

2009

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Recommended Citation

Kimberly A. Bruns & Alan R. Spies, *A Pharmacist's Duty to Warn: Promoting the Acceptance of a Consistent Legal and Professional Standard*, 47 Duq. L. Rev. 1 (2009).

Available at: <https://dsc.duq.edu/dlr/vol47/iss1/2>

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A Pharmacist's Duty to Warn: Promoting the Acceptance of a Consistent Legal and Professional Standard

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INTRODUCTION

For over two decades, published case law from state courts across the country have been addressing the issue of whether a pharmacist has a duty to warn patients about the potential dangers and adverse effects associated with prescription drugs.¹ Even after decades of appellate court decisions, the issue of a pharma-

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1. See NATIONAL ASSOCIATION OF CHAIN DRUG STORES, *Pharmacists' Duty to Warn, Lawsuits Claiming That Pharmacists Must Warn Customers About Dangers Associated With Prescription Drugs*, http://www.nacds.org/user-assets/pdfs/gov_affairs/dutytowarn.pdf (last visited April 4, 2008) [hereinafter NACDS Duty to Warn].

cist's duty to warn is still unsettled.² As the evolution of a pharmacist's duty to warn continues to provide legal inconsistencies among various state courts, there continues to be no clear guidance for the pharmacy profession as to exactly what legal responsibilities a pharmacist has in warning patients.³

In addition to state courts providing inconsistent legal standards regarding a pharmacist's duty to warn, the profession of pharmacy has also failed to publicly agree and work towards the acceptance and implementation of a consistent professional duty-to-warn standard.⁴ This failure is especially troubling, given today's practice environment where pharmacies and pharmacists emphasize now, more than ever, their specialized drug knowledge, advocating for additional responsibilities that extend beyond simply dispensing.⁵ Furthermore, pharmacists are now recognized as patient educators who discuss drug therapies with patients and other health care professionals, helping to assure the appropriateness of prescribed medications.⁶

To help resolve the legal uncertainties surrounding a pharmacist's duty to warn, a solution needs to be reached and adopted by state courts and the profession. This article proposes a number of changes that the authors consider important steps in reaching a reasonable and realistic duty-to-warn standard that will hopefully be used as guidance by state courts in future duty-to-warn civil litigation and supported by the profession of pharmacy. Specifically, this article recommends that state courts should first recognize that pharmacists do have a duty to warn. Then, in determining if a pharmacist breached that duty, a consistent standard of care should be applied. Equally important, as pharmacists continue to expand their professional role, the profession of pharmacy should also accept that with this expansion comes additional responsibilities, including a duty to warn. As such, necessary re-

2. *Id.* (describing how the state courts have various interpretations of a pharmacist's duty to warn and providing examples of appellate court decisions that continue to differ on if and when a pharmacist has a duty to warn).

3. See discussion *infra* Part II and III; David B. Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. LEGAL MED. 475, 509 (1997) (providing that courts of law have disagreed about the abilities of pharmacists to assist patients; the relationships between pharmacists, patients, and physicians; and the policy implications of expanded pharmacist responsibility which has led to a conflicting body of law that lacks cohesive expression of standards on which patients and pharmacists can base their expectations for each other).

4. See *infra* notes 93-116 and accompanying text.

5. See Fred Gebhart, *Here Comes the Judge*, Drug Topics, Vol. 149 No. 2, Jan. 24, 2005, at 30.

6. Brushwood, *supra* note 3, at 475.

sources are required to move towards a consistent professional standard.

Part I of this article reviews the background of the pharmacists' duty to warn. Part II discusses various duty-to-warn cases that highlight the legal inconsistencies that have continued to confuse the pharmacy profession. Part III of this article proposes the recognition of a duty to warn, as well as a duty-to-warn standard that can be met by pharmacists and promoted by the profession. Part IV concludes that the time is now to advance towards a consistent legal and professional standard regarding the pharmacists' duty to warn.

I. THE PHARMACISTS' DUTY TO WARN

Traditionally, malpractice actions against pharmacists were based solely on alleged inaccuracy in filling a prescription.⁷ However, in recent decades, the focus of the profession of pharmacy has shifted from that of a product-centered profession to a patient-centered profession. The profession has adopted the pharmaceutical-care standard that seeks more pharmacist involvement in patient care in order to achieve definite outcomes and to improve a patient's quality of life.⁸

The passage of the Omnibus Budget Reconciliation Act of 1990, also known as OBRA 90, significantly expanded the services that pharmacists were required to provide to patients.⁹ OBRA 90 recognized that a public expectation of pharmacists went beyond oversight of drug distribution to include the detection and resolution of problems with drug therapy, as well as minimum patient counseling standards.¹⁰ OBRA 90 was a federal law that required states to adopt expanded standards of pharmacy practice if they

7. See David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 2-3, 22 (1991); R. Paul Asbury, see also *Pharmacist Liability: The Doors of Litigation are Opening*, 40 SANTA CLARA L. REV. 907-08, 927 (2000).

8. ROBERT A. BUERKI & LOUIS D. VOTTERO, AMERICAN INSTITUTE OF HISTORY OF PHARMACY, *ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE* 21-22 (2d ed. 2002); see also Jennifer L. Smith, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2 HOUSE J. HEALTH L. & POL'Y 187, 201, 221-22 (2002) (defining pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" and explaining how the pharmaceutical care concept embraces the professionalism of pharmacists by expanding their role beyond dispensing to include drug therapy, disease management, patient counseling, and an overall outcome-oriented approach).

9. OBRA 90, 42 U.S.C. § 1396r-8(g) (2008).

10. RICHARD ABOOD, *PHARMACY PRACTICE AND THE LAW* 228, 231 (Jack Bruggeman ed., Jones and Bartlett 4th ed. 2005).

wanted to continue to receive Medicaid funds.¹¹ Although states were mandated by federal law to only expand pharmacy practice standards for prescription drugs dispensed to Medicaid patients, most states implemented the standards to be applicable to prescription drugs dispensed to all patients.¹² In particular, OBRA 90 requires pharmacists to screen prescriptions for potential drug therapy problems; offer counseling to patients or their caregivers in matters that, in the pharmacist's professional judgment, are deemed significant to the proper use of the product and how to manage potential problems that may arise; and maintain a written record of individual patient histories that includes disease states and known allergies.¹³

In addition to OBRA 90, other actions have recognized that pharmacist capabilities extend beyond the responsibility of drug distribution and technical accuracy. One such example is how many individual states have passed legislation allowing for the further expansion of state-licensed pharmacists' roles to include areas involving prescriptive authority and drug therapy management.¹⁴ Another example is the Medicare Modernization Act, through which the federal government recognized that pharmacists can be utilized to help obtain improved therapeutic outcomes by providing Medication Therapy Management Services.¹⁵

Overall, as a result of multiple factors, the practice of pharmacy has "evolved into much more than mechanical dispensing of medication."¹⁶ Likewise, as the pharmacists' role has continued to expand, the potential for imposition of professional and regulatory liability has subsequently increased.¹⁷ One particular area of malpractice litigation that has continued to evolve as the pharmacists'

11. *Id.* at 228-29.

12. Smith, *supra* note 8, at 209 (explaining that although OBRA 90 applied to Medicaid beneficiaries, most states passed legislation extending the requirements to all patients); Brushwood, *supra* note 3, at 485-86 (discussing in detail the OBRA 90 mandate and how federal guidelines allowed for state variances and how pharmacists must comply with the state version).

13. 42 U.S.C. § 1396r-8(g)(2)(A)(i-ii).

14. Smith, *supra* note 8, at 200-02.

15. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173 117 Stat. 2066; *see also* Robert A. Gallagher, *Pennsylvania Pharmacists Should No Longer Assume That They Have No Duty to Warn*, 45 DUQ. L. REV. 59, 76-77 (2006) (discussing how Medicare Part D has provisions for Medication Therapy Management Services which can be provided by health care professionals such as pharmacists).

16. Smith, *supra* note 8, at 204.

17. Asbury, *supra* note 7, at 907 ("Today, pharmacists take on a more active role in the health care system, encompassing more responsibilities and consequently greater liabilities").

role in health care has expanded is with duty-to-warn cases.¹⁸ Under this theory of liability, patients injured by prescription drugs claim that the pharmacist had a duty to warn about the potential adverse effects and other dangers associated with prescription drugs.¹⁹ With these types of cases, courts have been faced with the question of when—and to what extent—a pharmacist owes a duty to patients to warn of the dangers involved with a particular drug therapy.²⁰

The majority of jurisdictions that have addressed the duty-to-warn issue have held that there is no general duty for pharmacists to warn patients about their prescribed drugs.²¹ These cases reveal three theories relied upon by courts to support the view that pharmacists do not have a general duty to warn. These theories include: (1) interference with the physician-patient relationship, (2) violation of the learned intermediary doctrine, and (3) that the imposition of liability would contradict public policy.²²

In determining that pharmacists do not have a general duty to warn, numerous courts have based their holdings on the fact that to do otherwise would cause interference with the physician-patient relationship.²³ Courts have reasoned that pharmacists

18. Asbury, *supra* note 7, at 928 (relying on the legislative mandate of OBRA 90 and an expanded view of pharmacists' duty, a number of courts have found pharmacists liable for failing to warn of the inherent risks of drugs); James Barney, *Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists' Duty to Warn*, 39 GONZ. L. REV. 399, 410 (2004) ("The movement to establish a pharmacist's duty to warn quite possibly began with the passage of the Omnibus Budget Reconciliation Act of 1990."); Jaclyn Casey, *Prescription for Compromise: Maintaining Adequate Pharmacist Care Contraindicates Imposition of a General Duty to Warn*, 17 WASH. U. J.L. & POL'Y 287, 311 (2005) ("The pharmacists' role in the health care industry continues to evolve as does the imposition of liability on pharmacists for failure to warn patients of the adverse effects of prescription drugs").

19. See NACDS Duty to Warn, *supra* note 1, at 1.

20. Smith, *supra* note 8, at 192.

21. See NACDS Duty to Warn, *supra* note 1, at 1; see also Smith, *supra* note 8, at 196-200 (discussing cases in which the court found a pharmacist has no duty to warn); Barney, *supra* note 18, at 406 (noting that though courts do not generally recognize claims against pharmacists for failing to warn, courts have drawn a distinction between a pharmacist's duty to warn of potentially negative side effects and the duty to warn of potentially adverse drug interactions).

22. Smith, *supra* note 8, at 193-96 (discussing the three theories supporting the pharmacists' no duty to warn rule); see also Brian L. Porto, Annotation, *Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug*, 79 A.L.R. 5th 409 (2006) (providing that courts have cited several reasons for not requiring pharmacists to warn about potential drug interactions, including: (1) pharmacists are not obliged to intervene in physicians' prescription decisions; (2) the duty to warn about potential drug interactions should belong only to physicians; and (3) it would be burdensome and against public policy to impose such a duty on pharmacists).

23. Casey, *supra* note 18, at 308 n.143 (providing case examples that have expressed this concern).

would need access to patient medical records in addition to learning the patient's medical condition before they could properly warn a patient of the effects of a prescription drug, and that this required access would inappropriately place the pharmacist in the middle of the physician-patient relationship.²⁴ Other courts have reasoned that to place a duty to warn on pharmacists would cause pharmacists attempting to avoid liability to second-guess each physician's prescription, disrupting the physician-patient relationship.²⁵

In addition, other courts have held that pharmacists do not have a duty to warn based on the learned-intermediary doctrine.²⁶ This doctrine is derived from the theory that drug manufacturers have a duty to inform physicians of the dangers of prescription drugs, and that the physicians are in the best position to choose the appropriate medication and advise patients of the inherent risks of treatment.²⁷ When courts extend the learned-intermediary doctrine to lawsuits against pharmacists, it insulates pharmacists from liability and places upon prescribing physicians the responsibility of warning patients of the potential risks of prescription drugs.²⁸

Numerous other courts have also determined that pharmacists do not have a duty to warn because it would contradict public policy.²⁹ Some courts have reasoned that to place a duty to warn on pharmacists would burden the profession and expand the liability of pharmacists.³⁰ Other courts have reasoned that numerous or serious warnings provided by the pharmacist might frighten and confuse patients, causing them to refrain from taking the medication as prescribed, which could potentially endanger their health.³¹

24. See Edward Casmere, *RX for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule*, 33 J. MARSHALL L. REV. 425, 438 (2000).

25. *Id.* at 438-39.

26. Smith, *supra* note 8, at 194 n.45 (providing case examples that have extended the learned intermediary doctrine to pharmacists).

27. Asbury, *supra* note 7, at 913; see, e.g., Casey, *supra* note 18, at 291-98 (providing the policy reasons supporting the learned intermediary doctrine as a defense for pharmacists, including how it has traditionally shielded drug manufacturers from liability based on the premise that warnings regarding the drug are provided in the product labeling to the physician who in turn is in the best position to convey the warnings to the patient).

28. Asbury, *supra* note 7, at 912.

29. Smith, *supra* note 8 at 195 n.54 (providing case examples that have expressed this concern).

30. Casmere, *supra* note 24 at, 440; Smith, *supra* note 8, at 219.

31. Smith, *supra* note 8, at 195.

Although most courts have found that a pharmacist does not have a general duty to warn, there has been a modern litigation trend that continues to find ways to hold pharmacists liable for their failure to warn patients.³² A number of states have demonstrated a willingness to recognize that pharmacists do have a duty to warn, while other states have recognized a duty to warn under limited circumstances.³³ Courts in the minority of states that have determined that pharmacists have a duty to warn have either relied on the duty-of-reasonable-care standard, the counseling laws under OBRA 90, or rejection of the learned-intermediary doctrine.³⁴ Furthermore, a number of jurisdictions that follow the majority view, which states that pharmacists do not have a general duty to warn, have found exceptions under limited circumstances, including when obvious inadequacies or clear errors exist on the prescription; when the pharmacist voluntarily assumes the duty; and when the pharmacist has special knowledge regarding a patient.³⁵

Currently, in trying to assess if and when a pharmacist could be negligent for failing to warn a patient, one might notice that an essential factor to consider is in which state(s) the pharmacist is licensed to practice. With the practice of pharmacy being regulated by each individual state, so is the determination of whether a pharmacist has a duty to warn, and under what circumstances.³⁶ Unfortunately, what has evolved is a state-specific duty-to-warn standard for pharmacists that varies greatly among the states that have addressed the issue.

32. Casey, *supra* note 18, at 287, 311; Barney, *supra* note 18, at 401.

33. Smith, *supra* note 8, at 204 ("A number of courts are demonstrating a willingness to recognize the contemporary role of the pharmacy profession when addressing the issue of a pharmacist's duty to warn"); Barney, *supra* note 18, at 410 ("A number of courts have recently held that pharmacists have a duty to warn in certain limited circumstances").

34. For a general discussion on this issue and specific case examples illustrating when pharmacists have been held to have a duty to warn, see NACDS Duty to Warn, *supra* note 1 (providing a list of duty to warn cases by state); Casey, *supra* note 18, at 299-306 (discussing cases where courts have imposed a duty to warn and under what reasoning); Smith, *supra* note 8, at 204-11 (discussing cases where courts have demonstrated a willingness to recognize a pharmacist's duty to warn); Barney, *supra* note 18, at 407-12 (discussing cases that have found a duty to warn and under what theory).

35. See sources cited *supra* note 34. For a recent case that extended the learned intermediary doctrine to pharmacists and provided a list of limited circumstances when pharmacists would have a duty to warn, see *Deed v. Walgreens*, No. CV030823651S, 2004 WL 2943271 (Conn. Super. Ct. 2004).

36. Jesse C. Vivian, *Procedural Aspects of the Learned-Intermediary Doctrine*, U.S. Pharm., Vol. 29 No. 05, May, 2004, at 88, available at http://www.uspharmacist.com/index.asp?show=article&page=8_1269.htm (accessed April 20, 2008).

II. LEGAL INCONSISTENCIES

The issue of whether or not a pharmacist owes a duty to warn has been the subject of constant struggle for state and federal courts for many years. A ruling in which pharmacists were deemed to have "no duty" to warn of adverse drug effects was common among pharmacist malpractice appellate opinions of the 1980s.³⁷ Beginning in the early 1990s, a trend emerged adopting a different view, a view based on the description of duty provided in Prosser's hornbook on torts.³⁸ Specifically, Prosser states that the existence of a duty depends on the character of the relationship between the two parties rather than the nature of the actions those parties undertake.³⁹ Imposing a no-duty-to-warn rule forces the following issue to be addressed by the courts: "whether it is proper for courts to hold that no duty exists without inquiring into the relationship between the parties."⁴⁰ As noted below with the following cases, there is still much inconsistency as the courts wrestle with how to interpret the pharmacists' duty to warn.

Many state court decisions have held that pharmacists do not have a general duty to warn. For example, in *Sanks v. Parke-Davis*, a patient received a prescription for Rezulin, a medication used to treat diabetes that has since been withdrawn from the market.⁴¹ The prescription was taken to Eufaula Drugs, where it was correctly filled. In her complaint, the plaintiff, Sanks, alleged that the ingestion of Rezulin caused extensive liver damage, pain and suffering, and mental anguish. She further asserted that Eufaula Drugs did not warn her about Rezulin's potentially life-threatening side effects. Under the controlling Alabama law, however, a pharmacy or pharmacist who correctly fills a prescription in strict accordance with the prescribing physician's directions is protected by the learned-intermediary doctrine and is not required to warn patients of potentially adverse side effects.⁴² According to Sanks, a Eufaula Drugs pharmacist told her that

37. Brushwood, *supra* note 3, at 494.

38. W. PROSSER & W. KEETON, *THE LAW OF TORTS* (5th ed. 1984).

39. Brushwood, *supra* note 3, at 495.

40. Casmere, *supra* note 24, at 448.

41. *Sanks v. Parke-Davis*, No. 00-S-1122-E, 2000 WL 33910097 (M.D. Ala. 2000).

42. See *Lansdell v. American Home Prods.*, No. 99-S-2110-NE, 1999 U.S. Dist. LEXIS 22540 (N.D. Ala. 1999) (dismissing claims against pharmacist based on the learned intermediary doctrine based upon implicit holding of *Stafford v. Nipp*, 502 So.2d 702 (Ala. 1987)); see also, *Harrell v. Wyeth-Ayerst Lab. Inc.*, No. Civ.A. 98-1194BHM, 1999 WL 33548540 (S.D. Ala. 1999); *Orr v. Wyeth-Ayerst Lab. Co.*, No. CV-98-3000-DIET, 1999 WL 33548162 (Ala. Cir. Ct. 1999).

Rezulin did not have any side effects. Sanks appeared to argue that her interaction with the pharmacist demonstrated that Eufaula Drugs breached a voluntarily assumed duty to warn her about Rezulin's safety. The court, however, found this argument unpersuasive because Sanks did not establish that the pharmacist assumed a duty to warn. The crux of Sanks's argument was that, despite knowledge to the contrary, the pharmacist failed to warn her of the danger when he responded negatively to her questions about Rezulin's safety. The court disagreed by holding that a response to an inquiry was not the same as "volunteering" to act.⁴³

In *Morgan v. Wal-Mart Stores, Inc.*,⁴⁴ the patient's mother, Morgan, testified that when she went to Wal-Mart to pick up her son's medication, she "walked in and asked for the prescription for Cameron. And the checkout person gave [her] the prescription and charged [her] the money for it and [she] left and went home."⁴⁵ The parties stipulated that no Wal-Mart pharmacist orally counseled Morgan about Desipramine's possible side effects. They also agreed that Wal-Mart did not give Morgan the drug manufacturer's package insert, which contained substantial technical information about Desipramine, including warnings of potentially adverse reactions. Pursuant to valid prescriptions from Dr. Schroeder, the patient's physician, Morgan purchased Desipramine three more times at Wal-Mart, the last time in February 1993. Morgan testified that at no time did a Wal-Mart pharmacist advise her of anything with respect to the drug. After taking the medication for a lengthy period of time, the patient developed and died from hypereosinophilic syndrome, a multi-system disease affecting the liver, kidney, and central nervous system.

In their complaint, the plaintiffs alleged that Wal-Mart was negligent in the sale of Desipramine "by failing to properly warn intended users of the hazards and harms associated with the use of the product."⁴⁶ The court disagreed and held that, while administrative rules demonstrate that pharmacists in Texas are trusted professionals with varied and important responsibilities, "they cannot be reasonably read to impose a legal duty to warn

43. See *Sanks*, *supra* note 41, at 15.

44. *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455 (Tex. App. 2000).

45. *Id.* at 457.

46. *Id.* at 460.

patients of the adverse effects of prescription drugs.⁴⁷ It continued:

The imposition of a generalized duty to warn would unnecessarily interfere with the relationship between physician and patient by compelling pharmacists seeking to escape liability to question the propriety of every prescription they fill. . . . Furthermore, a patient faced with an overwhelming number of warnings from his or her pharmacist may decide not to take a medication prescribed by a physician, who has greater access to and knowledge of the patient's complete medical history and current condition than the pharmacist. Instead of imposing such an onerous and counter-productive duty, the administrative rules reinforce the notion that although pharmacists act as final auditors of the technical accuracy of a prescription and its appropriateness with respect to a patient's known condition and medication record, they do not possess the extensive knowledge of a physician with respect to a patient's complete medical history and are thus not legally obligated to warn a patient of adverse drug reactions.⁴⁸

In *Podgurski v. U.S.*,⁴⁹ however, the court held that a pharmacist has a limited duty to warn a customer about a physician's prescription if, for instance, the prescribed medication is obviously fatal or the dosage is unusual.⁵⁰ Thus, a pharmacist in Maryland does owe a duty to patients, but only under limited circumstances. In this case, Podgurski had her prescription filled at the NeighborCare pharmacy, where she previously had prescriptions filled. As part of NeighborCare's standard operations, new customers completed patient profiles that were maintained on the pharmacy's computer system. In the allergy section of Podgurski's patient profile, no warning appeared on the

47. *Id.* at 467.

48. *Morgan*, 30 S.W.3d at 467. See, e.g., Tex. Occ. Code Ann. § 157.001 (West 2000) (physician may delegate to pharmacist acting under physician's supervision the performance of specific acts of drug therapy management); Tex. Admin. Code § 291.33(b)(2)(B)(i) (pharmacists may provide drug therapy management as delegated by a physician).

49. *Podgurski v. U.S.*, No. Civ.CCB-03-3180, 2005 WL 2338851, (D. Md. 2005).

50. See *Moore v. Wyeth-Ayerst Labs.*, 236 F.Supp.2d 509, 512-13 (D. Md. 2002) (citing *People's Service Drug Stores v. Sommerville*, 161 Md. 662, 158 A. 12, 13 (Md. 1932)). See also *Rite Aid Corp. v. Levy-Gray*, 876 A.2d 115, 123, 162 Md. App. 673 (Md. App. 2005) (citing cases but affirming liability on express warranty theory).

pharmacist's computer screen when the Keflex prescription was filled. Neither of Podgurski's adult children had spoken to anyone at NeighborCare about their mother's allergy history nor had they any knowledge of Podgurski telling NeighborCare about her allergy history. After the patient ingested the medication, she immediately experienced an anaphylactic reaction and subsequently died. In finding for the defendant pharmacy, the court reasoned that the plaintiffs did not demonstrate that NeighborCare knew or should have known that Podgurski had an allergy to penicillin; thus, no duty to warn was present.⁵¹

The issue of foreseeability was raised in *Happel v. Wal-Mart Stores, Inc.*⁵² In *Happel*, the patient was prescribed Toradol. Prior to receiving this prescription, Heidi, the patient, had been to the Wal-Mart pharmacy about six times to have other prescriptions filled. Each time she went, pharmacy workers asked her if she had any drug allergies, and each time she told them she was allergic to aspirin, acetaminophen, and ibuprofen. A Wal-Mart pharmacy manager testified in his deposition that it was the pharmacy's policy and procedure to ask customers about their known allergies prior to dispensing medication. The purpose of this practice was to alert the pharmacist to any drug interactions or allergies. Both of the defendant's pharmacists testified that Heidi's allergy information was in the pharmacy's computer system and available to pharmacists when Heidi's Toradol prescription was filled. If the Toradol information had been in the pharmacy's computer, a "drug interaction" warning should have flashed across the screen, halting the prescription process for customers for whom Toradol was contraindicated. In that event, the pharmacist should have called the physician to report the contraindication. In Heidi's case, however, the pharmacist did not remember calling Dr. Lorenc about the prescription nor did she remember seeing any documentation indicating that she made such a call.

Once Heidi learned that the prescription had been called in to the Wal-Mart pharmacy, she telephoned her husband, Kent, at work, and asked him to pick it up. Prior to that time, neither she nor Kent had ever heard of Toradol, which is a non-steroidal anti-inflammatory drug (NSAID), similar to aspirin. Kent went to the pharmacy to pick up the prescription, but before it was filled, a

51. *Podgurski*, No. Civ.CCB-03-3180, at *8.

52. *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118 (Ill. 2002).

pharmacy worker asked him about Heidi's drug allergies. Kent informed the worker that Heidi was allergic to aspirin, ibuprofen, and acetaminophen.

There were directions on the bottle that Heidi received from the pharmacy, but there was no warning about contraindications. Heidi took the first dose of Toradol and, within forty minutes, she began to experience respiratory problems, including tightness in her chest. She began a breathing treatment with a nebulizer and called the pharmacy to ask if she could be having a reaction to Toradol. Her call was disconnected. She called again and was told that there should be no drug reaction problem. Heidi then called a friend who was a pharmacist and was aware of her allergies. He told her to begin a nebulizer treatment if she had not already done so and to go to the emergency room if her condition worsened. She went to the emergency room and was found to be experiencing anaphylactic shock. Heidi testified in her deposition that, as a result of taking Toradol, she subsequently experienced more frequent asthma attacks, as well as seizures and a worsening of her multiple sclerosis.

In finding for the plaintiff, the court found that the pharmacist owed a narrow duty to warn the patient. Specifically, the court stated:

A narrow duty to warn exists where, as in the instant case, a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger.⁵³

A duty to warn was also recognized by the court in *Horner v. Spalitto*.⁵⁴ Peter Spalitto was the pharmacist on duty at Anthony Spalitto's pharmacy and filled two prescriptions presented by Horner. One prescription was for a quantity of fifty, 750 milligram (mg) doses of Placidyl, a strong hypnotic drug. The prescribing physician instructed on the prescription that Horner was to take one dose every eight hours. The other prescription was for a quantity of fifty, 10 mg doses of Diazepam, a central nervous system depressant, and it instructed Horner to take one dose every eight hours. Before filling the prescriptions, Spalitto

53. *Happel*, 766 N.E.2d at 1129.

54. *Horner v. Spalitto*, 1 S.W.3d 519 (Mo. Ct. App. 1999).

consulted *Facts and Comparisons*, an authoritative pharmacy manual, which indicated that the normal dose for Placidyl was one 500 mg dose or one 750 mg dose before bedtime. The manual also warned that the drug's effects were enhanced when combined with other central nervous system drugs, such as Diazepam. Concerned about the physician's ordering such a high dose of Placidyl, Peter Spalitto telephoned the prescribing doctor's office. He later testified that someone in the physician's office told him that the prescription was "okay" because Horner "needed to be sedated throughout the day." Peter Spalitto filled the two prescriptions. Several days later, Horner died due to toxic effects of the prescription medicines. In finding for the plaintiff, the court held that accurately filling a prescription may be a pharmacist's only duty in particular cases, but in other cases, "a pharmacist's education and expertise will require that he or she do more to help protect their patrons from risks which pharmacists can reasonably foresee."⁵⁵ The court determined that the factfinder must decide what this duty requires of a pharmacist in a particular case.⁵⁶ The court noted that a pharmacist, as is the case with every other professional, must "exercise the care and prudence which a reasonably careful and prudent pharmacist would exercise."⁵⁷

The court in *Dooley v. Everett*⁵⁸ also found that a duty to warn could arise and went further in stating that pharmacists are judged according to the standard of care required by their profession.⁵⁹ However, it has been as difficult for the pharmacy profession to determine this standard of care as it has the courts. The National Association of Boards of Pharmacy (NABP), for example, has advocated for the elimination of the no-duty-to-warn rule.⁶⁰ The NABP has gone further in asserting that "excusing pharmacists from a duty to warn causes pharmacists to ignore their education, professional training, and the standards of practice established by the pharmacy profession."⁶¹ At least one state pharmacy association agrees with this position as well.⁶²

55. *Horner*, 1 S.W.3d at 522.

56. *Id.*

57. *Id.*

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

59. *Dooley*, 805 S.W.2d at 385.

60. Brief Amicus Curiae of the National Associations of Boards of Pharmacy at 33-34, *Happel v. Wal-Mart*, 744 N.E.2d 284 (Ill. 2001) No. 90482, 2001 WL 34157036 [hereinafter NABP Brief Amicus].

61. *Id.* at 16.

62. Supplemental Memorandum Amicus Curiae of the Illinois Pharmacists Association at 9-12, *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557 (Ill. 1992) (No. 72908).

From these few cases alone, it is apparent that state courts have reached inconsistent interpretations regarding a pharmacist's duty to warn. As it stands currently, pharmacists may be found in some states to not have a duty to warn as a matter of law, while other states could find that pharmacists do have a duty to warn or at least under limited circumstances. Unfortunately, one of the results of these legal inconsistencies among the states is that there is no clear guidance to practicing pharmacists (or to those that advise them), on what their legal expectations are regarding their duty to warn. To help resolve this problem, a consistent, reasonable solution regarding a pharmacist's duty to warn must be reached and adopted by state courts and the profession.

III. PROPOSAL

To continue down the current evolutionary duty-to-warn path will likely only bring additional years of inconsistent case law, providing no clear expectations for pharmacists. It is therefore time for the courts and the profession to make important changes in recognizing that pharmacists do have a duty to warn, as well as adopting a standard of care that can be provided by the reasonably prudent pharmacist.

In providing a solution to the current duty to warn issue, it should be noted that numerous experts and commentators have been providing suggestions, recommendations, and potential solutions for over a decade.⁶³ Specifically, numerous past recommendations have included: elimination of the general no-duty-to-warn rule; limiting the application of the learned-intermediary doctrine to drug manufacturers and physicians; and the adoption of OBRA 90 as the minimal standard of pharmacy practice in duty-to-warn litigation.⁶⁴ However, these suggestions and recommendations have largely gone unnoticed by the courts and the profession. For

63. Brushwood, *supra* note 3, at 476, 497 (suggesting that pharmacists do have a duty to warn based on the pharmacist-patient relationship and that the standard for pharmacy practice described in OBRA 90 ought to be adopted as the minimal standard of care); Casmere, *supra* note 24, at 445-49, 464 (advocating for the elimination of the no duty to warn rule as well as limiting the application of the learned intermediary doctrine to drug manufacturers and physicians; and suggesting that the question of whether a duty exists should be based on the foreseeability, relationship, and likelihood factors); Laura A. Carpenter & Kenneth R. Baker, *Pharmacists' Duty to Warn: Suggesting a Balance Between No Duty and Undoable Duty*, at 16 (2007) (unpublished manuscript, on file with the Duquesne University Law Review and author) (proposing that courts adopt the standards set forth by OBRA 90, state patient counseling laws and case law finding that pharmacists have a duty to warn where a reasonable prudent pharmacist would do so).

64. See *supra* note 63.

example, numerous courts that recently addressed the issue of whether a pharmacist has a duty to warn continued to extend the learned-intermediary doctrine to pharmacists.⁶⁵ Furthermore, very few courts have utilized OBRA 90 language when addressing the standard of care expected by pharmacists regarding their duty to warn.⁶⁶

The authors of this article agree with many of these past proposals, but assert that the profession must do more in addressing the duty-to-warn issue. A reasonable, consistent duty-to-warn standard would require the following changes: (1) recognition by the courts that pharmacists do have a duty to warn; (2) recognition by the courts of a reasonable duty-to-warn standard of care which incorporates OBRA 90; and (3) recognition and support by the profession of pharmacy that pharmacists do have a duty to warn, meeting a reasonable standard of care that is within pharmacists' abilities and training.

A. *Recognition by the Courts That Pharmacists Do Have a Duty to Warn*

Courts that continue to shield pharmacists from liability and hold that there is no duty to warn as a matter of law should acknowledge that the reasons supporting those holdings are outdated—or were invalid from the beginning. In other words, the minority of courts and commentators that have provided contrary information to support that pharmacists do have a duty to warn should be reevaluated.⁶⁷

65. For recent case examples that have applied the learned intermediary doctrine to pharmacists, see *Deed v. Walgreens*, *supra* note 35; *Moore v. Memorial Hospital of Gulport*, 825 So.2d 658 (Miss. 2002); *Walls v. Alpharma*, 887 So.2d 881 (Ala. 2004).

66. See Jesse C. Vivian & Joseph L. Fink III, *OBRA '90 at Sweet Sixteen: A Retrospective Review*, 33(3) U.S. Pharm., Vol. 33 No. 03, March 2008, at 65 (discussing how only six published opinions have addressed the standard of care exercised by pharmacists using OBRA 90 language). For case examples that have declined to consider OBRA 90 for the duty to warn standard, see *Deed v. Walgreens*, *supra* note 35; *Moore v. Memorial Hospital*, *supra* note 65; *Saukas v. Walker Street Pharmacy, Inc.*, No. 260560, 2005 WL 1846289 (Mich. Ct. App. 2005).

67. *Casmere*, *supra* note 24, at 444-49 (rebutting support for the no duty to warn rule and providing reasons why the pharmacist does have a duty to warn); *Brushwood*, *supra* note 3, at 493-97 (providing a discussion and case examples of why pharmacists have a duty); *Smith*, *supra* note 8, at 211-20 (arguing that the theories behind the no duty to warn rule should be invalidated); *Saukas v. Walker Street Pharmacy*, *supra* note 66, at 3-4 (Murphy, J., dissenting) (discussing how pharmacists have a legal duty to act in certain situations and that "by holding pharmacists accountable the quality of healthcare will improve, and that any burden on pharmacists is outweighed by the public benefit").

While the existence of a duty is a question of law, numerous courts have based the decision of whether a pharmacist has a duty to warn on reasons unrelated to the pharmacist-patient relationship or the foreseeability of the adverse consequences.⁶⁸ Therefore, courts should no longer rely on interference with the physician-patient relationship, the learned-intermediary doctrine, and public-policy reasons as ways to shield pharmacists from civil liability.⁶⁹ Instead, courts should recognize that pharmacists are patient educators who can provide counseling and valuable drug information, as well as perform interventions that can positively impact patient outcomes.⁷⁰ Additionally, courts should continue to move away from using or adopting the learned-intermediary doctrine regarding pharmacist liability and consider the various courts and commentators who have suggested that the learned-intermediary doctrine as a defense for pharmacists is a misapplication of the rule.⁷¹ Overall, if courts were to start finding that pharmacists do have a duty to warn, more legal actions against the pharmacist would be allowed to proceed past summary judgment to where the factfinder could determine if the pharmacist acted reasonably and met the standard of care applicable to the pharmacy profession.⁷²

B. Recognition by the Courts of a Reasonable Duty-to-Warn Standard Which Incorporates OBRA 90

If more courts were to determine that pharmacists do have a duty to warn, the next requirement would be for the factfinder to

68. Casmere, *supra* note 24, at 448-50, 460 (discussing how many cases in Illinois did not determine if there was a duty based on analyzing the relationship, foreseeability, or likelihood and that courts should state that it is erroneous to conclude that a defendant pharmacist has no duty to a plaintiff without first examining the relationship between the pharmacist and the plaintiff); Brushwood, *supra* note 3, at 493-97 (discussing how when a pharmacist-patient relationship exists, the pharmacist owes to the patient a duty to act with reasonable care, which includes preventing foreseeable adverse consequences and meeting administrative regulations promulgated under OBRA 90).

69. Casmere, *supra* note 24, at 444-47 (providing support that it is inappropriate to find pharmacists do not have a duty to warn based on the physician-patient relationship, the learned intermediary rule, and public policy reasons); Smith, *supra* note 8, at 211-20 (arguing that the theories behind the no duty to warn rule should be invalidated).

70. Casmere, *supra* note 24, at 462-63; Brushwood, *supra* note 3, at 475-76, 505-06.

71. Casmere, *supra* note 24, at 445-46; Smith, *supra* note 8, at 215; NABP Amicus Brief, *supra* note 60, at 33-41 (discussing case law examples that have rejected the application of the learned intermediary doctrine and how the application of the doctrine should solely be for manufacturers and physicians).

72. See NABP Brief Amicus, *supra* note 60, at 33-41 (providing examples of case law that decided to allow the question of whether a pharmacist met their duty to be decided by the trier of fact).

determine if the pharmacist met the required standard of care within the profession. However, as noted earlier, it has been difficult for the courts and the profession to determine what an appropriate standard of care is regarding a pharmacist's duty to warn. Therefore, it is important for courts to agree on a standard of care that is reasonable and realistic and that falls within the pharmacists' abilities and training.⁷³ To assign a standard of care that cannot be reached by pharmacists, such as counseling a patient regarding every possible side effect of each prescription, would only lead to unnecessary litigation and harm the profession.⁷⁴ Therefore, as past experts and commentators have suggested and as the authors of this article assert, a reasonable duty-to-warn standard should incorporate the already existing OBRA 90 practice standards passed by state laws or promulgated by state administrative agencies.⁷⁵

1. OBRA 90

In order to help assure that prescriptions are not likely to result in adverse medical results, OBRA 90 requires pharmacists to meet mandated prescription screening and patient education standards. The particular section of OBRA 90 mandating that pharmacists perform a prospective drug review, which requires a screening of prescriptions prior to dispensing; meeting minimal patient counseling standards; and keeping a record of patient information, could be used by courts in helping to adopt a reasonable standard of care regarding a pharmacist's duty to warn.⁷⁶

When counseling patients about prescription drugs, the pharmacist acts as a patient educator and risk manager.⁷⁷ Counseling helps to educate patients and allows them to manage the risks

73. Brushwood, *supra* note 3, at 502-03 (discussing how judicial expectations for pharmacists should be realistic and that they should reflect the pharmacist's collegial role in drug therapy); Carpenter, *supra* note 63, at 13-14 (suggesting that a "reasonable, consistent legal [standard] for pharmacists should be in harmony with the real-life roles of pharmacists . . . that legal duties must understand and take into [account] the abilities and training of the pharmacist;" and that to assign undoable duties will only hurt the profession).

74. Carpenter, *supra* note 63, at 14.

75. Brushwood, *supra* note 3, at 502-09 (discussing how OBRA 90 can be used as the standard for a reasonable and prudent pharmacist); Carpenter, *supra* note 63, at 16 (proposing that courts adopt the standards set forth by OBRA 90, state patient counseling laws and case law finding that pharmacists have a duty to warn where a reasonable prudent pharmacist would do so).

76. OBRA 90, 42 U.S.C. § 1396r-8(g)(2)(A)(i-ii) (2008).

77. Carpenter, *supra* note 63, at 14 (discussing how although "the pharmacist's knowledge of drugs is more general in nature," this knowledge can still provide benefits to the patient).

associated with taking the prescribed medication.⁷⁸ Although the physician assesses the risk when choosing the drug for the patient, it is the pharmacist that “counsel[s] the patient about how to appropriately use the drug.”⁷⁹ Therefore, the minimum counseling requirements under OBRA 90 can be used by pharmacists to help reach this goal in patient education and risk management and by courts when determining a reasonable standard of care regarding a pharmacist’s duty to warn.

The minimum counseling requirements under OBRA 90 read, in relevant part:

The pharmacist must offer to discuss with each individual who presents a prescription, matters which in the exercise of the pharmacist’s professional judgment, the pharmacist deems significant including the following:

- (aa) The name and description of the medication.
- (bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.
- (cc) Special directions and precautions for preparation, administration and use by the patient.
- (dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
- (ee) Techniques for self-monitoring drug therapy.
- (ff) Proper storage.
- (gg) Prescription refill information.
- (hh) Action to be taken in the event of a missed dose.⁸⁰

Under this language, when pharmacists counsel patients about appropriate drug use, the scope of the counseling discussion is determined by the individual pharmacist, which allows pharmacists the flexibility to include those matters that the pharmacist deems

78. *Id.* at 15.

79. *Id.* at 16.

80. OBRA 90, 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I) (2008).

significant.⁸¹ However, even with this flexibility, OBRA 90 lists specific items for potential topics of discussion. In particular, OBRA 90 provides for “common severe side or adverse effects” as a discussion topic that could be used by courts in formulating a duty-to-warn standard. In interpreting “common severe side effects,” as past commentators have also suggested, the duty-to-warn standard should only apply to side effects that are *both* common *and* severe.⁸² It is not enough that a side effect is either common or severe, as such a requirement could lead to pharmacists having to provide voluminous warnings.⁸³ Furthermore, “the determination of which side effects are common and severe is a question of fact to be determined by the court evaluating expert witness.”⁸⁴

This approach effectively requires the pharmacist, during counseling, to educate and warn patients about common and severe side effects. It is not meant as a limitation to counseling but as a compromise that seeks a reasonable balance between placing an absolute duty on the pharmacist to counsel about every potential side effect and holding that pharmacists have no duty to warn at all. This particular OBRA 90 language can be used as guidance by courts addressing cases that claim the pharmacist had a duty to warn or counsel about adverse drug effects. This language, if adopted into a duty-to-warn standard, would distinguish those cases where the plaintiff experienced a common and severe side effect from those cases where the plaintiff experienced a side effect of very low probability or one that was not severe. This approach is reasonable and realistic for the pharmacist, compared to various other cases where the plaintiff has argued that the pharmacist has a duty to warn of every potential side effect.⁸⁵

In addition to counseling patients about common and severe side effects, a duty-to-warn standard “should also require the pharmacist to act as a ‘safety net’ by evaluating known contraindi-

81. Carpenter, *supra* note 63, at 8.

82. *Id.* at 16 (discussing how the duty to counsel about appropriate drug use includes warning patients about common and severe side effects); Brushwood, *supra* note 3, at 490 (discussing that “common severe side effects” should include those that are both common and severe; however, this expert also suggested accepting common or severe).

83. *Id.* at 16 n.75 (providing for examples of why common and severe should be used instead of common or severe, and that to require common or severe side effects could potentially lead to frightening or discouraging the patient from taking necessary drugs).

84. *Id.* at 16-17.

85. For a recent case example highlighting how the plaintiff argued that the pharmacy had a duty to warn about a rare side effect that had less than a one in one million chance of occurring, see *Chamblin v. K-Mart Corp.*, 612 S.E.2d 25 (Ga. Ct. App. 2005).

cations, allergies, drug-drug interactions and other prospective drug utilization review factors.”⁸⁶ To better define this part of the standard, past case law and the OBRA 90 language that requires screening of prescriptions should be considered. Regarding past case law, various appellate court decisions from numerous states can be used as guidance in determining when it would be reasonable for a pharmacist to have a duty to warn. These circumstances include, but are not limited to, making an intervention, inquiring further about a prescription, considering special circumstances surrounding the patient known to the pharmacist, and correcting obvious inadequacies on the prescription.⁸⁷

Furthermore, in helping to determine when a pharmacist would have a duty to warn by acting as a “safety net,” the OBRA 90 language that requires screening of prescriptions should also be considered. Regarding the screening of prescriptions prior to dispensing, OBRA 90 reads in relevant part: “[t]he review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.”⁸⁸ Therefore, in addition to warning the patient during counseling of severe and common side effects, if circumstances particular to the patient exist that alert the pharmacist to a potential concern, the pharmacist should investigate those circumstances and warn the prescriber or patient when necessary.⁸⁹

The above-mentioned OBRA 90 language, which provides patient education and prescription screening standards, could be used by courts to adopt a defined standard of care regarding a pharmacist’s duty to warn. In addition, it is reasonable and realistic for the pharmacist. Not only would pharmacists be aware of and understand their expectations, they would also be able to reasonably obtain these expectations. Furthermore, for those states that place additional responsibilities on pharmacists beyond the minimal OBRA 90 standards, state courts could incorporate and consider those as well into the standard of care. For example,

86. Carpenter, *supra* note 63, at 17.

87. *Id.* (discussing how pharmacists have a duty to act as a “safety net” and mentioning various examples of cases that have found pharmacists have such a duty).

88. 42 U.S.C. § 1396r-8(g)(2)(A)(i).

89. Carpenter, *supra* note 63, at 16.

OBRA 90 only requires the offer to counsel the patient.⁹⁰ Numerous states have extended this minimal standard and require the pharmacist to counsel patients on each new prescription.⁹¹ These variations from the OBRA 90 minimal standards could then be considered by that individual state in determining whether the pharmacist met that state's particular duty-to-warn standard. However, this test would not place unreasonable expectations on pharmacists practicing in states with expanded requirements beyond OBRA 90. Pharmacists would have knowledge of the heightened requirements and could still seek advice regarding any special obligations.

Unfortunately, even with OBRA 90 having been in place for almost fifteen years, state courts continue to decline to incorporate OBRA 90 laws and regulations adopted by each state into a duty-to-warn standard for pharmacists.⁹² Ideally, courts will start turning to their state laws and regulations that stem from OBRA 90 for guidance regarding a pharmacist's duty to warn.

C. Recognition and Support by the Profession of Pharmacy That Pharmacists Do Have a Duty to Warn, Meeting a Reasonable Standard of Care That Is Within Pharmacists' Abilities and Training

With years of education and specialized training, pharmacists are recognized as the drug experts among members of the health-care team. Although the profession acknowledges that pharmacists play an important role in today's health care beyond dispensing, the profession has still yet to agree that pharmacists do have a duty to warn, as well as advocate and provide resources for pharmacists to meet a reasonable standard of care.

Various pharmacy organizations, companies, and associations have differed on their view of whether a pharmacist has a duty to warn.⁹³ For example, in an amicus brief to the Illinois Supreme

90. 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I).

91. Carpenter, *supra* note 63, at 9 (quoting ARIZ. ADMIN. CODE § R4-23-402(b)(2007) which goes above "the 'offer to counsel' and requires counseling when a prescription medication has not been previously dispensed to the patient in the same strength or dosage form or with the same directions").

92. See *supra* note 66 and accompanying text.

93. See *infra* notes 94-97 and accompanying text. For a discussion on various pharmacy professional organizations which have advocated for duties of a pharmacist consistent with the duties of the profession, see Casmere, *supra* note 24, at 455-56. For examples of recent case law that provide pharmacy companies arguing pharmacists do not have a duty

Court on behalf of the plaintiff in *Happel*, the NABP commented that “the recognition of a duty in this case is commensurate with the status of pharmacy as a profession and with the pharmacist’s professional responsibilities.”⁹⁴ On the other hand, in an amicus brief on behalf of the defendant pharmacy in *Happel*, the National Associations of Chain Drug Stores (“NACDS”) supported the defendant’s position that a pharmacist does not have the responsibility to warn a patient of potential adverse characteristics of a drug. In response to the NABP amicus brief, NACDS stated:

NABP has a vision of pharmaceutical care, in which pharmacists have the time and opportunity to have privileged discussions with consumers about all aspects of their drugs. NACDS supports that vision of the practice of pharmacy. However, that vision of pharmacy practice does not require the imposition of new tort liability against pharmacists.⁹⁵

Furthermore, pharmacy companies continue to take the position during litigation that pharmacists do not have a duty to warn. For example, in one recent case, the defendant pharmacy contended that “the pharmacist’s duty is to fill prescriptions, not write them, or warn patients about potential side effects,” and to “accurately fill a prescription in accordance with a physician’s instructions, not to question the propriety of the judgment made by the prescribing physician.”⁹⁶ However, while the defendant pharmacy in this case acknowledged that “the role of the pharmacist has changed from a simple dispenser of medicine to a trusted professional playing an essential part in medical treatment,” it also asserted that “courts have held that the learned intermediary doctrine applies to pharmacists because while they are not mere automotons, they do not have a doctor-patient relationship with the consumer and because they do not prescribe the medication they sell.”⁹⁷

to warn, see *Deed v. Walgreens*, *supra* note 35; see also *Brienze v. Casserly*, No. 01-1655-C, 2003 WL 23018810 (Mass. Super. Ct. 2003).

94. See NABP Brief Amicus, *supra* note 60, at 15; John F. Atkinson, *A Positive Step*, NABP Newsletter, Vol. 30 No. 1, Jan. 2001 at 4-6 (discussing how in *Happel* the NABP supports the pharmacist having a duty to warn where the NACDS supports the position that pharmacist do not have a responsibility to warn a patient of potential adverse characteristics of drugs).

95. Brief Amicus Curiae of the National Associations of Chain Drug Stores at 35; *Happel v. Wal-Mart*, 744 N.E.2d 284 (Ill. 2001) (No. 90482), available at 2001 WL 34157033.

96. See *Deed v. Walgreens*, *supra* note 35, at 3.

97. *Id.*

Therefore, given that various stakeholders within the pharmacy profession are unable to agree on whether a pharmacist has a duty to warn, the profession of pharmacy should accept as a professional standard that pharmacists do have a duty to warn and meet a reasonable standard of care. Although there may be concerns about additional pharmacist litigation, the opposite may occur: there may be a decrease in litigation through improved patient outcomes and having less patients experience adverse drug effects.⁹⁸ In addition, by recognizing that pharmacists do have a duty and by working towards meeting an agreed-upon standard of care, pharmacists will continue towards the professional recognition they deserve.⁹⁹

In order to meet this duty, the profession must advocate for improving the current working conditions for pharmacists. To adequately warn patients of common and severe side effects and intervene with potential drug therapy concerns, pharmacists must have adequate time to counsel patients and screen prescriptions. It is likely that many pharmacists across the country are already meeting or exceeding the recommended suggested duty-to-warn standard of care; however, recent national news reports suggested that there may not be adequate resources available for pharmacists to perform these important functions most or all of the time.¹⁰⁰ These news reports point to the pharmacists' workload, including high prescription volume and limited time for the prescription filling process, as well as staffing issues that pharmacists may encounter that could hinder their ability to meet the suggested duty-to-warn standard.¹⁰¹

In addition to highlighting medication errors that pharmacists make, recent news reports have also addressed how numerous pharmacy retail chains are potentially encouraging pharmacists to fill a high volume of prescriptions at a fast pace.¹⁰² One report described the concern as "overworked pharmacists are pushed to fill prescriptions at a fast food pace."¹⁰³ In this type of work environment, pharmacists may not have adequate time to counsel pa-

98. Casmere, *supra* note 24, at 461-63.

99. *Id.* at 462.

100. See Kevin McCoy & Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 12, 2008, at 1A, 8A; Kevin McCoy, *RX for Errors*, U.S.A. TODAY, Feb. 13, 2008, at 1B-2B; Kevin McCoy & Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 14, 2008, at 3B; *20/20: A RX for Disaster* (ABC television broadcast Mar. 30, 2007).

101. See sources cited *supra* note 100.

102. *Id.*

103. See *20/20: A RX for Disaster*, *supra* note 100.

tients regarding their prescription medications or to identify potential drug therapy problems.¹⁰⁴ Furthermore, as prescription volume has increased over 12 percent from 2002, pharmacy manpower has not accordingly increased.¹⁰⁵ This increasing workload and demand on pharmacists erodes the quality of care provided, especially with regard to the pharmacist's ability to counsel patients.¹⁰⁶ To illustrate this point, the media mentioned one particular lawsuit against a chain pharmacy where the jury awarded a family six million dollars. This verdict came after evidence was introduced that the pharmacist, after dispensing two pain medications at different times, neither warned the patient about the potential drug interaction nor verified with the physician that the two prescriptions were to be taken together.¹⁰⁷

Furthermore, these recent news stories noted that pharmacists often do not provide medication counseling to patients when prescriptions are picked up by patients. It was explained how, typically, pharmacy technicians ask patients if they have any questions for pharmacists, and if the patient declines, pharmacists often do not meet the patients.¹⁰⁸ Moreover, when pharmacy technicians offer patients to be counseled, it is unlikely that the offer will be accepted.¹⁰⁹ The suggestion that most patients decline the offer to ask their pharmacist questions is also supported by one recent duty-to-warn case, which commented "[l]ike most pharmacy customers, [the plaintiff] declined an offer to speak to the pharmacist at the time."¹¹⁰

In addition to many patients declining their offer to receive counseling, concerns have also been raised that other patients either do not receive an offer of counseling or do not understand that they are being given an offer of counseling.¹¹¹ One recent news report noted how states require pharmacies to offer face-to-face counseling to customers when they pick up their prescriptions, but that various state records have shown that numerous pharmacy chains were cited for failing to offer or provide counsel-

104. See sources cited *supra* note 100.

105. See Kevin McCoy & Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 12, 2008, at 1A, 8A.

106. Casey, *supra* note 18, at 308.

107. See Kevin McCoy & Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 12, 2008, at 8A.

108. See Kevin McCoy, *RX for Errors*, U.S.A. TODAY, Feb. 13, 2008, at 2B.

109. See Kevin McCoy and Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 14, 2008, at 3B.

110. See Brienze, *supra* note 93, at 1.

111. See *20/20: A RX for Disaster*, *supra* note 100.

ing.¹¹² Another journalist report noted that during an investigation, only 27% of patients receiving new prescriptions were offered counseling.¹¹³ In addition to patients potentially not receiving an offer to be counseled, there were concerns that patients are being misled into signing away their right to be counseled without ever realizing it.¹¹⁴

Therefore, if pharmacists had the resources to provide patient counseling and to act on potential drug therapy concerns, it would allow the profession to work towards meeting the duty-to-warn standard proposed in this article. Furthermore, if adequate resources were available, and if a patient declined the offer to counsel, a pharmacist could still take the initiative and alert the patient to the available information.¹¹⁵ The concept of universal counseling is possible only if pharmacy operators give pharmacists the staffing and the time to handle discussions with patients in an era of increasing prescription volume.¹¹⁶

IV. CONCLUSION

The evolution of the pharmacists' duty to warn has provided legal inconsistencies among the state courts that have addressed the issue. A variety of interpretations have been established regarding if and when pharmacists owe patients a duty beyond accurately filling prescriptions. As such, no clear guidance exists for the profession as to exactly what duty-to-warn responsibilities pharmacists must fulfill.

For years, the pharmacy profession has promoted and advocated its extended role in health care beyond that of just technical accuracy in the prescription order process. In accepting this responsibility, pharmacists should embrace a standard that utilizes their knowledge and skills in assisting patients and intervening on their behalf while increasing positive therapeutic outcomes.

Given the status of the pharmacists' duty to warn, time is of the essence for state courts and the pharmacy profession to work towards a solution that includes expanding the role of pharmacy

112. See Kevin McCoy and Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 12, 2008, at 8A.

113. See *20/20: A RX for Disaster*, *supra* note 100.

114. *Id.*

115. See Kevin McCoy and Erik Brady, *RX for Errors*, U.S.A. TODAY, Feb. 14, 2008, at 3B (quoting Carmen Catizone, Executive Director of NABP, that pharmacists should seize the initiative and counsel patients on all new prescriptions).

116. *Id.*

and its capabilities. To reach a solution, important changes are needed. Assuming pharmacists have a duty to warn by meeting a reasonable standard of care, which incorporates the patient counseling and prescription screening standards found in OBRA 90, the profession itself must advocate and provide adequate resources for pharmacists to meet this standard. Hopefully, state courts and the profession of pharmacy will recognize the importance of accepting and working towards a consistent legal and professional standard regarding the pharmacists' duty to warn.