Pennsylvania Pharmacists Should No Longer Assume That They Have No Duty to Warn

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Pennsylvania Pharmacists Should No Longer Assume That They Have No Duty to Warn*

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I. INTRODUCTION

The well-established rule is that pharmacists must conform their conduct to meet the degree of care that a reasonable and prudent person would use under similar circumstances. Courts have described the standards for pharmacists with phrases such

* This comment is authored by Robert A. Gallagher, who received a Doctor of Pharmacy Degree from the Mylan School of Pharmacy at Duquesne University in 2003 and currently practices at Brooks/Eckerd Pharmacy.
as "high degree of care" and "great care." Due to the dangerous nature of most prescription drugs, it is no wonder that pharmacists must adhere to these higher standards. The pharmacist, however, may be one of the only health care professionals required to practice in a completely error-free manner. Those involved in the field of pharmacy adopt a "no mistakes" approach, and practice standards reflect this impossible-to-achieve and self-imposed standard. Despite the higher degree of care that is expected and the self-imposed standards, courts and legislatures have been reluctant to expressly impose a duty to warn on pharmacists.

Traditionally, pharmacists had no duty to warn about a medication's risk. This proposition has been supported by the thought that the physician is the primary health care provider and the one on whom patients rely to make the correct medical decisions for them. Furthermore, some believe that the pharmacist lacks the education, skill, training, and information required to advise the patient properly. Courts and many physicians have also supported the theory that pharmacists have no duty to warn because the pharmacist's involvement would be a direct interference with the physician-patient relationship. Others argue that requiring the pharmacist to warn would place an undue burden on pharmacists because they would be forced to question every decision a physician makes.

Historically, pharmacists were instructed not to tell patients anything about the prescribed medication in order to maintain a clear distinction between the practice of medicine and the practice of pharmacy. Since the 1950's, federal and state laws have continued to expand the practice of pharmacy beyond the rudimentary tasks of counting and pouring. Despite the expansion of the practice, patients, attorneys, and pharmacists in Pennsylvania have yet to receive a definitive legal answer as to whether phar-

1. Ingram v. Hook's Drug, 476 N.E.2d 881 (Ind. Ct. App. 1985) (holding that the duty to warn of a drug's dangers rests with the physician and that the pharmacist has no duty to warn); RICHARD ABOOD, PHARMACY PRACTICE AND THE LAW 324 (4th ed. 2005).
2. ABOOD, supra note 1, at 324.
5. ABOOD, supra note 1, at 324.
6. Id.
7. Id. The Durham-Humphrey Amendment to the Food, Drug and Cosmetic Act was passed in 1951 and listed the information that the federal law required a pharmacist to place on the label of a dispensed medication. Durham-Humphrey Amendment of 1951, Pub. L. No. 215, § 578, 65 Stat. 648 (1951) (amending sections 303(c) and 503(b) of the Federal Food, Drug, and Cosmetic Act). Interestingly, the amendment does not require that the name of the drug be included on the label. ABOOD, supra note 1, at 324.
The Pharmacist’s Duty to Warn

Pharmacists have a duty to warn. The intent of this comment is to show why one should assume pharmacists have an affirmative duty to warn patients about the risks associated with their medications.

A. Overview of Topics Covered

To understand the issue of whether a pharmacist practicing in Pennsylvania has a duty to warn the patient, one must consider a multitude of legal, medical, and social issues. Following this introduction in Part I, this comment addresses the more prominent factors present amongst the myriad considerations that affect the pharmacist’s duty to warn. Part II discusses the learned intermediary doctrine; Part III outlines the history behind the duty to warn; Part IV addresses how the legislature and courts apply the duty to warn; and lastly, Part V of this comment evaluates where the practice of pharmacy is headed and how the duty to warn coincides with the evolution of the field of pharmacy.

B. Summary of Conclusion

Once these abovementioned items are explored, it should become obvious that pharmacists in Pennsylvania have a duty to warn. Despite the fact that no court or legislature has expressly stated this conclusion, Pennsylvania pharmacists have self-imposed a duty to warn. Remarkably, most practicing pharmacists have chosen to accept this duty without the courts or legislature forcing it upon them. This proactive approach is the impetus for the continual expansion of the field of pharmacy. It is also the reason why pharmacists today are such an integral part of the health care team and are often considered America’s most trusted professionals.

II. LEARNED INTERMEDIARY DOCTRINE

Before discussing the duty to warn, it is important to analyze the learned intermediary doctrine. For decades, patients have relied on their physician to provide them with adequate information and warnings concerning their prescription medications. For centuries, the doctor has been the commander of the health care arena. The physician has always held the ultimate power of deciding what is best for his patient. Today, one rule bestows that power on the doctor and the doctor only. That rule is known to many as the learned intermediary doctrine. However, through
case law, legislation, practice changes, technology, and much more, it appears that the doctrine's substance has been significantly reduced.

The current changes in pharmacist liability have left many questions for physicians, manufacturers, and attorneys attempting to apply the learned intermediary doctrine. The confusion involves issues of whether (1) the pharmacist is a learned intermediary, (2) manufacturers must adequately warn pharmacists similar to the way they inform doctors, (3) the public may rely on the pharmacist to convey needed information to them, and (4) doctors and pharmacists will be able to share the role of patient educator. To share this role, physicians and pharmacists must continue to strive for a better relationship. Even though the two professions have made monumental strides to improve and capitalize on their involvement with each other in patient care, turmoil between the two professions often surfaces.

A. Background

The general rule states that “drug manufacturers must warn physicians of a drug’s dangerous side effects and that the prescribing physicians have a duty to convey the warnings to their patients.” The rule was first conceptualized in the case of Marcus v. Specific Pharmaceuticals. The term “learned intermediary doctrine” was coined nearly twenty years later in the case of Ster-
ling Drug, Inc. v. Cornish.\textsuperscript{17} The basic theory underlying the rule is that the physician is trained to assess risks and choose the appropriate therapy course for each patient.\textsuperscript{18} The rule presumes that the physician, once made aware of the warnings involved with a drug, will transmit any information he deems appropriate to the patient.\textsuperscript{19} Because patients are assumed to be uneducated in medicine, the law selects the physician instead of the patient to receive warnings from the manufacturer.\textsuperscript{20} The belief has always been that direct information provided to the patient would not adequately protect a patient who is not trained to evaluate risks.\textsuperscript{21} Assuming that the physician was provided with the proper warning from the manufacturer, the patient who is subsequently harmed by the medication typically has no legal recourse against the manufacturer.\textsuperscript{22}

Prescription drugs are a unique exception to the general view under section 402A of the Restatement (Second) of Torts.\textsuperscript{23} Generally, a manufacturer is strictly liable for injuries caused to a user by a product sold in a defective condition that is unreasonably dangerous.\textsuperscript{24} Section 6 of the Restatement (Third) of Torts reiterates the learned intermediary rule that manufactures have a duty under most circumstances to adequately warn the prescribing physician and other health care providers instead of the patient.\textsuperscript{25} Prescription drugs have long posed a difficult challenge to American products liability law.\textsuperscript{26} The law must constantly balance the great benefits that so many people receive from prescription medications and the potential harm that these products may

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{17} 370 F.2d 82, 85 (8th Cir. 1966).
  \item \textsuperscript{18} Ozlem A. Bordes, The Learned Intermediary Doctrine and Direct-To-Consumer Advertising: Should the Pharmaceutical Manufacturer be Shielded from Liability?, 81 U. DET. MERCY L. REV. 267, 286 (2004).
  \item \textsuperscript{19} ABOOD, supra note 1, at 340.
  \item \textsuperscript{20} Id.
  \item \textsuperscript{21} Id.
  \item \textsuperscript{22} Id.
  \item \textsuperscript{23} RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).
  \item \textsuperscript{24} Id. § 402A.
  \item \textsuperscript{25} RESTATEMENT (THIRD) OF TORTS § 6 cmt. d (2005). Section 6(d) states:
  \begin{itemize}
    \item A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings.
  \end{itemize}
  \item \textsuperscript{26} Id. § 6(d)(1).
\end{itemize}
\end{footnotesize}
cause. To err on the side of public safety could substantially daunt the research and development of better and more innovative medicines; however, to err in favor of manufacturers could lead to a greater number of individuals harmed by unreasonably unsafe products.

B. Exceptions

As the health care system continues to evolve, the limitations on the learned intermediary doctrine continue to develop. The Restatement (Third) of Torts touched upon this in section 6(d)(2) where it states that there will be times when the health care provider is not in the best position to warn the patient of the dangers involved with a drug. While the American Law Institute chose to define some of the currently recognized exceptions to the rule, it specifically chose to defer to developing case law on what the other exceptions may be.

Currently, the common law does recognize some specific exceptions to the learned intermediary doctrine. Some of the repeatedly confirmed exceptions are: (1) mass immunizations; (2) oral contraceptives; and (3) direct-to-consumer advertising. As case law continues to develop, the behavior of the manufacturer continues to play an integral part in the courts’ evaluation of the application of the doctrine.

Courts have also found manufacturers to be unprotected by learned intermediaries when they engage in activities such as overpromotion, which results in adequate warnings becoming diluted, and promotion of “off label” or non-FDA approved indications. While physicians at this time remain the “gatekeeper” between patients and prescription drugs, many physicians argue that increased advertising has significantly affected the physician-patient relationship. Others argue that imposing liability on manufacturers for failing to warn is contrary to public policy because this will discourage research and development of new drugs

28. Id. at 199-200.
30. Id. § 6 cmt. e. “The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.” Id.
31. Bordes, supra note 18, at 286.
33. Id. at 1060-61.
and increase the price of already unaffordable medications. Pharmaceutical manufacturers claim that "Direct-to-Consumer ("DTC") advertising is beneficial because it works to increase patient awareness of available medications and disease states."

Attempts at increasing patient awareness have led the courts to use other exceptions to the learned intermediary doctrine. For example, the doctrine may not apply when the FDA requires specific information, called MedGuides, to be provided to the patients upon pick-up of their prescription. By applying an exception in these cases, the courts are essentially relying on the FDA’s determination that for these specified medications, the physician-patient relationship is not an effective intermediary to ensure patients receive an adequate warning. Because MedGuides are a relatively new phenomenon, it remains to be determined whether they will provide adequate warnings to the patient. One problem that may arise is that patients are not guaranteed to receive these guides when they pick up their medication at the pharmacy.

The Internet is burgeoning into another major exception to the learned intermediary doctrine. Internet content poses the same problem DTC advertising does. In fact, Internet sites often employ DTC advertising. Patients often go online to gain information

35. Bordes, supra note 18, at 279.
37. Edwards v. Basel Pharm., 116 F.3d 1341, 1342 (10th Cir. 1997). In Edwards, the plaintiff’s husband died from a nicotine overdose after applying a patch and continuing to smoke. Edwards, 116 F.3d at 1342. The manufacturer argued that it had satisfied its duty to directly warn the patient by warning the learned intermediary. Id. The Oklahoma Supreme Court, answering a certified question from the Tenth Circuit, ruled that the FDA mandate to directly warn the patient was an exception to the learned intermediary doctrine. Edwards v. Basel Pharm., 933 P.2d 298, 303 (Okla. 1997).
39. Larry D. Sasich & Sana R. Sukkari, Don’t Forget to Give Out MedGuides, DRUG TOPICS, Apr. 3, 2006, at 52. Possible reasons why patients are not being given MedGuides are:

(1) Pharmacists may not be aware of the MedGuide regulations; (2) pharmacists may believe that the written drug information they are distributing, produced by commercial vendors, meets the FDA’s regulatory requirements; and (3) the manufacturers may have failed to ensure that sufficient quantities of the MedGuides are reaching pharmacies for distribution to patients.

Id.
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regarding a medication or disease state before seeking advice from a doctor or pharmacist. Internet marketing and other available information directly affects patients’ beliefs about a product. Usually, Internet sites provided by the drug manufacturers include much more detailed information than is required for television or print advertisements. There is current uncertainty involving whether liability will be placed on the manufacturers for Internet content, specifically when material is posted on third-party sites which hyperlink to a manufacturer’s sponsored site.

Unfortunately, the uncertainty involving liability is a common theme that runs throughout the health care industry. With the number of exceptions carved out of the learned intermediary doctrine it remains unclear what is left of the doctrine or when it is applicable. Much of this ambiguity evolved from the advent of modern medical science and technology. Prior to the explosion of the pharmaceutical market, it was much simpler for the physician to maintain adequate oversight of his patients, but now it is a daunting challenge to stay abreast of the current products available for use. As a result, there is a constant struggle between the patients, manufacturers, doctors and pharmacists to determine who is or should be the “gatekeeper.”

The doctor has always been considered the barrier between the harmful effects of medicine and the patient. Through the learned intermediary doctrine, customarily the doctor possesses the duty to warn the patient of any potential drug interactions or adverse events. Many believe that shifting the duty to warn to the manufacturer or the pharmacist would cause doctors to lose the trust of their patients and ultimately destroy the physician-patient relationship. Others believe imposing the duty to warn on the pharmacist would violate “public policy” because, while it would provide patients easier access to drug information, it would substantially increase litigation. Both of these notions lack any substantial proof and should have no bearing on whether pharmacists have a duty to warn.

Most professionals know that by giving up liability they in turn give up power. This is likely a primary reason why liability remains centralized on the physician while other health care profes-

40. Rumore, supra note 32, at 1062-63.
41. Id. at 1063. “[The courts and legislature have not yet provided guidance on pharmaceutical liability pertaining to linking and framing; therefore, the threat of litigation exists.” Id.
The Pharmacist's Duty to Warn

sionals remain, for the most part, protected by the learned intermediary doctrine.

A strong argument exists, however, that supports rejecting the learned intermediary doctrine and imposing a duty to warn on the pharmacist. The argument is premised on the pharmacist being in the best position to communicate effectively with the patient. Furthermore, the pharmacist possesses the skills not only to convey the pertinent warnings, but also to promote patients' involvement in their own therapy protocol.

III. DUTY TO WARN

Commentators and courts in favor of pharmacists having no duty to warn generally rely on three theories: (1) the learned intermediary doctrine; (2) imposing a duty to warn on pharmacists would interfere with the physician-patient relationship; and (3) imposing a duty to warn on pharmacists would contradict "public policy." While these theories have existed for some time now, common law precedents dating back to the early nineteenth century support the argument that pharmacists should be responsible for more than accurately filling a prescription. Under the common law, pharmacists have always been expected to perform at the highest professional level.

A. Common Law

This high level of expected performance was the basis for many pharmacist liability cases that were decided in the early twentieth century. In Jones v. Walgreen Co., the Appellate Court of Illinois emphasized the high level of expectation placed on pharmacists to perform their jobs competently. In Jones, the subject pharmacy defended the claim against it by arguing, "the legal duty of a druggist to a purchaser can go no further than to dispense the

42. Jones v. Irvin, 602 F. Supp. 399, 402 (S.D. Ill. 1985) (discussing how the imposition of a duty to warn on pharmacists would adversely affect the physician-patient relationship); Leesley v. West, 518 N.E.2d 758, 763 (III. App. Ct. 1988) (holding that the learned intermediary rule would be violated by imposing a duty to warn on pharmacists, and that expanding the liability of health care professionals is contrary to policy).

43. Tessymond's Case, 1 Lewin's Crown Cases 169 (1828).


identical substance which his prescription calls for.” The court rejected this argument by stating:

[t]he instant contention is primarily based upon the assumption that a pharmacist is obliged to fill any and all prescriptions. Such is not the law. As a chemist he may know that the physician has erred in his prescription and that to fill it might cause death or serious injury to the patient.

The court relied heavily on precedent to reach its conclusion that the duty of the pharmacist includes monitoring for potential harm to the patient. Each case that was cited in Jones represented the principle that pharmacists must accept responsibility for their actions or for their failure to act. Moreover, if a pharmacist could possibly prevent harm to a patient and fails to do so, he may not blame another party as being solely responsible for causing the harm. The most prominent of the cases relied on in Jones was Tremblay v. Kimball.

The court in Tremblay held that the law requires of a druggist only “reasonable and ordinary” care in compounding prescriptions, in selling medicines, and in performing the other duties of his profession; such care with reference to him means the “highest practicable degree of prudence, thoughtfulness, and vigilance,” and it is “proportioned to the danger involved.” Furthermore, “a breach of such duty would be negligence rendering him liable for injuries resulting therefrom.” The court concluded that when the pharmacist applies his knowledge and exercises care and diligence, he is bound to use his best judgment. The pharmacist, however, by using his best judgment does not absolutely guarantee that no mistake will ever be committed in the execution of his duties, and it is plausible that a qualified pharmacist may make an error that would not be actionable negligence.

47. Id.
48. Id. See McGahey v. Albritton, 107 So. 751 (Ala. 1926); Martin v. Manning, 92 So. 659 (Ala. 1922); Tombari v. Connors, 85 Conn. 231 (1912); Faulkner v. Birch, 120 Ill. App. 281 (1905); Tremblay v. Kimball, 77 A. 405 (Me. 1910).
49. Brushwood, supra note 11, at 58.
50. 77 A. 405 (Me. 1910).
51. Tremblay, 77 A. at 408.
52. Id.
53. Id.
54. Id.
While the early twentieth century showed substantial reliance upon and confidence in the field of pharmacy, this responsibility has only recently begun to reappear in pharmacy litigation. For several decades following the Jones decision, courts denied the role of judgment in pharmacy, and cases were usually decided by whether the correct medicine was placed in the bottle. It was not until the early 1980s that the pharmacist's shield against expanded liability began to crack. Though the cases in the 1980s still held that the pharmacist had no general duty to warn, they began to cite early twentieth century cases such as Jones.

B. Standard of Care

Today, there appears to be a return to the prior common law, and it is no longer enough to get the right medication, in the right amount, to the right patient, with the right directions on the label. Fortunately, most practicing pharmacists accept this notion and embrace the act of counseling the patient. However, how far a pharmacist must go in fulfilling professional and legal duties to advise patients on the proper use of drugs remains undefined. Unfortunately, as with any profession, a standard of care cannot be easily expressed in regulations or by statute. The standard of care for professionals is usually a culmination of tradition, expert opinions, and court rulings. This standard of care is often summarily defined as the skill and intelligence that ordinarily characterizes the profession.

Allowing professional standards to dictate when pharmacists must warn eliminates the concept that pharmacists have no obli-

57. Docken v. Ciba-Geigy, 790 P.2d 45 (Or. Ct. App. 1990) (holding that whether a pharmacy has a duty to warn its customers of potential risks of prescription drugs is an issue to be answered by expert testimony as to the standard of care in the community).
58. Lasley v. Shrake's Country Club Pharmacy, 880 P.2d 1129, 1132-33 (Ariz. Ct. App. 1994). The Arizona Court of Appeals noted: Health care providers and other professionals are held to a higher standard of care than that of the ordinary prudent person when the alleged negligence involves the defendant's area of expertise. The standard is based on "the usual conduct of other members of the defendant's profession in similar circumstances." We impose this higher standard of care upon pharmacists because they are professionals in the health care arena.
gation for safe use of medications and that any information provided should be done on a voluntary basis. It also emphasizes that counseling patients is part of a pharmacist's required tasks. This standard of care approach to warning the patient would certainly be better for the profession, as well as the patients, because it positions the pharmacist as the primary source of drug advice.

IV. DUTY TO WARN CASES

Courts still generally hold that pharmacists do not have a general duty to warn. However, courts have developed many exceptions to this holding, such as (1) when the pharmacist has special knowledge regarding a patient, (2) examination of the prescription shows that the patient will be harmed if the drug is used as prescribed, (3) the pharmacist voluntarily undertakes the duty, or (4) the pharmacist induces the public to believe counseling will be provided. Modern courts are beginning to recognize that today's pharmacist plays a vital role in the health care system. Moreover, these same courts hold pharmacists to a professional standard of care. Under this modern approach, it is much easier for courts to create duties and impose liability on pharmacists, including liability for failure to warn.

A. Pennsylvania Cases

One of the first cases in the United States to impose a duty to warn on the pharmacist was a Pennsylvania case. Riff v. Morgan Pharmacy was one of the first judicial opinions since Jones to recognize an expanded role for pharmacists. A woman was given Cafergot® suppositories for the treatment of migraine headaches without being told of any limit to the use of the prescription. The doctor prescribed the suppository to be used every 4 hours and the pharmacist typed the directions exactly as the doctor prescribed. The patient used them exactly as the direction on the bottle read; however, she was not told that the suppository's use should be limited to two suppositories per headache or five per

59. Id. at 1132.
61. Lasley, 880 P.2d at 1132-33.
63. Riff, 508 A.2d 1247.
64. Id.
65. Id.
week. As a result, she had a toxic reaction to the suppository and subsequently sued both the doctor and pharmacist.\textsuperscript{66}

The pharmacy argued that it had filled the prescription in accordance with the doctor’s orders, that the patient had received the accurate medication and amount, and the pharmacy therefore was not liable to the patient. The Superior Court of Pennsylvania disagreed with this argument and stated that each member of the health care team “has a duty to be, to a limited extent, his brother’s keeper.”\textsuperscript{67} The court held that the pharmacy had breached its duty to warn the patient or notify the prescribing physician of the obvious inadequacies on the face of the prescription that created a substantial risk of serious harm to the patient.\textsuperscript{68} In reaching this conclusion, the court was careful to limit this duty to notification only.\textsuperscript{69} Furthermore, the court emphasized that the pharmacist has no duty to assume complete control of the patient’s drug therapy.\textsuperscript{70}

While some argue that \textit{Riff} opened the door for expanded legal responsibilities, others have used \textit{Riff} as a foundation to expand the practice of pharmacy further into the realm of patient care. After the court’s ruling in \textit{Riff}, many believed that it suggested that pharmacists in Pennsylvania now had an absolute duty to warn the patient. Many subsequent decisions by Pennsylvania courts, however, have suggested otherwise.\textsuperscript{71}

\begin{itemize}
\item \textsuperscript{66} \textit{Id.}
\item \textsuperscript{67} \textit{Id.} at 1253. The court supported this notion by stating: Fallibility is a condition of the human experience. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team.
\item \textsuperscript{68} \textit{Riff}, 508 A.2d at 1252.
\item \textsuperscript{69} \textit{Id.}
\item \textsuperscript{70} \textit{Id.} at 1251.
\item \textsuperscript{71} \textit{See} Mazur v. Merck & Co., 964 F.2d 1348 (3d Cir. 1992) (finding that Pennsylvania law does not impose an independent duty to warn patients of the risks of prescription drugs the pharmacists dispense); Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85 (E.D. Pa. 1986) (despite expert testimony and excerpts from the “Standards of Practice for Professional Pharmacy” recommending a duty to warn, public policy and jurisprudence compel the ruling that pharmacists are not under a general duty to warn customers of potential adverse effects of prescription drugs); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1989) (pharmacist has no duty to warn customer regarding risks associated with a prescription drug); White v. Weiner, 562 A.2d 378 (Pa. Super. Ct. 1989), aff’d, 583 A.2d 789 (Pa. 1991) (bulk supplier of pharmaceutical chemicals does not have the duty to warn the final manufacturer of the prescription drug of potential risks of that chemical, citing previous courts’ reluctance to extend a duty to warn to pharmacists and reiterating that the duty
B. Other States

Like Pennsylvania, other states across the country have struggled with the duty to warn issue. Most states continue to follow the general rule that pharmacists do not have a duty to warn. However, they have also started to define many circumstances where this general rule may not apply. For example, a Florida court recently held that a pharmacist had a duty to warn patients of the risks inherent in filling prescriptions that are not indicated for treatment of the patient or that duplicate other medications that the patient is already taking.

The Illinois Supreme Court ruled in Happel v. Wal-Mart Stores, Inc., that a pharmacy has a duty to warn a customer of a known drug contraindication when the pharmacy is aware of both a customer's drug allergies and that the prescribed drug is contraindi-
cated for a person with those allergies.\textsuperscript{76} By imposing this duty to warn on pharmacists, the court rejected the applicability of the learned intermediary doctrine in this factual situation.\textsuperscript{77} Instead of applying the learned intermediary doctrine in \textit{Happel}, the court reasoned that the doctrine is inapplicable when the pharmacy possesses both patient-specific medical information and knowledge of a contraindication.\textsuperscript{78}

In determining whether such a duty existed, the Illinois Supreme Court looked to several factors, including: "(1) the reasonable foreseeability that the defendant's conduct may injure another, (2) the likelihood of an injury occurring, (3) the magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendant."\textsuperscript{79} In applying these factors, the court held that because the pharmacy knew of both Happel's allergy and the medication's contraindication, it was foreseeable that failing to warn Happel or her doctor of the contraindication could result in injury or death.\textsuperscript{80} Moreover, the court reasoned that imposing a duty to warn on pharmacists recognizes that pharmacists often have a better opportunity to reduce medication-based risks.\textsuperscript{81}

Similarly, Tennessee courts have held that a pharmacist has a duty to warn.\textsuperscript{82} In \textit{Pittman v. Upjohn Co.}, the Supreme Court of Tennessee held that the subject pharmacy had a duty to warn based on standards of practice.\textsuperscript{83} The court noted that other pharmacies regularly made warnings when dispensing the same product.\textsuperscript{84} Additionally, in reaching its conclusion the court relied on the fact that the pharmacist was aware that the customer had not received a warning from her physician.\textsuperscript{85}

Because of the ambiguity in the case law in the Commonwealth and the other states throughout the country, it is clear that a Pennsylvania pharmacist may no longer rely on the general rule

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\textsuperscript{76} \textit{Happel}, 766 N.E.2d at 1120.
\textsuperscript{77} \textit{Id.} at 1130.
\textsuperscript{78} \textit{Id.}
\textsuperscript{79} \textit{Id.} at 1123-24.
\textsuperscript{80} \textit{Id.} at 1124.
\textsuperscript{81} \textit{Happel}, 766 N.E.2d at 1124.
\textsuperscript{82} \textit{Pittman v. UpJohn Co.}, 890 S.W.2d 425 (Tenn. 1994). See also \textit{Dooley v. Everett}, 805 S.W.2d 380 (Tenn. Ct. App. 1990) (issue of whether pharmacist had a duty to warn customer of potential drug interactions is a question of fact to be determined by a jury; pharmacists are judged according to the standard of care required by their profession).
\textsuperscript{83} \textit{Pittman}, 890 S.W.2d 425.
\textsuperscript{84} \textit{Id.} at 435.
\textsuperscript{85} \textit{Id.}
\end{flushleft}
that there is no duty to warn. Federal case law fails to clarify the instant matter. The cases available only serve to further blur the issue. As a result, a pharmacist in Pennsylvania should not practice under the premise that there is no duty to warn patients.

C. Federal Cases

The regulation of pharmacy practice is generally a power reserved to the states. The federal cases construing state law involving duty to warn issues, therefore, mirror the holdings found in many state cases. Unfortunately, because of the contradictory case law across the country, federal law fails to provide additional guidance to the issue at hand. Similar to the majority of states, the United States Court of Appeals for the Fifth Circuit, construing Texas law, has held that pharmacists do not have a duty to warn customers in Texas when physicians prescribe the wrong medicine.\(^{86}\) Moreover, federal courts have mirrored most states in holding that pharmacists voluntarily assume the duty to warn when they advertise to customers about special drug utilization review services.\(^{87}\) While federal cases may not provide the required assistance to determine the duties and liabilities of pharmacists in Pennsylvania, federal legislation may shed some light on the issue. As the pharmacy profession gains recognition and attention in the courts, the federal government has continued to place more emphasis on the role of the pharmacist, as is evident from recently implemented federal legislation.

V. IMPACT OF GOVERNMENT

Over the past twenty years, litigation involving the pharmacist’s duties to warn and counsel has significantly increased. As explained below, the federal government has responded by including practice guidelines for pharmacies in Federal Medicare and Medicaid assistance legislation. In the early 1990s, Congress began to recognize the improvement in care resulting from pharmacist consultation. As a result, it required all states to implement counseling requirements in order to receive funding for Medicaid patient prescriptions. This statute is referred to commonly as OBRA-90. More recently, Congress implemented the Medicare

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Part D program that was the first prescription drug coverage program made available for all Medicare recipients. External influences such as the OBRA-90 and Medicare Part D have forced attorneys and judges to rethink the traditional role of the pharmacist.

A. OBRA-90

The United States Congress expanded, both indirectly and directly, the duty of pharmacists through its enactment of drug use review provisions in the Omnibus Budget Reconciliation Act of 1990. The purpose of OBRA-90 is, in part, to “enhance the role of pharmacists in providing quality medical care, through a comprehensive drug utilization review program.” Under OBRA-90, the pharmacist is required to discuss with each person who presents a prescription matters that are significant in the pharmacist’s professional judgment, such as special directions and precautions for preparing, administering and using the drug, common severe or adverse effects or interactions, and contraindications.

The pharmacist must also make a reasonable effort to obtain a record and maintain the patient’s history, including known allergies, drug reactions and the medications taken.

Although OBRA-90 only applies to Medicaid patients, many commentators and courts see it as establishing a minimum standard of care for pharmacists. Furthermore, many states, including Pennsylvania, require pharmacists to undertake drug review activities for all drugs dispensed. In these states, pharmacists must offer counseling, similar to what is required under OBRA-90, to all patients.

At least one jurisdiction has imposed greater duties on pharmacists based upon a statute enacted after OBRA-90. Based on a variety of factors, the Supreme Court of Tennessee held that a


89. 42 U.S.C. § 1396r-8.

90. Id. § 1396r-8(g)(2)(a)(ii).

91. Id.


93. 42 U.S.C. § 1396r-8(g). Pharmacists must provide counseling for their customers about matters that in their professional judgment, are important, including: dosage and drug administration; precautions, side effects, adverse effects and interactions; and proper storage and refill information. Id.
pharmacist has a duty to warn patients of the dangers of the prescription drug dispensed by the pharmacist. 94 The court explained that although the standards promulgated by the state board of pharmacy pursuant to OBRA-90 did not establish the duty owed by a pharmacist, they provided guidance in determining that duty. 95 The court concluded that the pharmacist had a duty to warn the customer about the dangers of the prescription drug at issue, especially when the pharmacist knew that the physician had not warned the patient about the drug. 96

B. Medicare Part D

In general, Medicare Part D provides prescription drug benefits to everyone who is enrolled in Medicare, regardless of their income or the source of their health care or drug coverage. 97 Medicare Part D substantially affects a great number of Americans, and the federal government chose to utilize the pharmacist to obtain improved therapeutic outcomes for these many Americans. Under the Medicare Part D provisions, prescription drug plans are required to provide Medication Therapy Management (“MTM”) services for “targeted beneficiaries” who have multiple chronic diseases, multiple medications, and are likely to incur costs above a certain level. 98

MTM services are to be provided by health care professionals, such as pharmacists, and the services are to encompass a broad range of professional activities and responsibilities within the licensed pharmacist’s scope of practice. 99 The services include patient-specific and individualized services provided directly by a pharmacist to the patient. For providing the services, the phar-

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95. Pittman, 890 S.W.2d 425.
96. Id. at 435.
98. Id. See also Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/Medicare (last visited Oct. 12, 2006).
The pharmacist will receive payment based on time, clinical intensity, and resources required to provide the services. The liability potentially involved with providing these services has yet to be determined. As pharmacists in Pennsylvania begin to provide these services they must be mindful of the duty to warn. Even courts following the no duty to warn tradition may find pharmacists providing these services to have expanded duties. Furthermore, the Pennsylvania State Board of Pharmacy will likely set forth guidelines that will help define the expected standards of practice.

C. Current Pennsylvania Law

States regulate not only who may practice pharmacy and where it may be practiced, but also how pharmacy is practiced. Even though a state has promulgated a mandatory patient counseling regulation, a pharmacist will not necessarily be held civilly liable for failing to counsel patients. In Pennsylvania, the State Board of Pharmacy determines the standards of pharmacy practice. The counseling laws that Pennsylvania enacted following the mandate of OBRA-90 require records that indicate the type of care provided by a pharmacist. Under the State Board of Pharmacy Standards, a pharmacist must conduct a Prospective Drug Review ("PDR") and offer patient counseling with each new prescription.

The PDR requires that the pharmacist review a patient’s profile maintained in the pharmacy prior to dispensing medication to the patient. The offer to counsel must be made to each patient or caregiver when the pharmacist fills, delivers or sends a new retail or outpatient prescription.

The pharmacist should make a reasonable effort to obtain, record and maintain the following information about each patient: (i) the name, address, telephone number, date of birth and gender; (ii) individual history, if significant, including known allergies and drug reactions, and a list of medications and relevant devices, as provided by the patient or caregiver; and (iii) pharmacist comments relative to the individual’s therapy. Id. § 27.19(g).

If the patient or caregiver accepts...
counseling, the pharmacist is the only person who may provide counseling, and if the offer to counsel is rejected it must be documented and maintained for at least two years. Thus, during inspection, a state inspector can easily learn whether a patient was counseled and what information was conveyed to the patient. If there is no record that the pharmacist counseled the patient or made any recommendation to the doctor, it is assumed he failed to meet the standard of care.

Since the enactment of Pennsylvania’s state counseling laws, most pharmacies have conformed their conduct to meet these requirements. It is yet to be determined, however, whether these counseling laws have created a standard of practice that the courts will use to find a duty to warn. In *Ramirez v. Richardson-Merrell, Inc.*, the United States District Court for the Eastern District of Pennsylvania, applying Pennsylvania law, held that despite expert testimony and excerpts from the “Standards of Practice for Professional Pharmacy” recommending a duty to warn, public policy and jurisprudence compelled the ruling that pharmacists are not under a general duty to warn customers of potential adverse effects of prescription drugs. Although a majority of courts reject the notion that state counseling laws create a duty to warn, a minority of courts point to counseling laws as evidence that pharmacists have a duty to warn.

VI. THE PHARMACY PRACTICE

A. Assuming the Duty to Warn

Liability may also be based upon the pharmacist’s voluntary assumption of a duty. A pharmacy, like any other person or entity, may voluntarily assume a duty that would not otherwise be imposed on it, and thus may voluntarily assume a duty to provide

caregiver: (i) the name and description of the medication; (ii) the route of administration, dosage form and duration of drug therapy; (iii) special directions and precautions for preparation, administration and use by the patient; (iv) common severe side effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them, and the action required if they occur; (v) techniques for self-monitoring drug therapy; (vi) proper storage; (vii) prescription refill information; and (viii) action to be taken in the event of a missed dose. *Id.*

107. *See e.g.*, Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70 (Ga. Ct. App. 1997) (prior to the implementation of Board of Pharmacy regulations requiring pharmacists to counsel patients, pharmacists had no duty to warn about side effects associated with discontinued use of a prescription drug).
information, advice, or warnings to patients. Following this logic, one can conclude that most pharmacists already have a duty to warn. Rare are the pharmacies that do not offer screening for drug interactions or contraindications. Most pharmacies today are equipped with intricate software programs that provide automatic screening of each patient's profile. Every prescription entered into the system is crosschecked against the patient's allergies, disease states, and other medications. With technology such as this in place, it is hard to imagine how pharmacies have not already assumed the duty to warn patients. States that have been faced with cases where a pharmacist has advertised services or utilized these computer systems have consistently ruled that the pharmacist assumed the duty to warn. In addition to new technology, other advancements may also indicate assumption of a duty. For example, the decision to implement heightened education requirements for pharmacists may induce a court to raise its expectations regarding the duties of a pharmacist.

B. The Doctor of Pharmacy Degree and Pharmacists' Enhanced Abilities

In a study conducted prior to the countrywide shift to the Doctor of Pharmacy degree, approximately one third of the pharmacists tested were unaware of the seriousness of the interacting combinations present in the study. Studies such as this indicated that the pharmacy profession as a whole was not ready to assume the duty to warn. In the late 1990s, most pharmacy schools across the country switched to the mandatory Doctor of Pharmacy ("PharmD") degree program. The PharmD degree has added a

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110. Sanderson v. Eckerd Corp., 780 So.2d 930 (Fla. Dist. Ct. App. 2001) (pharmacy that advertised a promise that its computer system would detect and warn customers of adverse drug reactions and interactions voluntarily assumed a duty to warn, the scope of which was measured by the level of care and skill which, in light of all relevant circumstances, is recognized as acceptable and appropriate by other reasonably prudent pharmacists); Baker v. Arbor Drugs, Inc., 544 N.W.2d 727 (Mich. Ct. App. 1996) (a pharmacy, which implemented and advertised a computer system designed to detect harmful drug interactions, voluntarily assumed a duty to operate the system with due care); Ferguson v. Williams, 374 S.E.2d 438 (N.C. Ct. App. 1988), appeal after remand, 399 S.E.2d 389 (N.C. Ct. App. 1991) (holding even though a pharmacist has no general duty to warn a customer about potential risks, a pharmacist who undertakes to advise a client concerning a medication has a duty to give correct advice).
substantial amount of clinical and practical experience to the course load. Today's graduating students spend countless credit hours reviewing drug interactions, contraindications, suboptimal therapy, missed opportunities, side effects, and much more. This substantial increase in training that a graduating student receives will surely influence both the boards of pharmacy and the courts to continue to place more responsibility on the pharmacist. Naturally, the duty to warn comes with this increased responsibility.

C. Expansion of Pharmacy

As the practice of pharmacy continues to expand, so too will the evolution of the clinical pharmacist. Historically, clinical pharmacy was centered on the pharmacist ensuring that the patient was aware of the doctor's orders and was adhering to them. Today, the clinical pharmacist provides services well beyond just warning patients and ensuring that they heed their doctor's advice. The clinical practitioners interview patients and explain the importance of drug therapy. They also work with physicians during rounds and help make decisions on therapeutic alternatives. This increased collaboration with doctors and involvement with patients has produced a new approach to pharmacy practice known as pharmaceutical care.

D. Pharmaceutical Care

The pharmaceutical care model includes pharmacists that encourage patients to assume responsibility for drug therapy within the framework of their own lifestyles, values, and environmental factors. This model represents a shift in pharmacy practice to focusing on the patient's needs instead of only the doctor's orders. Pharmacists and doctors alike have embraced pharmaceutical care, and it has given way to substantial improvements in patient outcomes. With this newfound autonomy, a career as a pharma-

112. Clinical Pharmacy is a commonly used term in pharmacy practice and literature. It is a health specialty, which describes the activities and services of the clinical pharmacist to develop and promote the rational and appropriate use of medicinal products and devices. Clinical Pharmacy includes all the services performed by pharmacists practicing in hospitals, community pharmacies, nursing homes, home-based care services, clinics and any other setting where medicines are prescribed and used. The American Pharmacy Association, Definition of Clinical Pharmacy as a Specialty in Clinical Practice, 19(2) THE ANNALS OF PHARMACOTHERAPY 149, 149-50 (1985).
113. ABOOD, supra note 1, at 324.
114. Id.
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Pharmacist is becoming more exciting, more fulfilling, and more challenging than ever before. However, with this autonomy there must also be responsibility, which in turn, gives rise to liability. As courts continue to recognize the importance of the pharmacist, they will continue to increase the pharmacist's exposure to liability. As this occurs in Pennsylvania, it is important that pharmacists view the increase in liability as an opportunity to better serve their patients, rather than a restriction on their ability to do their job free from limitations.

For example, some of the pharmacy-related programs currently being implemented or considered by independent, chain, and hospital pharmacists in Pennsylvania are the following: (1) Medication Therapy Management under Medicare Part D; (2) pharmacist immunization certifications and clinics; (3) pharmacist oversight of the distribution of Psuedoephendrine and emergency contraceptives; (4) “Ask the Pharmacist” or “Brown-Bag” programs; (5) pharmacies with in-house nurse practitioners available to see patients; and (6) potential prescribing rights for pharmacists. These programs are an indication of the expanding role the pharmacist is establishing in health care. If pharmacists wish to continue to participate in programs such as these and implement others, they must be willing to accept the increase in liability that will prove beneficial to both the public and the profession of pharmacy.

E. Improvements for Pharmacy Practice

Imposing a duty to warn on pharmacists in Pennsylvania will continually improve patient involvement in their treatment and the outcomes that they receive. This progressive improvement may potentially lead to monumental advancements in the field of pharmacy. For example, “fee for service” programs may actually become a reality that will ultimately increase, not only pharmacy pay, but also job satisfaction. Moreover, the duty to warn will ultimately increase patient counseling, and that would lead to the reduction in monotonous job tasks that pharmacists often criticize.

VII. CONCLUSION

As pharmacies continue to expand their services and pharmacists continue to further their education, it is unlikely that courts in this Commonwealth will continue to find no duty to warn. Regardless of the learned intermediary doctrine, the physician-patient relationship, and “public policy,” pharmacists in Pennsylvania must remain mindful of the duty to warn. Despite the con-
trary case law in Pennsylvania and in most states throughout the country, no pharmacist should continue to practice under the premise that he has no duty to warn patients about their prescription medications. Put simply, the practice of pharmacy is growing at an exponential rate, and it will take some time for legislatures and courts to catch up; but when the law does, pharmacists must be prepared to accept this liability, and attorneys must be ready to advise them. Fortunately, most pharmacists throughout the Commonwealth are already ahead of the law and will continue to include meaningful patient consultations in their job description. Despite immense pressure to practice error free in a highly time-sensitive fashion, Pennsylvania pharmacists must continue to maintain the highest standards possible in regards to warning patients. Practicing beyond the requirements of current case law will help to ensure that the pharmacist remains one of the most respected and trusted professionals in this Commonwealth and throughout the country.

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