alcohol was dangerous after having warned that the drug may cause drowsiness. The defendants contended that a pharmacist "cannot be held liable to [a customer] because the law imposes no duty upon a pharmacy or its agents to warn customers of the dangers of taking prescription drugs in combination with other drugs or to warn of the dangerous side effects of prescription drugs."⁷² The court, agreeing with the defendant in part, held that the pharmacist had "no initial duty to protect the plaintiff, but voluntarily assumed a duty by placing a warning on the drug."⁷³ The court further held that a pharmacist is "liable for injuries or death to the consumer if they undertook to warn the consumer of the dangerous side effects of a prescription drug and did so negligently."⁷⁴

Many jurisdictions appear to hold the prescribing physician responsible for counseling the patient regarding the medications prescribed.⁷⁵ In *Jones v. Irvin*,⁷⁶ the court held that:

[i]t is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug.⁷⁷

This proposition has been supported in numerous jurisdictions,⁷⁸ and is apparently based upon the concept that counselling the customer regarding his or her medication "would require a pharmacist to learn the customer's condition and

⁷¹ 579 N.E.2d 1255 (Ill. App. Ct. 1991).

⁷² *Id.* at 1256.

⁷³ *Id.* at 1259.

⁷⁴ *Id.*

⁷⁵ See generally *Pysz v. Henry's Drug Store*, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984); *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985). See also *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987); *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881 (Ind. Ct. App. 1985); *Cobb v. Syntex Laboratories, Inc.*, 444 So. 2d 203 (La. Ct. App. 1983). While holding that a pharmacy was not liable for injuries allegedly caused by the pharmacist's failure to warn of the effects of using alcohol while taking certain prescription medication, the Louisiana court noted that at that time (1984), only one other case could be found which dealt with a pharmacist's duty to warn. See *Kinney v. Hutchinson*, 449 So. 2d 696, 698 (La. Ct. App. 1984).

⁷⁶ 602 F. Supp. 399 (S.D. Ill. 1985).

⁷⁷ *Id.* at 402.

⁷⁸ See also *Pysz v. Henry's Drug Store*, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984), and see *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987); *Kinney v. Hutchinson*, 449 So. 2d 696 (La. Ct. App. 1984); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987).

monitor his drug usage . . . [thus requiring the pharmacist] . . . to interject himself into the doctor-patient relationship and practice medicine without a license."⁷⁹ Interestingly, this type of conduct on the part of the pharmacist is precisely what the Act requires.⁸⁰

PHYSICIAN'S STANDARD OF CARE AND THEORIES OF LIABILITY

Negligence

Since the Act apparently shifts the duty to inform patients regarding the effects of their medication from the physician and places it with the pharmacist, a review of the traditional standard of care required of physicians regarding prescription medication may be appropriate. For example, in Ohio, this standard of care was enunciated in *Bruni v. Tatsumi*.⁸¹ Here, the Ohio court held that a physician is liable for malpractice where:

a preponderance of evidence [establishes] that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under similar conditions and circumstances, and that the injury complained of was the direct and proximate result of such doing or failing to do some one or more of such particular things.⁸²

Therefore, it is reasonable to presume that a physician who fails to inform his or her patient of the potential adverse side effects of prescribed medication may be held liable for resulting injuries arising from such failure to do so if it can be established that other physicians of ordinary skill, care and diligence would not have failed to so inform the patient.⁸³

Lack of Informed Consent

Such failure to warn patients of the side effects of prescribed medication may also be viewed within the scope of malpractice for lack of informed consent. Depending on in which jurisdiction a claim is filed, this theory of liability requires

⁷⁹ *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551, 553 (Ill. App. Ct. 1985).

⁸⁰ Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g) (1992).

⁸¹ 346 N.E.2d 673 (Ohio 1976).

⁸² *Id.* at 675 (syllabus of the court).

⁸³ Some jurisdictions have recognized this duty. See *Wilschinsky v. Medina*, 775 P.2d 713 (N.M. 1989). However, no such cases directly on point with this issue were found in Ohio.

either that a physician disclose all information that would be material to a reasonable patient's decision to consent to a treatment,⁸⁴ or that the physician disclose that information which a reasonable physician of ordinary skill, care and diligence would disclose under the same circumstances.⁸⁵ Liability for lack of informed consent is established when:

- (a) The physician fails to disclose to the patient and discuss the material risks and dangers inherently and potentially involved with respect to the proposed therapy, if any;
- (b) the unrevealed risks and dangers which should have been disclosed by the physician actually materialize and are the proximate cause of the injury to the patient; and
- (c) a reasonable person in the position of the patient would have decided against the therapy had the material risks and dangers inherent and incidental to treatment been disclosed to him or her prior to the therapy.⁸⁶

In *Harbeson v. Parke-Davis, Inc.*,⁸⁷ the Ninth Circuit Court of Appeals held a physician liable for failure to inform a patient of the teratogenic⁸⁸ effects of Dilantin.⁸⁹ The court held that a physician *must* disclose material information regarding drug therapy for the patient to consider.⁹⁰ However, not all jurisdictions would agree with *Harbeson*. In *Boyer v. Smith*,⁹¹ a Pennsylvania court refused to extend the doctrine of informed consent to apply in situations where the only treatment was the administration of medication.⁹² The court stated that "in light of the day-to-day realities of providing professional medical care, traditional medical

⁸⁴ See *Nickell v. Gonzalez*, 477 N.E.2d 1145 (Ohio 1985) where, in reference to informed consent, the Ohio Supreme Court stated that "[o]ne of the great dilemmas in applying this test is the question of how far a doctor must go in establishing whether a potential danger, albeit improbably remote, is sufficiently material to require disclosure. To this end the reasonable patient standard is utilized." *Id.* at 1148.

⁸⁵ *W. KEETON*, *supra* note 49, at § 32. See also *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972). See also *Nickell v. Gonzalez*, 477 N.E.2d 1145 (Ohio 1985); *Bruni v. Tatsumi*, 346 N.E.2d 673 (Ohio 1976).

⁸⁶ *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148 (Ohio 1985).

⁸⁷ 746 F.2d 517 (9th Cir. 1984). Here, the patient who planned to become pregnant asked her gynecologist about the safety in taking her anti-seizure medication while pregnant. No information regarding the drug's potential for producing birth defects was disclosed, and the patient later gave birth to two children with birth defects. The unusual fact that the patient had specifically requested the information which was not disclosed may have been dispositive of this case and may explain why this case is one of very few cases which hold a physician liable under lack of informed consent regarding the use of prescribed medication. *Id.* at 522-24.

⁸⁸ "Teratogenic" means "[t]ending to produce anomalies of formation" *DORLAND'S ILLUSTRATED MEDICAL DICTIONARY* 1516 (24th ed. 1965). This term may be more fully defined through the description of the drug as a "teratogen" which is defined as "[a]n agent or factor that causes the production of physical defects in the developing embryo." *Id.*

⁸⁹ Dilantin is the trade name of the drug diphenylhydantoin which is "used as an anticonvulsant in grand mal epilepsy." *DORLAND'S ILLUSTRATED MEDICAL DICTIONARY* 424 (24th ed. 1965). See also *PHYSICIAN'S DESK REFERENCE* 1713, 1714 (46th ed. 1992).

⁹⁰ *Harbeson*, 746 F.2d at 522.

⁹¹ 497 A.2d 646 (Pa. Super. Ct. 1985).

⁹² *Id.* at 648.

malpractice actions, sounding in negligence, are an adequate legal medium for compensating patients for the injurious consequences of therapeutic drug treatment."⁹³

THEORIES OF LIABILITY AS AGAINST PHARMACISTS

Negligence

One of the theories under which pharmacist liability for failure to warn would arise is negligence. However, for liability to arise under negligence, there must be a duty as well as evidence of a breach of that duty.⁹⁴ Generally, the courts have held that a pharmacist has no duty to warn patients of the hazards associated with their prescription medication.⁹⁵ In the absence of judicial recognition of the duty to warn patients of the hazards associated with their prescribed medication, a litigant may seek statutory support of such duty.⁹⁶ However, little sanctuary has been found within the statutes.

For example, Ohio's statutes defining the "practice of pharmacy" place no direct duty on the pharmacist to warn patients.⁹⁷ At best, an indirect duty to warn is placed on the Ohio pharmacist by the requirement to participate in "reviews of drug utilization" expressed within the statutory definition of the practice of

⁹³ *Id.* The court appeared to indicate that it was rejecting the claim only because it was presented in terms of "informed consent" and that had the litigants discussed "negligence", these same facts would have resulted in the physician being held liable.

⁹⁴ See generally W. KEETON, *supra* note 49, at § 30 which states:

The traditional formula for the elements necessary to such a cause of action may be stated briefly as follows:

1. A duty, or obligation, recognized by the law, requiring the person to conform to a certain standard of conduct, for the protection of others against unreasonable risks.

2. A failure on the person's part to conform to the standard required: a breach of the duty. These two elements go to make up what the courts usually have called negligence; but the term quite frequently is applied to the second alone. Thus it may be said that the defendant was negligent, but is not to be liable because he was under no duty to the plaintiff not to be.

Id.

⁹⁵ See *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987). See also *Jones v. Irvin*, 602 F. Supp. 399 (N.D. Ill. 1985); *Ullman v. Grant*, 450 N.Y.S.2d 955 (N.Y. App. Div. 1982).

⁹⁶ However, even the Food, Drug, and Cosmetic Act appears to recognize that a pharmacist has no independent duty to warn a patient concerning prescription medication. "Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt . . . [from the packaging requirements imposed upon manufacturers] . . . if the drug bears a label containing the name and address of the dispenser, the serial number and the date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and *cautionary statements, if any, contained in such prescription.*" 21 U.S.C. § 353(b)(2) (1988).

⁹⁷ See OHIO REV. CODE ANN. § 4729.02 (Baldwin 1992) which states in pertinent part:

"(B) To "practice pharmacy" means to interpret prescription, to compound or to dispense drugs, dangerous drugs, and poisons, and related devices that under the federal "Food, Drug, and Cosmetic Act" must be labeled for sale only on the order of a practitioner; to participate in drug selection pursuant to Chapter 3715 and section 4729.38 of the Revised Code; and to participate with practitioners in reviews of drug utilization"

Id. at 4729.02(B).

pharmacy.⁹⁸ Participation in drug utilization reviews requires the pharmacist to communicate to the physician potential drug interactions, drug allergies, and "other pertinent information related to the patient for the purpose of avoiding adverse effects."⁹⁹ Conceivably, a litigant could contend that the pharmacist is liable for damages resulting from the breach of the pharmacist's duty to communicate "pertinent information related to the patient for the purpose of avoiding adverse effects" to the physician as required by the statute.¹⁰⁰ This would thereby result in the inability of the physician to adequately warn the patient.¹⁰¹ However, despite this Ohio statute, the courts have repeatedly stated that the ultimate responsibility to warn the patient remains with the physician.¹⁰² Therefore, despite the weak connection to a potential statutory duty, it would appear unlikely that pharmacist liability would be found without a more direct statutory or factual establishment of this duty. However, the Act provides the necessary direct statutory duty that the courts have yet to encounter.

Strict Products Liability

Another theory under which pharmacist liability for failure to warn may arise is strict products liability as seen in section 402A of the *Restatement (Second) of Torts*.¹⁰³ Comment K of section 402A states in pertinent part:

⁹⁸ See OHIO REV. CODE ANN. § 4729.02 (Baldwin 1992).

⁹⁹ See OHIO ADMIN. CODE § 4729-5-01 (1991) which states in pertinent part:

(F) To participate with practitioners in reviews of drug utilization" means, through appropriate communication with the practitioner(s) involved, monitoring the use of drugs to detect possible drug misuse by the patient, abnormal dispensing patterns, duplicated prescriptions, potential interactions, interferences or incompatibilities by reviewing the drug regimen and the medication record or drug profile which is based on available drug history, any known drug allergies or sensitivities, and other pertinent information related to the patient for the purpose of avoiding adverse effects.

Id.

¹⁰⁰ See OHIO REV. CODE ANN. § 4729.02 (Baldwin 1992). See also OHIO ADMIN. CODE § 4729-5-01 (1991).

¹⁰¹ If the pharmacist actually *knew* of specific information that could be critical for the physician to know in order to avoid an adverse reaction and yet the pharmacist did not convey this information, then, some courts could view the situation as being analogous to *Hand v. Krakowski*, 453 N.Y.S.2d 121 (N.Y. App. Div. 1982) where the pharmacist was found liable for having failed to warn a *known* alcoholic of the dangers of taking the medication while under the influence of alcohol.

¹⁰² See generally *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); *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987); *Kinney v. Hutchinson*, 449 So. 2d 696 (La. Ct. App. 1984); *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881 (Ind. Ct. App. 1985).

¹⁰³ RESTATEMENT (SECOND) OF TORTS § 402A (1965) provides in pertinent part:

Sec. 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

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

(a) the seller is engaged in the business of selling such a product, and

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

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product,
and

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, *and accompanied by proper directions and warning*, is not defective, nor is it unreasonably dangerous. (emphasis added)¹⁰⁴

In *Palmer v. A. H. Robbins Co. Inc.*,¹⁰⁵ the Colorado court held that "a manufacturer or seller may be strictly liable to users of a product when the failure to provide adequate warnings [concerning the effects of a medication or device] renders the product defective and unreasonably dangerous."¹⁰⁶ However, the applicability of this general rule to the "practice" of pharmacy is debatable.¹⁰⁷ In *Murphy v. E.R. Squibb*,¹⁰⁸ a California court discussed the dual function of a pharmacy as both providing a service and selling a product. The court concluded that although a product is provided to the customer, the essence of the transaction as between the patient and the pharmacist is providing a service.¹⁰⁹ Therefore, a pharmacist was held not liable for the failure to warn a patient of the long-term adverse side effects of a prescribed medication.¹¹⁰ Another reason behind this absence of duty is the fact that:

when a consumer asks a druggist to fill a prescription, thus enabling him to obtain a drug which is not otherwise available to the public, he does not rely on the druggist's judgement as to whether that particular drug is inherently fit for its intended purpose but rather he places that confidence and reliance in the physician who prescribed the remedy.¹¹¹

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

¹⁰⁴ *Id.*

¹⁰⁵ 684 P.2d 187 (Colo. 1984).

¹⁰⁶ *Id.* at 199.

¹⁰⁷ Here, "practice" is not intended to be read within the statutory definition of "pharmacy" but rather in a more practical day-to-day view where one could confuse whether a product is being sold or a service is being performed. *Id.*

¹⁰⁸ 710 P.2d 247 (Cal. 1985).

¹⁰⁹ *Id.* at 252.

¹¹⁰ *Id.*

¹¹¹ *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 886 (Ind. Ct. App. 1985).

The rationale . . . [of those authorities holding a pharmacist under no duty to warn]. . . is that the duty to warn of hazards associated with prescription drugs is part and parcel of the physician-patient relationship because it is best appreciated in this context. . . . The decision of weighing the benefits of a medication against potential dangers that are associated with it requires an individualized medical judgment. This individualized treatment is available in the context of a physician-patient relationship which has the benefits of medical history and extensive medical examinations. It is not present, however, in the context of a pharmacist filling a prescription for a retail customer. The injection of a third-party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of the ongoing medical treatment. We perceive the better rule to be one which places the duty to warn of the hazards of the drug on the prescribing

There is also a strong public policy argument against holding pharmacists strictly liable under a products liability theory. It has been said that "[t]o hold a druggist strictly liable would be to make the druggist an insurer of the safety of the manufactured drug."¹¹² The position of the pharmacist is dissimilar to that of the pharmaceutical manufacturer.¹¹³ The manufacturer is in the business of selling products (medications) *to physicians* and is required to provide adequate warnings regarding those products *to the physician*.¹¹⁴ In *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*¹¹⁵ the court explained the rationale behind this general rule by stating that

[t]he purpose of the requirement that all warnings as to potential dangers associated with prescription drugs be provided to prescribing physicians is that the prescribing physicians are, in the case of prescription drugs, the actual consumers. In most instances, the patient-consumer would be unable to properly assess and weigh the benefits and risks attendant to the use of such drugs.¹¹⁶

physician and requires of the pharmacist only that he include those warnings found in the prescription.

Id. at 886-87.

This extensive discussion regarding the "better rule" that a pharmacist only be required to provide those warnings contained on the written prescription is in accordance with the position implied in the Food, Drug, and Cosmetic Act which states in part:

(b)(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt . . . from the packaging requirements . . . [applicable to manufacturers of such drugs] . . . if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and *the directions for use and cautionary statements, if any, contained in such prescription.*

21 U.S.C. § 353(b)(2) (1988)(emphasis added).

¹¹² *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986).

¹¹³ When legally marketing pharmaceuticals, the physician is viewed as the actual consumer. "The purpose of the requirement that all warnings as to potential dangers associated with prescription drugs be provided to prescribing physicians is that the prescribing physicians are, in the case of prescription drugs, the actual consumers." *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987).

¹¹⁴ *See id.* The court discussed why the warnings are to be directed to the physician and not the patient as follows;

it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as "[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.

Id. (citing *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 444, 457 (Pa. Super. Ct. 1985)).

¹¹⁵ 523 A.2d 374 (Pa. Super. Ct. 1987).

¹¹⁶ *Id.* at 378.

The clear distinction between pharmacist liability and that of pharmaceutical manufacturers appears well established.¹¹⁷ However, the Act appears to place the pharmacist in the position of the consumer of the medications rather than the physician when discussing the manufacturer's duty to inform.

Some courts have already blurred this distinction. In *Bichler v. Willing*,¹¹⁸ a New York court held a pharmacist not liable under products liability. The opinion indicated that the plaintiff's pleadings presented a *valid cause of action under strict products liability* due to her allegations that the pharmacist "knew or, in the exercise of reasonable diligence, should have known that said drug was unsafe and unfit for use by reason of the dangerous effects . . . and that he failed to warn of these dangers."¹¹⁹ Obviously, this court was prepared to recognize that a pharmacist may be held strictly liable under a products liability theory. The Act would appear to support this conclusion. However, the court found that there was not sufficient evidence to support the plaintiff's allegations.

IMPACT OF THE "ACT" ON CLAIMS AGAINST PHARMACISTS

Two key phrases in this Act are likely to trigger a change in the malpractice statutes of states that do not already include pharmacists. The first is the Act's statement of purpose, which appears to include pharmacists within that group who provides "medical care."¹²⁰ This phrase would appear to place a pharmacist on the very edge of Ohio's definition of a "medical claim" as an action arising out of the "medical diagnosis, care, or treatment of any person."¹²¹ (emphasis added). The use of this terminology within the Act would facilitate the inclusion of pharmacists within various medical malpractice statutes of limitation because the proposed Act would require that pharmacists become involved in "care."

Second, the Act specifically allows for the "exercise of . . . [the pharmacist's] . . . professional judgment" when deciding which side effects and interactions to discuss with a patient.¹²² Prior to nurses being included in Ohio's malpractice

¹¹⁷ See generally *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987); *Bichler v. Willing*, 397 N.Y.S.2d 57 (N.Y. App. Div. 1977).

¹¹⁸ 397 N.Y.S.2d 57 (N.Y. App. Div. 1977).

¹¹⁹ *Id.* at 60.

¹²⁰ Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g) (1991).

¹²¹ OHIO REV. CODE ANN. § 2305.11(D)(3) (Baldwin 1992) (emphasis added). However, although the definition uses the term "care", this is not the controlling term of the definition. Rather, the individuals enumerated appear the core of the definition.

¹²² Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I) (1991). However, no parameters are set up as to what standard of "professional judgment" shall be followed.

statute,¹²³ the Ohio Supreme Court reasoned in *Richardson v. Doe*¹²⁴ that since a nurse was not "required to exercise . . . independent judgment on matters which may mean the difference between life and death . . . [that there was] . . . no compelling reason for a nurse to be given the protection of a one-year statute of limitations."¹²⁵ The Act has expressly rendered similar reasoning moot with regard to pharmacists since it would *require* the exercise of independent judgment.¹²⁶ Without this mandatory exercise of independent judgment, a pharmacist's duties have generally been held to be quite narrow, thereby avoiding the necessity of modifying statutes of limitation.¹²⁷ Through the exercise of "professional judgment," pharmacists will become vulnerable to attack for those judgments made.

Furthermore, in light of the fact that some jurisdictions have held physicians liable in malpractice for failing to warn a patient of adverse side effects associated with prescribed medications¹²⁸ even where there was no statutory duty to so inform the patient, it would appear even more likely that a pharmacist would be found liable for a similar failure to warn that same patient since the Act provides a statutory duty to warn.¹²⁹ This likelihood is even more certain in view of the fact that the legislation places an affirmative duty upon the pharmacist to exercise "professional judgment" in determining which information would be appropriate to discuss with a patient.¹³⁰ Naturally, with the pharmacist's increased statutory standard of care and mandate to exercise discretion comes increased litigation for failing to exercise that standard of care or discretion that a pharmacist of ordinary skill, care and diligence would have exercised under similar circumstances.

¹²³ Currently, "medical claim" is defined as "any claim that is asserted in any civil action against a physician, podiatrist, or hospital, against any employee or agent of a physician, podiatrist, or hospital, or against a *registered nurse* or physical therapist, and that arises out of the medical diagnosis, care, or treatment of any person." OHIO REV. CODE ANN. § 2305.11(D)(3) (Baldwin 1992). However, at the time *Richardson v. Doe*, 199 N.E.2d 878 (Ohio 1964) was decided, a "medical claim" was defined as "any claim asserted in any civil action against a physician, podiatrist, or hospital arising out of the diagnosis, care, or treatment of any person." OHIO REV. CODE ANN. § 2305.11(D)(3) (Baldwin 1978).

¹²⁴ 199 N.E.2d 878 (Ohio 1964).

¹²⁵ *Id.* at 880.

¹²⁶ Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g) (1991).

¹²⁷ "A pharmacist cannot dispense such drugs himself but can do so only upon the direction of a physician." *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987). "[A] druggist has the duty to compound the drug prescribed, to use due and proper care in filling the prescription, to use proper methods in the compounding process, and to ensure that the drug is not adulterated with a foreign substance." *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 88 (E.D. Pa. 1986).

¹²⁸ See *Wilschinsky v. Medina*, 775 P.2d 713 (N.M. 1989). See also Robert A. Brazener, Annotation, *Physician's Liability for Injury or Death Resulting From Side Effects of Drugs Intentionally Administered or Prescribed for a Patient*, 45 A.L.R. 3d 928 (1972 and Supp. 1991).

¹²⁹ This is because the physician has no statutory duty to warn a patient of the side effects of medication unless that particular jurisdiction views the prescribing of medication as a procedure requiring informed consent. See *Harbeson v. Parke-Davis, Inc.*, 746 F.2d 517 (9th Cir. 1984). But see *Boyer v. Smith*, 479 A.2d 646 (Pa. Super. Ct. 1985). In contrast, under the proposed Act, the pharmacist would have an affirmative duty to warn or inform and failure to do so would likely stand as *prima facie* proof of negligence. See 42 U.S.C. § 1396r-8(g).

¹³⁰ Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g)(2)(A) (1991).

The enactment of this amendment to the Social Security Act¹³¹ has expressly shifted any burden to warn to the pharmacist where that pharmacist is compelled to disclose the precautions and side effects of prescription medication.¹³² Each pharmacist must use his or her discretion as to whether a side effect or precaution is of such significance that it must be disclosed to the patient.¹³³ Since the Act is silent on the standard to which such disclosure will be held, only future litigation will define which standard (materiality to the reasonable patient,¹³⁴ or prevailing standards of pharmaceutical practice¹³⁵) will be applied with regard to pharmacists. In jurisdictions which follow the "materiality to the reasonable patient" standard¹³⁶ in informed consent cases, this same standard can be expected to be applied to pharmacists.¹³⁷

One of the expressed purposes of the Act is to control the price of medications that will eventually be paid through medicaid.¹³⁸ However, the terms of the Act are likely to increase the cost of providing that medicine due to the increased costs of litigation that will be associated with the liability claims of a pharmacist's failure to warn. A purpose similar to that of the Act was expressed by the Ohio General Assembly with regard to Ohio's malpractice statute.¹³⁹ The purpose of the recent amendments to the malpractice statute, which broadened the scope of those included within that statute, was "to stabilize the marketplace for medical, dental, optometric, and chiropractic professional liability insurance in this state, *with the concomitant effects of slowing the upward spiral of medical, dental, optometric, and chiropractic care costs* in this state. . . ." (emphasis added).¹⁴⁰ This same rationale is the basis of California's cap on recovery of non-economic damages in malpractice actions.¹⁴¹ Interestingly, the California statute pertaining to such actions and the cap on recovery refers to "health care providers," which includes pharmacists.¹⁴² The enactment of the Act will likely create an atmosphere

¹³¹ 42 U.S.C. § 301 (1988).

¹³² Prudent Purchasing Act, 42 U.S.C. § 1396r-8(g) (1991).

¹³³ "The pharmacist must offer to discuss with each patient or caregiver who presents a prescription all matters which *in the exercise of his professional judgment he deems significant*. . . ." *Id.* (emphasis added).

¹³⁴ See *Nickell v. Gonzalez*, 477 N.E.2d 1145 (Ohio 1985).

¹³⁵ See *W. KEETON*, *supra* note 49, at § 32. See also *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972); *Bruni v. Tatsumi*, 346 N.E.2d 673 (Ohio 1976).

¹³⁶ See *Nickell v. Gonzalez*, 447 N.E.2d 1145 (Ohio 1975).

¹³⁷ However, the "material to the reasonable person" test for informed consent is applied in Ohio with respect to medical procedures and not yet with regard to therapeutic medication cases. Considering the explicit nature of the Act, the courts may hold pharmacists to the more stringent test.

¹³⁸ 136 CONG. REC. S5982-04, *supra* note 2.

¹³⁹ OHIO REV. CODE ANN. § 2305.11 (Baldwin 1989).

¹⁴⁰ See OHIO REV. CODE ANN. § 2305.11 (Baldwin 1989) (legislative history).

¹⁴¹ *Fein v. Permanente Medical Group*, 695 P.2d 665, 668 (Cal. 1985).

¹⁴² CAL. CODE OF CIV. PROC. § 340.5 (West 1982).

where other states will follow the California model.¹⁴³ Michigan¹⁴⁴ and Florida¹⁴⁵ have done so by including pharmacists within their malpractice statutes.

CONCLUSION

Until the enactment of the Pharmaceutical Access and Prudent Purchasing Act of 1990, pharmacists could practice their profession without need for *excessive* concern regarding whether he or she fully informed "our" Mr. Jones in this article's opening scenerio of *all* the potential side effects of his prescription medication and *all* the potential drug interactions. As long as the pharmacist correctly prepared the medications prescribed by physicians; as long as the pharmacist was unaware of any peculiar reactions or conditions which would contraindicate the use of a particular medication in a particular patient; as long as any warnings placed within the prescription by the physician were communicated to the patient by the pharmacist, the pharmacist had met his or her obligations. As a result, pharmacists' liability insurance has been relatively inexpensive. Therefore, the current cost of providing prescription medication needs to include the cost of extensive litigation and the accompanying expensive malpractice insurance premiums that have been seen by physicians in recent years.

The Pharmaceutical Access and Prudent Purchasing Act of 1990, however, threatens to dramatically change the practice of pharmacy. Though the Act was introduced to save money in the medicaid provided health care benefit area, it would appear that an opposite result will be seen for several reasons. First and most elementary, filling prescriptions will be more time consuming if the pharmacist must take a complete medical history of each patient before filling the prescriptions as required by the Act. The increased time spent per patient will require more pharmacists per pharmacy and more technical support. This will naturally lead to increased prescription prices for the general public not covered by a fixed reimbursement program for prescription medications.

Second and more significantly, along with the increased duties will come increased litigation and liability. Where a physician has prescribed "our" Mr. Jones a dangerous combination of medications, and where Mr. Jones or his estate sues

¹⁴³ *Id.*

¹⁴⁴ MICH. COMP. LAWS ANN. § 600.2912 (1986).

A civil action for malpractice may be maintained against any person professing or holding himself out to be a member of a *state licensed profession*. The rules of the common law applicable to actions against members of a *state licensed profession*, for malpractice, are applicable against any person who holds himself out to be a member of a *state licensed profession*.

Id. (emphasis added).

¹⁴⁵ FLA. STAT. ANN. § 95.11 (West 1982 and Supp. 1992). "An Action for medical malpractice is defined as a claim in tort or in contract for damages because of the death, injury, or monetary loss to any person arising out of any medical, dental or surgical diagnosis, treatment, or care by any *provider of health care*." (emphasis added) *Id.*

the physician for failure to warn, it is virtually certain that defense counsel will introduce the terms of the Act. Defendants may claim either that the Act relieved the physician of any duty to warn Mr. Jones, or that at the very least, the pharmacist and the physician should be held jointly and severally liable for the failure to warn, thereby reducing the extent of recovery attributable to the physician's acts. The increased litigation and liability of pharmacists will logically cause a disproportionate increase in the cost of pharmacist's liability insurance if insurance industry practices hold true to those of the past. Naturally, these increased costs will be passed on to the consumer, thus resulting in an "upward spiral" of pharmacy costs in all states. Therefore, it would appear that the only means of achieving the goals set forth in both the Act and malpractice statutes would be to include pharmacists within the one year statute of limitations as a preemptive move. Such preventive treatment would be an intelligent step towards cost containment, rather than waiting for the severe consequences of the Act to be reflected in prescription prices followed by enactment of legislation as a means of damage control.

The Act has significantly shifted the duty to warn patients concerning the side effects of medication to pharmacists. This shift of duty is certain to result in pharmacists being held liable for the failure to warn under theories of negligence, lack of informed consent, and possibly strict products liability. However, under current law in most jurisdictions, the pharmacist is not provided the protection of a "malpractice" statute of limitations. Unless these statutes are expanded to expressly include pharmacists, the resulting upward spiral of pharmacist malpractice insurance will further fuel the inevitable explosion of prescription drug prices due to the pharmacists' other requirements under the Act. The unfortunate result of not including pharmacists within these statutes will be the total defeat of the primary goal of the Act; namely, to maintain the price of prescription medications at a reasonably low level.