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NO DUTY TO WARN OF DRUG INTERACTIONS: A DANGEROUS PRESCRIPTION

RYANNE BUSH DENT*

I. Introduction

The drug industry is a major force in the United States that affects about half of the country's population in any given month. According to the Centers for Disease Control (CDC) Office Visit Study, in 2008, there were more than 2.3 billion "drug mentions" at office visits in the United States in which there was medical documentation in a patient's record of a drug provided, prescribed, or continued. Also, more than 711 million visits in the United States in 2008 were "drug visits," meaning drugs were either provided or prescribed. In a 2011 CDC study, it stated that prescription drug sales by retail outlets exceeded \$234 billion.

- * The author would like to thank Professor Alberto Bernabe for guidance throughout law school, including direction to the topic of this Comment.
- 1. Nat'l Ctr. For Health Statistics, Health, United States, 2010: With Special Feature on Death and Dying, CTRS. FOR DISEASE CONTROL AND PREVENTION 318 (2011), http://www.cdc.gov/nchs/data/hus/hus10.pdf#094 [hereinafter Special Feature on Death and Dying]. This part of the study asked people whether they were taking a prescription drug currently (that month). Id. Almost half of the participants (47.9%) were taking a prescription drug that month. Id. Additionally, the study shows that 21.4% of the participants indicated they were taking three or more prescription drugs that month. Id.
- 2. Ambulatory and Hospital Care Statistics Branch, Nat'l Ctr. For Health Statistics, Nat'l Ambulatory Medical Care Survey: 2008 Summary Tables, Ctrs. For Disease Control and Prevention 25 (2008), http://www.cdc.gov/nchs/data/ahcd/namcs
- _summary/2008_namcs_web_tables.pdf. This study showed that 2,325,368,000 documentations were made in patients' records about drugs at an office visit. *Id.* This figure, however, was capped at eight drug documentations for each visit. *Id.* Therefore, if a patient was actually taking ten drugs at the time of the office visit, only eight were counted toward this total. *Id.*
- 3. *Id.* In the study, a drug visit is one in which at least one drug is either prescribed or provided. *Id.* Table 23 breaks each drug visit into different physician specialties, with the total being 711,368,000. *Id.* This means that 74.4% of office visits were "drug visits" in which one or more drugs were prescribed or provided. *Id.* Intuitively this makes sense, as most people do not go to the doctor unless they are sick in some way, hoping that the doctor will prescribe them medication so they can get better.
- 4. Special Feature on Death and Dying, supra note 1, at 369. The study tracks national health trends in order to present the findings to the

While physicians actually prescribe these drugs, pharmacists must fill those prescriptions and make direct contact with patients. Because prescription drugs are so vital, and yet so dangerous, pharmacists carry a heavy burden. With this heavy burden, there is specific education and training that pharmacists must complete to be licensed.⁵

When pharmacists become licensed to practice, they agree to abide by the established ethics of their profession. Many pharmacists agree to these ethics even earlier, such as while they are still in pharmacy school. Of particular importance, almost all of the ethics guidelines relate to the patient in some capacity. From the onset of his pharmaceutical practice, the pharmacist knows he owes certain duties to his patients simply by being a

President and Congress. *Id.* This part of the study showed the national expenditure for different types of medical expenses in 2008 compared to previous years. *Id.*

5. U.S. Dept. of Labor, Occupational Outlook Handbook: Pharmacists (2012-13 ed.), Bureau of Labor Statistics (Mar. 29, 2012), http://www.bls.gov/ooh/Healthcare/Pharmacists.htm [hereinafter Bureau of Labor Statistics]. To become a licensed pharmacist, students must obtain a doctor of pharmacy (Pharm.D.) and subsequently take various licensing tests depending on the state in which the pharmacist will practice. Id. Every state requires that students must take the North American Licensure ExaminationTM as well. Am. Pharm. Ass'n, Getting Your License, Pharmacist.com,

https://portal.pharmacist.com/AM/Template.cfm?Section=Career_Resources&Template=/CM/ContentDisplay.cfm&ContentID=11570 (last visited Jan. 19, 2013).

- 6. Am. Pharm. Ass'n, Code of Ethics for Pharmacists (adopted Oct. 27, 1994), PHARMACIST.COM, http://www.pharmacist.com/code-ethics (last visited Jan. 19, 2013) [hereinafter Code of Ethics]. The American Pharmacist Association (APhA) also has a Pharmacist Oath. Am. Pharm. Ass'n, Oath of a PHARMACIST.COM, Pharmacist (adoptedJuly 2007), http://www.pharmacist.com/oath-pharmacist (last visited Jan. 19, 2013) [hereinafter Oath of a Pharmacist]. Prior to 2003, the American Pharmacists Association was known as the American Pharmaceutical Association, and from 1994 until 2003 when it changed its name, the Association had a Code of Ethics for Pharmacists that its members were required to uphold, which was basically a shorter version of the Oath of a Pharmacist. See Am. Pharmaceutical Ass'n, Code of Ethics for Pharmacists, PHARMWATCH (July 19, http://www.pharmwatch.org/reports/ethics.shtml (providing American Pharmaceutical Association's Code of Ethics as adopted on October 27, 1994).
- 7. See Am. Pharmaceutical Ass'n Acad. of Students of Pharmacy—Am. Ass'n of Colls. of Pharmacy Council of Deans Task Force on Professionalism, White Paper on Pharmacy Student Professionalism, 40 J. AM. Pharmaceutical Ass'n 96, 97 (2000), http://www.cop.ufl.edu/wpcontent/uploads/dept/studaff/forms/whitepaper.pdf [hereinafter AphA-ASP/AACP COD] (stating that the professionalism courses must start early in a pharmacist's educational career).
- 8. See id. at 101-02 (replicating the oaths and ethical guidelines that pharmacists follow from different organizations).

pharmacist.

Typically, the pharmacist does not have a general duty to warn patients, particularly of drug interactions. The possibility of liability for pharmacists is very narrow. The pharmacist is usually liable only if he fills the prescription incorrectly. This is mainly because the learned intermediary doctrine shields pharmacists from liability related to the duty to warn of dangers related to prescription drugs. The learned intermediary doctrine places the responsibility on the physician, instead of the pharmacist, to warn the patient.

Although the legal landscape has been changing to hold pharmacists liable in a broader context, it has not gone far enough. The law currently provides for exceptions to create pharmacist liability under circumstances when pharmacists act negligently. With the technology and roles of pharmacists changing, the even additional exceptions later developed will not be enough.

Instead of creating exceptions to the general rule, the old rule should be abolished. There should be an affirmative duty on

^{9.} See 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 (2000) (noting that most courts reviewing that question have held there is no duty for pharmacists); see also Edward Casmere, Rx for Liability: Advocating the Elimination of the Pharmacist's No Duty to Warn Rule, 33 J. MARSHALL L. REV. 425, 428-59 (2000) (pointing out the deficiencies of the no duty rule and advocating for the elimination of such a rule).

^{10.} See Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 461 (Tex. App. 2000) (citing multiple Texas cases where courts found that pharmacists had no duty to inform patients about side effects or hazards).

^{11.} *Id*.

^{12.} Leesley v. West, 518 N.E.2d 758, 763 (Ill. App. 1988).

^{13.} *Id*.

^{14.} See Porto, supra note 9, at § 2(a) (explaining that traditionally, as long as the pharmacist accurately filled the prescription as the doctor wrote it, he was immune from liability). See infra note 31 and accompanying text (explaining that liability from drug interactions has historically fallen on the prescribing physician in accordance with the learned intermediary doctrine).

^{15.} See infra notes 46-49 and accompanying text (detailing cases with exceptions based on assumption of risk, special knowledge, ethical duties, and OBRA legislation).

^{16.} Gary G. Cacciatore, Computers, OBRA 90 and the Pharmacist's Duty to Warn, 5 J. PHARMACY & L. 103, 116 (1996). The pharmacy industry has become highly computerized allowing pharmacists to accurately and effectively inquire as to drug interactions, which may eventually give rise to even more responsibilities, not just to warn of drug interactions, but also to check for such interactions, and to ensure that the computer system is working properly. Id.; see also Baker v. Arbor Drugs, Inc., 544 N.W.2d 727, 731 (Mich. App. 1996) (explaining that a pharmacy may assume the duty to warn because it advertised a computerized system to check for drug interactions); infra note 48 and accompanying text (same).

pharmacists to warn patients of drug interactions. The courts should also explicitly recognize that the learned intermediary doctrine no longer shields pharmacists who act negligently with respect to warnings of drug interactions.

This Comment discusses the pharmacist's duty to warn of potential interactions between drugs, emphasizes the need to place an affirmative duty to warn of drug interactions on pharmacists, and argues that pharmacists should no longer be shielded by the learned intermediary doctrine. Part II of this Comment discusses the background of professional negligence law and how it specifically relates to pharmacists. It also discusses how the learned intermediary doctrine applies to pharmacists, and the changing role of pharmacists.

Part III analyzes the current state of the law regarding pharmacists and the no duty to warn of drug interactions rule, with special emphasis on the learned intermediary doctrine. Part IV proposes courts should impose an affirmative duty to warn of drug interactions on pharmacists, created through custom or through pharmacists' professional standards, regardless of the learned intermediary doctrine.

II. BACKGROUND

A. Creating a Professional Standard of Care

A professional must "exercise ordinary care in delivery of professional services." Exercising ordinary care means that the professional is not engaging in conduct that would create an unreasonable risk of harm. When this standard of care is not met, there is a breach of the professional duty. When a

^{17.} Jennings v. Badgett, 230 P.3d 861, 865 (Okla. 2010); see also RESTATEMENT (SECOND) OF TORTS § 299A (1965) (stating the well-accepted definition of professional liability). A professional is "required to exercise the skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities." *Id.* The Restatement also mentions that a pharmacist is a type of profession or trade that is bound by the same professional liability standards as other professions. *Id.* at cmt. b. The standard of care thus determines what is the duty of the professional.

^{18.} RESTATEMENT (SECOND) OF TORTS § 281 cmt. e (1965).

^{19.} Paul M. Coltoff et al., Negligence, 65 C.J.S. Negligence § 163 (2011); see also META B. LINDLEY, ELEMENTS OF A NEGLIGENCE CLAIM, 6 MS PRAC. ENCYCLOPEDIA MS LAW § 52:2, MSPRAC-ENC § 52:2; RICHARD S. ROSEN ET AL., BURDEN OF PROOF, 18 S.C. JUR. NEGLIGENCE § 13 (discussing elements of negligence, in general); John C. P. Goldberg & Benjamin C. Zipursky, The Restatement (Third) and the Place of Duty in Negligence Law, 54 VAND. L. REV. 657, 684 (2001) (discussing negligence, in general, and that there can be no breach absent a duty); BREACH OF DUTY, 9 TEX. JUR. PL & PR. FORMS § 178:7 (2d ed.) (defining breach of duty, generally); J.D. LEE & BARRY LINDAHL, ELEMENTS OF NEGLIGENCE, 1 MODERN TORT LAW: LIABILITY AND LITIGATION § 3:2 (2d ed.) (generally defining elements of negligence); LAURA

professional breaches a duty, he may be civilly liable for damages to the party injured in the form of a negligence action.²⁰

The cause of action available to a plaintiff when the professional breaches a duty is normally referred to as malpractice.²¹ There are many different types of malpractice, for example, legal or medical malpractice. For a plaintiff to prove malpractice, he must establish negligence by proving a duty, breach of duty, causation, and injury.²²

The professional duty is typically established through the particular profession's custom practices.²³ Custom is the

HUNTER DIETZ ET AL., EXISTENCE OR BREACH OF DUTY; LACK OF PROPER CARE, 57B AM. JUR. 2D *Negligence* § 1262 (2012) (discussing the doctrine of *res ipsa loquitor*).

20. See Laura Smalley, Pharmacist Malpractice: Trial and Litigation Strategy, 78 AM. Jur. Trials 407, § 3 (2001) (explaining a patient injured by a drug dispensed by a pharmacist may maintain tort actions against the pharmacist, including theories based on negligence and/or failure to warn). A malpractice action sounds in tort, and is a negligence action, thus requiring the elements of a normal negligence action. Id. See supra notes 17 and 18 (explaining that for malpractice, however, there is a special emphasis on a different standard of care, that of the professional).

21. VICTOR E. SCHWARTZ, KATHRYN KELLY & DAVID F. PARTLETT, PROSSER, WADE & SCHWARTZ'S TORTS CASES AND MATERIALS 177 (12th ed. 2010).

22. See David G. Owen, The Five Elements of Negligence, 35 HOFSTRA L. REV. 1671, 1673-74 (2007) (arguing that there are in fact five elements instead of the traditional four which combined proximate cause and cause in fact into one element simply called causation). A plaintiff must be able to show that a duty was owed by the defendant to the plaintiff and what that duty was. Id. at 1674-75. The plaintiff also has the burden to prove that the defendant did not meet that duty, showing a breach of that duty. Id. at 1676-66. If the first two elements can be shown, the plaintiff must also show that the injury was caused by the breach. Id. at 1679-80. Causation includes both cause in fact and proximate cause. Id. at 1674. Finally, the plaintiff must show that the defendant's conduct actually caused an injury to him. Id.

23. See Advincula v. United Blood Servs., 678 N.E.2d 1009, 1027 (Ill. 1996) (stating that generally, and in this case, the standard of care is determined by custom in the specific professional field); see also JOHN L. DIAMOND, LAWRENCE C. LEVINE & ANITA BERNSTEIN, UNDERSTANDING TORTS 93-94 (4th ed. 2010) (explaining that the standard of care for professionals must be placed in context of the profession and the courts defer to the expertise of the profession for that custom); Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994) (imposing a professional standard of care on pharmacists based on the reliance relationship between the expert pharmacist and the patient, not shielded under the learned intermediary doctrine); see Horner v. Spalitto, 1 S.W.3d 519, 523 (Mo. App. 1999) (determining that pharmacists should not act as robots in dispensing prescriptions, but are in reality professionals that should act according to a professional standard of care); see Klasch v. Walgreen Co., 264 P.3d 1155, 1160 (Nev. 2011) (upholding the learned intermediary doctrine protection for generalized risks, but holding that pharmacists are not insulated by the learned intermediary doctrine when the pharmacist has patient-specific knowledge).

systematic way that a group handles particular situations.²⁴ This would mean that if a plaintiff could show that it is customary for a pharmacist to always act in a specific way so as not to create an unreasonable risk of harm, and the defendant pharmacist did not act in that way, this failure may constitute a breach of the pharmacist's professional duty.

Alternatively, or in conjunction with custom, the standard of care can be shown through professional rules of conduct for that particular profession.²⁵ Although these professional rules do not always constitute a duty that the professional must legally abide by, courts sometimes do find this plausible and impose such a duty.²⁶

Historically, a duty to warn has not been included in the pharmacists' standard of care when drug interactions are considered²⁷—in spite of the customs and rules of conduct/ethics that exist for pharmacists.²⁸ A drug interaction is defined as "an interaction between a drug and another substance that prevents the drug from performing as expected. This definition applies to

^{24.} See BLACK'S LAW DICTIONARY 442 (9th ed. 2009) (defining custom as "[a] practice that by its common adoption and long, unvarying habit has come to have the force of law"); see also RESTATEMENT (SECOND) OF TORTS § 299A cmt. e (1965) (stating the custom for the purposes of professional negligence is the skill and knowledge that is "commonly possessed by members of that profession or trade in good standing").

^{25.} See Marc R. Greenough, The Inadmissibility of Professional Ethical Standards in Legal Malpractice Actions After Hizey v. Carpenter, 68 WASH. L. REV. 395, 398-99 (1993) (stating that jurisdictions take different approaches in the legal malpractice context, but that some jurisdictions do allow professional ethical standards to create the standard of care). This general rule may be extended to pharmacist malpractice as well.

^{26.} See id. (explaining how some jurisdictions have applied professional codes of conduct in ascertaining the standard of care); see also MODEL RULES OF PROF'L CONDUCT Preamble & Scope [20] (2011) (stating that the rules do not inherently establish a duty, however, "since the rules do establish standards of conduct by lawyers, a lawyer's violation of a Rule may be evidence of a breach of the applicable standard of conduct"). Although this is the legal context, the same premise spans professions. For each profession there is generally some code of ethics or conduct that the professional is expected to meet. Even though this code itself may not impose such a duty on the professional, the custom that is created out of this code very well could be the imposition of a duty on the professional.

^{27.} Porto, *supra* note 9, at § 2(a); Johnson v. Walgreen Co., 675 So.2d 1036, 1037 (Fla. Dist. Ct. App. 1996). Like the Florida court in *Johnson*, the small group of jurisdictions that have discussed whether a duty to warn of drug interactions should be imposed on pharmacists have declined to impose such a duty. The pharmacist only needs to fill the prescription accurately with due care. *Johnson*, 675 So.2d at 1037.

^{28.} See AphA-ASP/AACP COD, supra note 7, at 101 (replicating the Commentary on Oath of a Pharmacist in which it states that the pharmacist embraces a covenantal relationship with patients, yet courts have repeatedly not applied a duty to warn of dangerous drug interactions).

interactions of drugs with other drugs (drug-drug interactions) . . . "29 Additionally, the pharmacist is shielded from the duty to warn under the learned intermediary doctrine. 30

B. The Learned Intermediary Doctrine Shielding Pharmacists and the Exceptions to the General Rule

According to the learned intermediary doctrine, doctors are responsible to the patient for injuries caused by the medication the doctor prescribed.³¹ The doctor has the duty to ensure there are no interactions with the medications they are prescribing to the patient.³² The learned intermediary doctrine originally protected drug manufacturers from liability from a failure to warn patients.³³ Now the learned intermediary doctrine shields pharmacists, like drug manufacturers, from the duty to warn.³⁴

Proponents of shielding pharmacists under the learned intermediary doctrine advance three primary arguments. First, proponents of the learned intermediary doctrine argue that the physician prescribing the medication is in the best position to know the medical history and current condition of the patient, so the liability should not fall on the pharmacist.³⁵ In determining this, courts reasoned that it was an unreasonable burden to impose a duty to warn on pharmacists, and that it was against public policy to expand liability to other health professionals.³⁶ However, this Comment proposes it is entirely reasonable to impose such a duty on pharmacists because they are trained to spot drug interactions and have technology to further assist them

^{29.} Omudhome Ogbru, *Drug Interactions*, MEDICINENET.COM (Jay W. Marks ed.), http://www.medicinenet.com/drug_interactions/article.htm (last visited Jan. 9, 2013).

^{30.} See infra Part II(B) (discussing the learned intermediary doctrine and how it has shielded pharmacists from a duty to warn patients).

^{31.} Jennifer L. Smith, Comment, Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacist's Expanding Liability and Duty to Warn, 2002 HOUS. J. HEALTH L. & POL'Y 187, 194 (2002). "[A] manufacturer's duty to provide an adequate warning of the dangers associated with a drug runs only to the physician." Id.

^{32.} See id. (determining in part that the doctor is in the best position to know the specifics of the patient's medical history and needs and thus the doctor should be the one to decide the appropriate medication and warn the patient if needed in the doctor's discretionary opinion).

^{33.} *Id*.

^{34.} See Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1127 (Ill. 2002) (electing to follow the underlying reasons for the learned intermediary doctrine by allowing the pharmacist to contact the physician with drug interaction information).

^{35.} Id.

^{36.} Bob Neiner, Casenote, A New Cure for Contraindication: Illinois Supreme Court Prescribes a Duty to Warn on Pharmacists: Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118 (Ill. 2002), 28 S. Ill. U. L. J. 483, 487-88 (2004).

in this task.37

Second, proponents of the learned intermediary doctrine argue that finding otherwise would inject the pharmacist into the doctor-patient relationship.³⁸ Courts have refrained from imposing a duty on the pharmacist citing this concern.³⁹ Although the doctor-patient relationship is important, the pharmacist-patient relationship is significant as well. As described later, there is a "covenantal relationship"⁴⁰ embraced by pharmacists, creating trust between the patient and pharmacist.⁴¹ If pharmacists do not warn patients of potentially deadly drug interactions, pharmacists will not be as trusted and the relationship between patient and pharmacist will suffer.

Third, proponents have argued that allowing claims against pharmacists would allow the injection of non-diverse pharmacists into lawsuits solely to prevent removal to federal courts based on diversity jurisdiction. ⁴² Although this may be true, this issue is not unique to pharmacist defendants. ⁴³ Issues of "misjoinder" or "fraudulent joinder" could occur with all types of claims and defendants. ⁴⁴ Thus, it is not a valid objection only to claims against pharmacists, and it prompts a broader legal discussion, which is not encompassed in this Comment. The mere potential for improper joinder should not bar a claim against a wrongdoer absent other problems with the claim.

If an injury occurs from the medication that the doctor prescribes, but the pharmacist accurately filled the prescription, then the doctor may be civilly liable, but the pharmacist is shielded from liability under the learned intermediary doctrine.⁴⁵

^{37.} Baker, 544 N.W.2d at 731; Cacciatore, supra note 16, at 104; see also infra note 119 and accompanying text (explaining the pharmacist assumes a duty to warn by advertising he will use a computer system to check for drug interactions).

^{38.} See Happel, 766 N.E.2d at 1127 (declining to impose a duty on the pharmacist that would "interject himself into the doctor-patient relationship . . .").

³⁹ *Id*

^{40.} AphA-ASP/AACP COD, supra note 7, at 101; see also infra note 153-56 (explaining the importance of the conventional patient-pharmacist relationship, pharmacist's code of ethics, and how it may be undermined).

^{41.} See GALLUP POLL, infra note 70 (explaining how highly pharmacists are trusted as opposed to other professionals).

^{42.} Jim Beck, *Pharmacists and the Learned Intermediary Rule*, DRUG AND DEVICE DRUG L. BLOG (Feb. 24, 2011), http://druganddevicelaw.blogspot.com/2011/02/pharmacists-and-learned-intermediary.html.

^{43.} Paul Rosenthal, Improper Joinder: Confronting Plaintiffs' Attempts to Destroy Federal Subject Matter Jurisdiction, 59 Am. U. L. Rev. 49, 50-52 (2009).

^{44.} Id.

^{45.} See Kirk v. Michael Reese Hosp. and Med. Ctr., 513 N.E.2d 387, 399 (Ill. 1987) (deciding for the first time, by the Supreme Court of Illinois, that the learned intermediary doctrine shields drug manufacturer's from the duty

In fact, courts have determined that if there is a duty to warn at all, it is to warn the physician of the drug interaction and not the patient.⁴⁶

In limited circumstances, however, the view of the pharmacist and his duties to his patients has been changing, bringing it in conflict with the traditional notions of the protections under the learned intermediary doctrine. There are now particular exceptions⁴⁷ to the notion that the pharmacist has few duties, if at all, owed to the patient. Some states now recognize exceptions when the pharmacy assumes the duty to warn of potential drug interactions.⁴⁸ Usually, this is because the pharmacy has advertised that it has a computer system to check for drug interactions, ⁴⁹ Therefore, the pharmacy assumes the duty to check for drug interactions, and not doing so qualifies as a breach of that assumed duty.⁵⁰ Another exception arises when the pharmacist has special knowledge that would prevent a dangerous

to warn); see also Cottam v. CVS Pharm., 764 N.E.2d 814, 821 (Mass. 2002) (extending the learned intermediary doctrine to pharmacists and establishing there is no general duty to warn imputed to a pharmacists); Leesley, 518 N.E.2d at 763 (expanding the Kirk decision where the court determined that the pharmacist was also protected under the learned intermediary doctrine). Even though Cottam is about side effects instead of drug interactions, many courts have since used this seminal case for the proposition that the pharmacist has no general duty to warn. See Deed v. Walgreen Co., 927 A.2d 1001, 1003 (Conn. 2007) (invoking the learned intermediary doctrine in defense of pharmacy when the pharmacy had no special knowledge that drugs being taken would result in a toxic interaction); see also Hand v. Krakowski, 89 A.D.2d 650, 650 (N.Y. 1982) (stating that it was an issue of fact for the jury to determine if the pharmacist had breached his professional duty in filling a prescription that interacted with alcohol when the pharmacist had special knowledge that the patient was an alcoholic).

- 46. DiGiovanni v. Albertson's, Inc., 940 N.E.2d 73, 77 (Ill. App. Ct. 2010); see also Happel, 766 N.E.2d at 1122 (explaining that when the pharmacist knew or should have known of an interaction between the prescribed drug and a known allergy, the pharmacist had a duty to either warn the physician or the patient, despite the learned intermediary doctrine). Contra Silves v. King, 970 P.2d 790, 794 (Wash. App. Ct. 1999) (determining that the pharmacist has no duty to warn the patient, not even a duty to warn the physician of a clear drug interaction).
- 47. Neiner, *supra* note 36, at 495. For instance, in Illinois, there are four factors that courts take into consideration when determining if a duty should exist, thus carving out an exception under the learned intermediary doctrine. *Id.* These four factors are: "(1) the reasonable foreseeability of harm; (2) the likelihood of an injury occurring; (3) the magnitude of the burden; (4) the consequences of imposing a duty on pharmacists." *Id.*
- 48. *Baker*, 544 N.W.2d at 731 (deciding that when a pharmacy advertises that its computer system will detect drug interactions, the pharmacy assumes the duty to warn the patient of drug interactions, and is therefore not shielded by the learned intermediary doctrine).

^{49.} Id.

^{50.} *Id*.

interaction.⁵¹ Much of the movement to impose new duties on pharmacists started with the federal Omnibus Budget Reconciliation legislation in the 1990s⁵² and with the changing role of the pharmacist in the United States.⁵³

C. The Changing View of Pharmacists' Roles and Duties

The Omnibus Budget Reconciliation Act of 1990 (hereinafter "OBRA") legislation imposes a duty on pharmacists with respect to Medicaid subscribers.⁵⁴ Among other things, this legislation mandates Medicaid subscribers must be consulted by pharmacists about the medication they receive at a pharmacy and screened for potential drug interactions between prescribed drugs.⁵⁵ As a

^{51.} See Bobay v. Walgreen Co., 2009 WL 1940727 (Ind. Dist. Ct. 2009) (stating no duty imposed on the pharmacist was established, but the court did not foreclose the possibility that under different circumstances, where the pharmacist had specific knowledge of the other prescriptions that may cause an interaction, that the duty to warn of the drug interaction would be imposed on the pharmacist); see also Brienze v. Casserly, No. 01-1655-C, 17 Mass.L.Rptr. 214 (Mass. 2003) (stating that because the pharmacy had filled both prescriptions within days of each other, and there was in fact a known direct interaction, the pharmacy had a duty to warn of the potentially dangerous interaction).

^{52.} Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388. See discussion infra Part II(B).

^{53.} See infra notes 61-68 and accompanying text (giving explanations about the way the roles have changed).

^{54. 104} Stat. at 1388; see also Kenneth R. Baker, The OBRA 90 Mandate and its Developing Impact on the Pharmacist's Standard of Care, 44 DRAKE L. REV. 503, 503 (1996) (explaining the provisions in OBRA that affect pharmacists and Medicaid patients, including the responsibility of counseling patients, part of which is looking for adverse reactions and interactions with the prescribed drug).

^{55.} Cacciatore, supra note 16, at 110-12. OBRA imposed upon states the requirement of creating state legislation to comply with OBRA. Id. This included the creation of the drug use review ("DUR") program to ensure that the drugs prescribed were medically necessary and that they were in fact working how they were supposed to work. Id. The DUR program included an educational aspect. Id. Pharmacists were required to screen for potential problems with the drug prescribed, including looking for drug interactions. Id. OBRA also required pharmacists to offer patient consultations related to the prescribed drug. Id. This provision is often referred to as the "offer to counsel" provision. Id.; see also Jesse C. Vivian & Joseph L. Fink III, OBRA '90 at Sweet Sixteen: A Retrospective Review, U.S. PHARM., Mar. 20 2008,, at 59-65, available at http://www.uspharmacist.com/content/d/featured_articles/c/10126/ (explaining that different states interpreted the need to counsel patients under OBRA in different ways, some deciding that the counseling session had to be conducted in-person while others stated that in-person consultation was not necessary); OBRA 90 Mandated Drug Use Review (DUR), IDAHO STATE College OF PHARMACY, University availablehttp://idahodur.isu.edu/mission.html (last visited Oct. 21, 2011) (stating that one of the College's missions is to abide by and improve the drug review process, and that specialized computer systems are integrated into this

matter of reference in the OBRA legislation, it mentions the Drugdex System as an acceptable system for pharmacies to use in order to check for drug interactions.⁵⁶

Even though OBRA mandates technically apply to Medicaid patients only, most states have instituted the same policies across all patient groups.⁵⁷ For this reason, pharmacies have patient counseling windows where the pharmacist can ask whether a patient has any allergies or questions regarding the prescribed medication.

Although OBRA appears to place additional "duties" on pharmacists, it does not actually allow for a private right of action in accordance with these "duties." Thus, OBRA was not the solution to impose a duty to warn on pharmacists for which there would be civil liability for the breach of that duty. Instead, OBRA has fallen out of the spotlight, especially with state regulation largely overshadowing the federal mandates.

In addition to OBRA, the pharmacist's role has changed greatly to be more patient-oriented.⁶¹ In the 1920s, pharmacists had to mix over eighty percent of all prescriptions.⁶² By 1974, that number dropped to only one percent.⁶³ Over the years, pharmacists' duties have shifted, becoming more in line with patient issues.⁶⁴

The pharmacist's role has changed both through outside legislation and from within the profession itself.⁶⁵ While OBRA

process to ensure effectiveness); Strengthening the Texas Medicaid Drug Utilization Review Program, HEALTH AND HUMAN SERVS. COMM'N (Dec. 2009), http://www.hhsc.state.tx.us/reports/Rider49_MedicaidDrug_1209.pdf (analyzing the Texas mandates and how the program in that state resulted in revenue cost savings).

- 56. OBRA, 42 U.S.C. § 1396r-8 (2006); Products and Services, Drugdex System, DRUG DISCOVERY ONLINE, http://www.drugdiscoveryonline.com/product.mvc/Drugdex-System-0001 (last visited Jan. 9, 2013).
- 57. South Carolina Pharmacy Practice Act, S.C. CODE Ann. § 40-43-88 (1976); Wyoming Pharmacy Act, Wyo. Stat. § 33-24-9 (2002); Or. Rev. Stat. § 414.385 (2009).
- 58. See Kowalski v. Rose Drugs of Dardanelle, Inc., No. 10-459, 2011 Ark. 44, *12 (Ark. 2011) (failing to impose a private right of action under OBRA); see also Johnson v. Badger Acquisition of Tampa LLC, 983 So. 2d 1175, 1182 (Fl. Dist. Ct. App. 2008) (finding that OBRA did not create a private cause of action).
- 59. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388.
- 60. See supra note 55 (explaining state regulations that emerged in compliance with OBRA).
 - 61. Cacciatore, *supra* note 16, at 104.
 - 62. Id.
 - 63. *Id*.
 - 64. See AphA-ASP/AACP COD, supra note 7, at 96.
 - 65. See Cacciatore, supra note 16, at 104 (explaining that the pharmacy

and state legislation have mandated specific changes to the pharmacist's role, internally in the pharmacy profession there has also been a change. 66 Marketing strategies are now focused on the pharmacist's relationship with the patient. 67 Additionally, young pharmacists are now learning about the "advanced patient care objective" in pharmacy school, 68 with some schools even participating in patient-counseling competitions. 69

The enhanced communication and relationship between pharmacists and patients has created more reliability on pharmacists to warn patients of various dangers.⁷⁰ Meanwhile, the pharmacist still does not have a legal duty to warn the patient of drug interactions,⁷¹ even though pharmacists often have knowledge of potential interactions and are taught to notify patients of such interactions.

While the changing role of pharmacists has potentially opened pharmacists up to additional liability, they are still protected under the learned intermediary doctrine. ⁷² Because of this, the burden to warn patients of drug interactions continues to fall on the prescribing physician.

profession has become more patient oriented).

^{66.} *Id*.

^{67.} Id.

^{68.} *Id.*; see also Mark R. Amsler et al., *Pharmaceutical Care in Chain Pharmacies: Beliefs and Attitudes of Pharmacists and Patients*, J. AM. PHARM. ASSOC., 2001 (explaining the expanded roles of pharmacists as providers of "pharmaceutical care" and not merely dispensers of drugs).

^{69.} American Pharmacists Ass'n, AphA-ASP National Patient Counseling Competition, PHARMACIST.COM, http://www.pharmacist.com/apha-asp-national-patient-counseling-competition (last visited Jan. 9, 2013) [hereinafter Patient Counseling Competition]. The competition focuses on the "art of patient counseling," where students counsel patients "on the safe and effective use of a medication after consulting drug information resources and a patient medication profile." American Pharmacists Ass'n, 2013 AphA-ASP National Patient Counseling Competition, PHARMACIST.COM, http://www.pharmacist.com/sites/default/files/files/NPCC%20Poster%202013.p df (last visited Jan. 9, 2013).

^{70.} See GALLUP POLL, HONESTY AND ETHICS OF PROFESSIONS (2009), available at http://www.gallup.com/poll/124625/honesty-ethics-poll-finds-congress-image-tarnished.aspx (demonstrating that patients trust and rely on pharmacists more than other professions); see also Cacciatore, supra note 16 (explaining the changing role of the pharmacist to be more patient-oriented).

Happel, 766 N.E.2d at 1127; Leesley v. West, 518 N.E.2d 758, 763 (Ill. App. 1988).

^{72.} Happel, 766 N.E.2d at 1127; Leesley, 518 N.E.2d at 763.

III. ANALYSIS

Pharmacists have unique responsibilities and knowledge.⁷³ Because of these special skills, they are trusted with dangerous drugs.⁷⁴ As professionals, pharmacists must adhere to the custom in their profession.⁷⁵ Although pharmacists may act negligently when dispensing prescription drugs that may interact with other drugs or conditions, they are shielded by the learned intermediary doctrine.⁷⁶ Thus, pharmacists have no duty to warn patients of drug interactions.

A. Pharmacists as Professionals

Pharmacists, like many professional professions,⁷⁷ have special education and training requirements.⁷⁸ Because of their special knowledge and training, pharmacists are not laypeople, but are professionals held in a position of trust.⁷⁹ When a professional has specific knowledge that other people do not have, ordinary people trust these professionals to exercise this special knowledge on their behalf.⁸⁰ In fact, pharmacists are one of the most trusted types of professionals.⁸¹ Less trusted professionals included medical doctors, engineers, and lawyers, all of which have

^{73.} See BUREAU OF LABOR STATISTICS, supra note 5, at 1 (explaining that pharmacists must have specific knowledge, degrees, and must pass tests to show they are competent in unique areas of pharmacy).

^{74.} *Id.* (explaining that pharmacists must have specific knowledge, degrees, and must pass tests to show they are competent in unique areas of pharmacy).

^{75.} See DIAMOND, LEVINE, & BERNSTEIN, supra note 23, at 93-94 (explaining that professionals are held to a standard of care, usually expressed through custom).

^{76.} Leesley, 518 N.E.2d at 763.

^{77.} See in ra note 82 (explaining instances in which different types of professionals were held to a heightened professional standard of care).

^{78.} See BUREAU OF LABOR STATISTICS, supra note 5, at 1 (explaining that pharmacists must now complete a six year program and be licensed in each state where they wish to practice).

^{79.} BLACK'S LAW DICTIONARY 414 (9th ed. 2009) (defining layperson as "a person who is not a member of a profession or an expert on a particular subject"); see also GALLUP POLL, supra note 70 (stating that pharmacists are one of the most trusted professionals, second only to nurses). See Lynda Jensen, Pharmacists: A Matter of Trust, HERALD JOURNAL, http://www.herald-journal.com/health/pages/previous/trust.html (last visited Jan 9, 2013) (noting that pharmacists are one of the most trusted professionals because they are often an easy way to get access to a health care professional in order to obtain unbiased opinions about drugs and medical conditions). The article also points out that communication and individualized relationships with the patients are main motivators in trusting pharmacists. Id.

^{80.} GALLUP POLL, supra note 70.

^{81.} *Id.* The Gallup poll reported that sixty-six percent of Americans thought that pharmacists had very high/high honesty and ethical standards. *Id.*

been held to a professional standard of care.82

B. Custom Establishes the Professional Standard of Care

For a plaintiff to establish a prima facie case for negligence, he must show that the defendant acted in a manner not in conformity with the duty owed and caused the plaintiff's injuries.⁸³ To do so, the plaintiff must establish that the defendant's conduct fell below the applicable standard of care.⁸⁴ For a professional, the standard of care would be to act as a reasonably prudent professional.⁸⁵

The standard of care may be established through various means, but usually for a professional, it is established through custom.⁸⁶ Thus, if a plaintiff could prove that a specific custom existed in the profession, then that custom may be used to establish the duty. By proving that the professional did not adhere to the custom, the plaintiff could show a breach of the duty.⁸⁷

To prove that a custom exists, expert witnesses are used in a testimonial capacity.⁸⁸ Each expert would present to the court

- 83. See 57A AM. JUR. 2D Negligence § 71 (laying out the elements needed for a negligence action, including breach of a duty).
- 84. Horner v. Spalitto, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999) (discussing pharmacists are a professionals who should be held to the professional standard of care); S.Y. TAN, MEDICAL MALPRACTICE UNDERSTANDING THE LAW, MANAGING THE RISK 37 (2006).
 - 85. Horner, 1 S.W.3d at 522; TAN, supra note 84.
- 86. See RESTATEMENT (SECOND) OF TORTS § 299A cmt. e (1965) (explaining that the custom is the accepted practice in the profession).
- 87. See Owen, supra note 22, at 1673-74 (stating that breach of duty is the second element for a cause of action in a negligence case).
- 88. TAN, *supra* note 84, at 38. Experts are helpful in establishing the custom because they too have the required knowledge, schooling, and experience that one in the profession has as well. *Id.* Most often both the

^{82.} Id. Among the lowest ranked professions were medical doctors, engineers, and lawyers. Id. All these professionals have been held to a professional standard of care in various cases. See Broadway v. Bay Hosp., Inc., 638 So. 2d 176, 177 (Fla. 1st Dist. App. 1994) (stating that the medical malpractice case must be proved by showing that the professional standard of care was not met); see also Chapman v. Bearfield, 207 S.W.3d 736, 739 (Tenn. 2006) (applying the professional standard of care statewide to lawyers in Tennessee): Ahimsa Technic, Inc. v. Lighthouse Shores Town Homes Dev. Co... 543 So. 2d 422, 422 (Fla. 5th Dist. App. 1989) (upholding the finding that the engineer did comply with the professional standard of care of engineers); Hous. Auth. of City of Carrollton v. Ayers, 88 S.E.2d 368, 373 (Ga. 1955) (stating architects are held to the professional standard of care); Allied Enters., Inc. v. Brooks, 93 S.E.2d 392, 397 (Ga. App. 1956) (imposing professional standard of care on building contractors); Coyne & Delany Co. v. Selman, 98 F.3d 1457, 1472 (4th Cir. 1996) (stating that the professional standard of care is applicable to an employee benefit company that had negligently designed and administered group health plans); Lewis v. Rodriguez, 759 P.2d 1012, 1016 (N.M. App. 1988) (holding that polygraphers are professionals that are subject to the professional standard of care).

evidence that he or she is part of the particular profession of the defendant in the negligence case.⁸⁹ The expert would then present evidence, often with the aid of authoritative evidence, as to what the standard of care is in that particular profession.⁹⁰

For example, in medical malpractice cases, the expert witness would also be a doctor in the same specialty as the defendant and would testify to the accepted practice among doctors in that specialty. If the defendant did not act in accordance with the customary practice of doctors described by the expert, then it is likely that the jury would find that the doctor breached the duty and was therefore negligent.

Just as in the medical malpractice context, pharmacists are also professionals who should be expected to adhere to the professional standard of care. ⁹² As such, expert witnesses would testify to the pharmacy industries' customs. Then the jury would decide if the pharmacist adhered to the applicable standard or breached his duty. In the scenario discussed here, an expert would be used to demonstrate that the custom in the pharmacy profession is to warn the patient when a drug interaction is possible. When the pharmacist does not warn the patient of an interaction, the pharmacist breaches the duty to warn and may be liable in a negligence action.

Alternatively, a plaintiff may establish the standard of care in other ways. The standard of care may also be established through common knowledge, 93 statutes, 94 or the profession's code of

plaintiff and the defendant present their own expert witnesses to establish the custom. *Id.* Thus, if more than one custom is proposed, it is up to the fact-finder, most likely a jury, to decide which expert to believe. *Id.*

^{89.} *Id*.

^{90.} Id.

^{91.} See Perdieu v. Blackstone Fam. Prac. Ctr., Inc., 568 S.E.2d 703, 709-10 (Va. 2002) (asserting that an expert witness was needed to establish the custom and that the expert used here was not qualified to the same specialty because he did not have specific experience in nursing homes); see also Coston v. Bio-Med. Applications of Virginia, Inc., 654 S.E.2d 560, 562 (Va. 2008) (articulating that while there are some rare circumstances in which an expert is not needed because common knowledge would suffice, in most situations expert testimony is needed to establish the custom). Although the example in the text of the article is that of medical malpractice, the same basic theory is used for all professions in professional negligence actions. Id. For instance, expert testimony was needed in a professional negligence case against an electrical contractor because the information was technical and the complexity of the information was not suitable for an ordinary (lay) juror to understand without the aid of expert testimony as to the standard of care. Midwest Iron & Metal, Inc. v. Zenor Elec. Co., Inc., 19 P.3d 181, 183-84 (Kan. App. Ct. 2000).

^{92.} See generally supra Part III(a) (explaining that pharmacists are professionals).

^{93.} See Leonard v. Watsonville Cmty. Hosp., 305 P.2d 36, 42 (Cal. 1956) (explaining that leaving operating instruments in a patient's abdomen during a medical procedure is so obviously negligent that it is common knowledge to

ethics.95

C. Impact of the Learned Intermediary Doctrine Extended to Pharmacists and Its Implications on the Duty to Warn

Originally, the learned intermediary doctrine was created to shield drug manufacturers from liability for failure to warn patients of adverse side effects and interactions. The learned intermediary doctrine may be invoked to absolve the drug manufacturer of liability if it had provided warnings to the prescribing physician. The responsibility, then, falls on the physician to warn the patient of adverse side effects and interactions. Under these rules, the patient must sue the physician for recourse, and cannot sue the drug manufacturer.

jurors and that no further evidence of the standard of care is required beyond this common knowledge).

94. See Bryant v. Delmarva Power & Light Co., 1995 WL 653987 (Del. App. 1995) (stating that one of the ways in which the standard of care can be established is through statutes); see also Bob Godfrey Pontiac, Inc. v. Roloff, 630 P.2d 840, 844 (Or. 1981) (considering the types of statutes that give rise to the standard of care).

95. See Allen v. Lefkoff, Duncan, Grimes & Dermer, P.C., 453 S.E.2d 719, 722 (Ga. 1995) (articulating that the code of professional ethics that lawyers follow may indeed be instructive on determining what the standard of care is in a legal malpractice case).

96. See generally Marcus v. Specific Pharm., Inc., 77 N.Y.S.2d 508 (App. Div. 1948) (embodying for the first time the rule that would later evolve into the learned intermediary doctrine). The court held that the pharmaceutical company did not have a duty to warn the patient of drugs that were available only through the physician's prescription). Id. at 510; Love v. Wolf, 38 Cal Rptr. 183, 193 (Dist. Ct. App. 1964) (establishing for the first time the "no duty rule," which states that as long as the drug manufacturer warns the physician, they have no further duty to warn the patients). The explicit reasoning behind the "no duty rule" and the term "learned intermediary" came about two years after the Love decision, in Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). The reasoning was that because the drug was only available through prescription, the liability and warning should be placed on the prescribing physician to then convey the pertinent information to the patient. Id.

97. Diane Schmauder Kane, Annotation, Construction and Application of Learned Intermediary Doctrine, 57 A.L.R. 5TH 1 (1998); Paul M. Coltoff et al., To Whom Warnings Must be Provided: the Learned-Intermediary Doctrine, 28 C.J.S. Drugs and Narcotics § 128; Richard B. Goetz & Karen R. Growdon, A Defense of the Learned Intermediary Doctrine, 63 FOOD & DRUG L.J. 421, 422 (2008); John A. Camp & Gary M. Pappas, The Learned Intermediary Doctrine in Florida: Courts Wrestle with Claimed Exceptions to the Doctrine in Drug and Device Litigation, 82 FLA. B.J. 8, 9 (Dec. 2008); Kyle T. Fogt, The Road Less Traveled: West Virginia's Rejection of the Learned Intermediary Doctrine in the Age of Direct-to-Consumer Advertising, 34 J. CORP. L. 587, 590 (2009).

98. 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, 403-04 (2004).

1. The History and Intent of the Learned Intermediary Doctrine

The learned intermediary doctrine was created to alleviate the pressure on the drug manufacturing industry to warn patients of the dangers of prescription medications. Because drugs are inherently dangerous depending on medical condition, allergies, dosage requirements, and interactions, the drug manufacturer could be open to endless liability. Liability may impede the drug manufacturers from continuing to research and create new drugs that benefit patients. As such, there was a need to create a defense to this endless liability, and thus the learned intermediary doctrine was created. Under this doctrine, the liability would be passed to the physician as long as the drug manufacturer warned the physician.

The learned intermediary doctrine also has the effect of putting the information about the dangers of these drugs in more capable hands.¹⁰⁴ Physicians, as opposed to patients, know much more about drugs, medical conditions, and drug therapy.¹⁰⁵ Therefore, it was thought that the physicians are in a better position than the patient to make an informed choice about drug treatment methods.¹⁰⁶ Despite the original intent, it has been argued that the doctrine does not adequately protect patients and that the purpose of the doctrine has become obsolete.¹⁰⁷

^{99.} In re Norplant Contraceptive Prods. Litig., 165 F.3d 374, 379 (5th Cir. 1999).

^{100.} According to product liability theory, the drug manufacturer would be liable for the failure to warn of the product's dangers because the product is unreasonably dangerous. Fogt, *supra* note 97, at 589.

^{101.} See Goetz & Growdon, supra note 97, at 422 (explaining the rationale behind the inception of the learned intermediary doctrine).

^{102.} See Sterling, 370 F.2d at 85 (enunciating for the first time, the learned intermediary doctrine).

^{103.} Id.

^{104.} Id.

^{105.} Id.

^{106.} McKee v. Am. Home Prods., Corp., 782 P.2d 1045, 1050 (Wash. 1989).

^{107.} See Camp & Pappas, supra note 97, at 8 (discussing the recent changes and exceptions to the learned intermediary doctrine); Stephen R. Kaufmann & Jason D. Johnson, The Learned Intermediary Doctrine and Pharmaceutical Company Liability, 95 ILL. B.J. 202, 206 (2007) (explaining that some jurisdictions have created exceptions to the protection of the learned intermediary doctrine in circumstances where the drug manufacturer directly marketed the drug to consumers). This exception is called the direct-to-consumer-advertising/marketing exception. Id.; see also Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1264 (N.J. 1999) (deciding not to allow the learned intermediary doctrine to protect drug manufacturers when direct-to-consumer advertising has occurred).

2. Extension of the Learned Intermediary Doctrine to Pharmacists

Although the learned intermediary doctrine was originally developed to shield drug manufacturers from liability, it has since been extended to shield pharmacists from liability as well. ¹⁰⁸ In extending the learned intermediary doctrine to pharmacists, it is taking away a safety precaution in warning the patient of potentially dangerous drug interactions. Thus, the physician is truly the only safeguard left to stop a potentially deadly drug interaction that a patient may know nothing about and for which he is never given notice. In doing this, the patient is also kept in the dark, unable to make his own decisions about his healthcare treatment and the potential risks.

Interference with the doctor-patient relationship has been cited as the primary concern that could arise from shielding pharmacists from liability under the learned intermediary doctrine. Proponents of that approach worry that opening pharmacists up to liability will encourage pharmacists to second-guess doctors. Also, others argue that pharmacists usually collect patient information to flag possible problems with a prescription, but that if pharmacists were opened up to liability based on the information they collect, they will stop gathering patient information, therefore depriving patients of an important service. Additionally, it is argued that doctors are in the best position to know which prescriptions the patient is on and which ones to prescribe at any given time. However, pharmacists are

108. Barney, supra note 98, at 404. In re New York Cnty. Diet Drug Litig., 691 N.Y.S.2d 501, 502 (N.Y. App. Div. 1st Dept. 1999) (deciding that pharmacists are shielded by the learned intermediary doctrine); Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85, 87 (E.D. Pa. 1986) (stating that the court will not impose a duty to warn the patient in this case because it does not think the pharmacist should have a duty when the drug manufacturer does not. The drug manufacturer in this case, of course, does not have a duty because it is shielded under the learned intermediary doctrine. Thereby this case illustrates the court taking a round-about way of extending the learned intermediary doctrine to pharmacists.); Jones v. Irvin, 602 F. Supp. 399, 402 (S.D. Ill. 1985) (stating again that it is the physician's responsibility to warn the patient of drug interactions, or adverse side effects, and not the pharmacist); Silves, 970 P.2d at 794 (nothing that there is no duty to warn imposed on the pharmacist because it would interject the pharmacist into the doctor-patient relationship. Instead, the duty is placed on the physician to warn the patient.); Johnson 675 So. 2d at 1038 (imposing the duty to warn on the physician instead of the pharmacist); McKee, 782 P.2d at 1050 (extending the learned intermediary doctrine to pharmacists).

109. See supra note 36 and accompanying text (discussing the main reasons why pharmacists have remained under the learned intermediary doctrine, specifically citing the importance of the doctor-patient relationship in *Happel*, 766 N.E.2d at 1124).

- 110. Jones, 602 F. Supp. at 402.
- 111. Happel, 766 N.E.2d at 1124.
- 112. Id. at 1126.

trained specifically in prescription medication.¹¹³ Thus, it is logical that pharmacists actually know much more about specific drugs and their interactions with other drugs than a doctor normally would. As discussed later, shielding pharmacists under the learned intermediary doctrine does not best serve patients and is contrary to the oaths pharmacists have sworn to uphold.¹¹⁴

3. Exceptions to the Learned Intermediary Doctrine Shielding Pharmacists from Liability

Currently, the majority of jurisdictions extend the learned intermediary doctrine to pharmacists, finding that they are not liable in negligence actions, despite acting negligently. Some jurisdictions do allow for certain limited exceptions, taking the case out from under the safeguard of the learned intermediary doctrine, and finding possible liability instead. Most of these exceptions, however, came about because of adverse drug side effects about which the pharmacist did not warn the patient. Some exceptions have been applied, or have the possibility of being applied, in instances of a pharmacist's failure to warn of drug interactions as well.

a. Assumed Duty to Warn

One such instance is when the pharmacy assumes the duty to warn. This usually happens in the context of a pharmacy

114. See Happel, 766 N.E.2d at 1127 (explaining the traditional reasons to shield pharmacists from liability under the learned intermediary doctrine with responses to such reasons); see also infra notes 150, 154, 167 and accompanying text (proposing that pharmacists' roles, codes of ethics and custom already establish that pharmacists seek to prevent drug interactions and should not be protected under the learned intermediary doctrine any longer).

115. McKee, 782 P.2d at 1050; Cottam, 764 N.E.2d at 821; Leesley, 518 N.E.2d at 762; Jones, 602 F.Supp. at 399; Ramirez, 628 F.Supp. at 88; Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 552-53 (1985); Batiste v. Am. Home Prods. Corp., 32 N.C.App. 1, 231 S.E.2d 269, 274 (1977).

116. See supra Part II(B), with emphasis on cases in note 46 (explaining the limited circumstances in which courts have determined there may be a duty imposed on pharmacists regardless of the learned intermediary doctrine).

117. See generally supra note 45 (most cases arise from some kind of side effect and not from a drug interaction).

118. *Happel*, 766 N.E.2d at 1127 (applying partial responsibility on the pharmacist to warn of drug interactions, but falling short of imposing an affirmative duty on the pharmacist to notify the patient of drug interactions).

119. See 57A AM. JUR. 2D Negligence § 193 (describing the "assumed-duty doctrine" as that which imposes the duty voluntarily assumed to not act negligently in performing the duty and asserting that the person that assumes the duty may be liable in a negligence action if he breaches that assumed duty).

To apply the doctrine, the defendant must have (1) acted in an

^{113.} Horner, 1 S.W.3d at 523.

advertising that its computer system will check for drug interactions.¹²⁰ When such a situation occurs, then the duty to warn is imputed on the pharmacy to use those mechanisms to check for drug interactions and to warn the patient if one is found.¹²¹ Of course, this also means that the pharmacy implicitly takes on the duty to properly use the mechanism to check for these possible interactions.

b. Personal Knowledge Creates a Duty to Warn

Another instance is the personal knowledge exception. 122 This exception allows the plaintiff to bring a negligence action against the pharmacist when the pharmacist has actual, personal knowledge of a condition in which a drug interaction is blatantly apparent. 123 Such an instance has been upheld when the pharmacist had actual knowledge that the patient was an alcoholic and that the drug prescribed would adversely interact with alcohol. 124 Another example is when the pharmacist actually knew that the patient's allergy would interact with the prescribed drug and filled the prescription anyway, without warning the patient. 125

affirmative way or through a promise to act, undertook to render a service that was reasonably calculated to prevent the type of harm that befell the plaintiff; and either (2) that the plaintiff relied on the defendant to perform the service; or (3) that defendant's undertaking increased plaintiff's risk.

Wark v. U.S., 269 F.3d 1185, 1189 (10th Cir. 2001). See Baker, 544 N.W.2d at 730 (stating that the pharmacy assumed the duty to warn of drug interactions when it advertised its computer system that checks for these interactions); Cottam, 764 N.E.2d at 821 (indicating that the defendant pharmacy assumed the duty to warn when it warned the patient of some side effects but not others).

120. See Baker, 544 N.W.2d at 730-31 (deciding that the learned intermediary doctrine does not apply when the pharmacy assumes the duty to warn the patient). This exception is a spin-off of the exception to the drug manufacturer's application of the learned intermediary doctrine with direct-to-consumer marketing. See also Charles J. Walsh, Steven R. Rowland & Howard L. Dorfman, The Learned Intermediary Doctrine: The Correct Prescription For Drug Labeling, 48 RUTGERS L. REV. 821, 875-77 (1996) (explaining that when the drug manufacturer advertises its drug directly to the patient, they are no longer shielded by the learned intermediary doctrine and have a duty to warn the patient).

- 121. Baker, 544 N.W.2d at 729-31.
- 122. Hand, 453 N.Y.S.2d at 651.
- 123. *Id*.
- 124. Id.
- 125. Happel, 286 F. Supp. 2d at 947.

4. The Learned Intermediary Doctrine as an Impediment to Liability in Today's Pharmacies

The fact is that many, if not all, pharmacies now have software that check for drug interactions. The time has long passed that pharmacists did all their work by hand. Now pharmacies are highly computerized and almost all have systems that specifically check for drug interactions.

Most drug interaction cases sounding in negligence, however, are simply barred by the learned intermediary doctrine. ¹²⁸ The learned intermediary doctrine is a significant impediment to courts imposing a duty on pharmacists to warn patients of drug interactions. Even with the limited exceptions to the learned intermediary shield of liability, patients are still being injured and are unable to recover from pharmacists' negligence.

D. The Pharmacist's Changing Role from Drug Dispenser to Provider of Pharmaceutical Care

The role of the pharmacist has changed drastically in recent years. While pharmacists' duties were once exclusively to mix and dispense drugs, the duties are now more patient oriented. Along with OBRA, and each state's legislation, and the pharmacy industry has internally changed its focus and image. In commercials and other avenues of advertising, pharmacies hold the profession out to patients as being patient oriented. Pharmacy schools teach that the profession is one that is patient oriented.

126. Ctr. for Med. & Healthy Aging, *Drug Interactions, Steps You Can Take To Decrease Your Risk of Drug Interactions, available at* http://www.medsandaging.org/DrugInteractions.htm (last visited Apr. 20, 2012).

127. Cacciatore, supra note 16, at 104.

128. Leesley, 518 N.E.2d at 763; Cottam, 764 N.E.2d at 821; Deed, 927 A.2d at 1003.

129. Cacciatore, supra note 16, at 104.

130. See supra Part II(C) (explaining the OBRA legislation specifics).

131. See id. (articulating that states have expanded pharmacy laws beyond what was required under OBRA).

132. See Am. Pharm. Assoc., Pharmacists Offer Guidance on Top Over-the-Counter Medications (Apr. 25, 2011), available at http://www.reuters.com/article/2011/04/25/idUS110518+25-Apr-

2011+PRN20110425 (stating that pharmacists should attempt to conduct patient consults, and that on average they take merely three minutes).

133. AM. PHARM. ASSOC., USING RELATIONSHIP MARKETING TO EXPAND PHARMACY SERVICES 3 (2007), http://www.pharmacist.com/oitco/default/files/files/mtm.using.relationship.m.

 $http://www.pharmacist.com/sites/default/files/files/mtm_using_relationship_m~arketing.pdf.$

134. Cacciatore, *supra* note 16, at 110-112.

135. AphA-ASP/AACP COD, supra note 7, at 101-102; Patient Counseling Competition, supra note 69.

This change in the view of the role of a pharmacy, both from the outside and from within the profession, necessitate that pharmacists take on additional responsibilities. With those responsibilities come certain liabilities, one being the duty to warn the patient of drug interactions.

No jurisdiction has gone as far as to find that there is an unconditional duty to warn of drug interactions imposed on pharmacists. The consequence, of course, is that the liability is placed solely on physicians. Alternatively, if the patient cannot bring a case against the physician for some reason or the case fails at trial, then the patient has no recourse. 137

For instance, when a plaintiff originally brought a claim against multiple defendants, including doctors and the pharmacy, summary judgment was entered favoring all but one doctor and the hospital pharmacy. The remaining doctor settled for a comparatively small amount while the trial continued for the hospital pharmacy. He jury trial, the plaintiff received a jury verdict of over four million dollars, but the appellate court reversed, stating that the learned intermediary doctrine shielded the pharmacy. Thus, the plaintiff was left with the small settlement from one doctor with no further recourse. Surely imposing a duty on the pharmacist to warn of drug interactions far surpasses the original goals of the learned intermediary doctrine applied to drug manufacturers, and is in line with the pharmacists' new patient oriented role.

IV. Proposal

Pharmacists should have a duty to warn patients of drug interactions and should not be shielded by the learned intermediary doctrine. Further, to comply with this duty, pharmacists should also have a duty to inquire as to whether a drug interaction is present. It should not be tolerated when the pharmacist notifies the physician about a drug interaction, the physician does nothing, and the pharmacist nonetheless fills the

^{136.} While no jurisdiction has explicitly adopted the view of this article, one jurisdiction has come close. In *Dooley v. Everett*, 805 S.W.2d 380, 384-86 (Tenn. App. 1990), the court determined that the pharmacist should be held to the professional standard of care, but that it was up to the jury to determine whether there was in fact a duty to warn the patient of drug interactions.

^{137.} See Springhill Hospitals, Inc. v. Larrimore, 5 So. 3d 513, 516 (Ala. 2008) (overturning a jury verdict of over four million dollars, stating that the pharmacy was shielded by the learned intermediary doctrine).

^{138.} *Id*.

^{139.} *Id.* While the plaintiff and last remaining doctor settled for \$200,000, the original jury verdict included more than \$4,000,000. *Id.*

^{140.} Id. at 519.

^{141.} Id. at 516.

prescription without providing any warning to the patient.¹⁴² The duty to warn the patient of drug interactions is established through the custom of the profession and should not be abrogated by the learned intermediary doctrine because pharmacists' ethical codes display intent to serve patients without a doctrinal shield.

A. Pharmacists' Standard of Care Established by Custom

As professionals, pharmacists must be held to a professional standard of care. This standard is determined by custom¹⁴³ and demonstrated through expert testimony.¹⁴⁴ In the context of drug interactions, an expert would need to testify that pharmacists usually do check for drug interactions and inform the patient of any such drug interactions.¹⁴⁵

Once this is established, then the standard of care may be compared to the actual conduct of the individual pharmacist to show whether he complied with that standard or breached the duty. ¹⁴⁶ The duty would be breached when the pharmacist either did not check for any drug interactions or did not notify the patient of any known drug interactions.

Due to the changing role of the pharmacy profession, it is even more likely that an expert would testify to the fact that

^{142.} See DiGiovanni, 940 N.E.2d at 77 (explaining that the pharmacist's duty to warn was fulfilled when the pharmacist warned the physician of the drug interaction, even though the doctor did not decide to change the drug and the interaction still occurred, severely harming the patient).

^{143.} See RESTATEMENT (SECOND) OF TORTS § 299A cmt. e (1965) (explaining that the custom is used to determine the standard of care for professionals).

^{144.} See McKee, 782 P.2d at 1057 (articulating that the standard of care where professional duties are concerned is often determined by the use of expert witnesses, including in a pharmacist negligence action). "In general, expert testimony is required when an essential element in the case is best established by an opinion which is beyond the expertise of a layperson . . . [t]hus, expert testimony will generally be necessary to establish the standard of care" Id.

^{145.} See Lasley v. Shrake's Country Club Pharm., Inc., 880 P.2d 1129, 1134 (Ariz. App. 1st Div. 1994) (explaining that in this case experts were presented to determine whether the pharmacist has a duty to warn established by custom, such that there was a genuine issue of material fact, reversing the summary judgment decision previously entered); see also Nail v. Publix Super Markets, Inc., 72 So.3d 608, 616 (Ala. 2011) (determining that sufficient expert testimony was presented to allude to the determination that the pharmacist has a duty to counsel patients in order to detect potentially dangerous drug interactions). See contra Bobay v. Walgreen Co., 2008 WL 3256368 (N.D. Ind. 2008), on reconsideration, 2009 WL 1940727 (N.D. Ind. 2009) (deciding that when no expert testimony from a pharmacist was offered to establish the standard of care, no corresponding breach of a duty could be shown and the defendant pharmacist was granted summary judgment).

^{146.} See Owen, supra note 22, at 1673-74 (indicating that breach is one of the required elements for a negligence action).

pharmacists normally do warn patients of drug interactions.¹⁴⁷ Not only do pharmacists dispense drugs, but they also consult with patients about the prescribed drugs, answer questions about generic drugs, and help patients with over-the-counter medication questions and choices.¹⁴⁸ The statutory regulations¹⁴⁹ for the professional standards of ethics of pharmacists¹⁵⁰ show a clear duty to patients and a responsibility to ensure the patient's welfare in dispensing drugs.

Again, because most pharmacists now take on these new responsibilities to patients, it is likely now considered custom in the profession.¹⁵¹ Thus, if a pharmacist's conduct does not adhere to the custom of warning the patient of drug interactions, then a breach of duty exists. Clearly, through the use of custom, courts should impose on pharmacists a duty to warn patients of drug interactions.

B. The Learned Intermediary Doctrine May Not Shield the Pharmacist from Liability in Denial of the Pharmacists' Code of Ethics or Oath

Even if pharmacists have a professional duty established by custom, the learned intermediary doctrine continues to shield pharmacists from liability. This can no longer be tolerated. Because both the general negligence principles and the pharmacists' professional standards of conduct, ethics, and oaths

^{147.} See Your Pharmacist: A Partner in Drug Safety, PFIZER 1 (Oct. 2011), http://www.pfizer.com/files/health/medicine_safety/4-4_Your_Pharmacist.pdf (stating that "pharmacists are medication experts, checking each prescription to help ensure that...the new medication will not interact with anything else they know you are taking"). Going even further, Pfizer later states that "your pharmacist is a resource and an educator for you and your family." Id. Additionally, Pfizer tells patients in its brochure to "[l]isten to the pharmacist's advice." Id. at 2.

^{148.} George Hradecky, *The Evolving Role of the Pharmacist, Pharmaceutical Representative*, SPECTROSCOPY (Sept. 1, 2001), http://www.spectroscopyonline.com/

spectroscopy/article/articleDetail.jsp?id=113520; Your Pharmacist: A Partner in Drug Safety, supra note 147, at 1; Cacciatore, supra note 16, at 104; see also Patient Counseling Competition, supra note 69 (explaining that even students participate in a competition naming the best student to perform patient consultations).

^{149.} See discussion supra Part II(C) (explaining the OBRA legislation specifics).

^{150.} See Greenough, supra note 25, at 398-99 (stating that the profession's code of ethics may be an acceptable way to establish the duty owed). For a further discussion of the ethics standards applicable to pharmacists, abrogating the learned intermediary doctrine, see discussion infra Part IV(B).

^{151.} See Nail v. Publix Super Markets, Inc., 72 So.3d 608, 614 (Ala. 2011) (determining that sufficient evidence through expert testimony established that a duty to consult patients was an accepted custom).

^{152.} Happel, 766 N.E.2d at 1127; Leesley, 518 N.E.2d at 763.

clearly show that the profession itself should accept liability, the learned intermediary doctrine should not shield pharmacists.

While there are multiple pharmacist codes of ethics or oaths that exist, they are very similar.¹⁵³ Pharmacists take these oaths or undertake these codes to abide by the goals of the profession. Because the profession creates these standards, it is logical that these standards are an accurate gauge of how the pharmacy profession determined that pharmacists should conduct themselves.¹⁵⁴ Although some of these standards seem vague, courts should use these standards to impose liability regardless of any protection under the learned intermediary doctrine.¹⁵⁵ The pharmacist standards are relevant here by looking at both the purpose and the language of these standards.

Each of the pharmacist standards clearly has a purpose of creating a responsibility to the patient, emphasizing the "covenantal relationship" with him. Mainly, pharmacists are to

153. See AphA-ASP/AACP COD, supra note 7, at 101-02 (reproducing multiple oaths and codes that pharmacists follow, making it easy to see the similarities among them). Each code speaks of obligations to patients and the goals and values of the profession. *Id.* Of the eight codes in the Code of Ethics for Pharmacists, three are geared specifically toward patients, while the remaining five are either geared toward other pharmacy professionals or society at large. *Id.* at 102. Also, the Pledge of Professionalism mentions a relationship to the patient in three of the five pledges. *Id.*

154. See Dale J. Atkinson, NABP Legal Briefs: Doody to Warn, NAT'L ASS'N OF BOARDS OF PHARMACY (Dec. 10, 2010), http://www.nabp.net/news/nabplegal-briefs-doody-to-warn/ (stating that the pharmacy profession and patients' trust is undermined when courts determine that pharmacists do not have a duty to warn, contrary to professional standards). Specifically, Atkinson attacks the Illinois decision in DiGiovanni, 940 N.E.2d 73, because the court determined, without looking at the professional standards within the pharmacy field, that there was no duty imposed on pharmacists. Id.; see also LAURA A. CARPENTER & KENNETH R. BAKER, PHARMACISTS' DUTY TO WARN: SUGGESTING A BALANCE BETWEEN NO DUTY AND UNDOABLE DUTY 1, 16-17 (2007), available at http://ebookbrowse.com/pharmacists-duty-to-warn-suggesting-a-balance-between-no-duty-and-an-undoable-duty-doc-d142904135 (stating that pharmacy professional standards are a tool to measure what is expected of licensed pharmacists and that not holding pharmacists liable for duties that the profession requires is a disservice to the pharmacy profession).

155. See AphA-ASP/AACP COD, supra note 7, at 101-02 (duplicating the Oath of a Pharmacist, Pledge of Professionalism, and the Code of Ethics for Pharmacists). For example, in the Oath of a Pharmacist, it states that a pharmacist will "assure optimal drug therapy outcomes for the patients I serve." Id. at 101. It is open to debate to determine what "optimal" means. Another example is from the Pledge of Professionalism, which states that the pharmacist will "facilitate the covenantal relationship required of the pharmaceutical caregiver." Id. at 102. Also, in the Code of Ethics for Pharmacists, it states that a pharmacist "respects the covenantal relationship between the patient and pharmacist." Id. What exactly is included in the "covenantal relationship" needs further exploration.

156. See id. (showing that the covenantal relationship language is in both the Pledge of Professionalism and the Code of Ethics for Pharmacists).

uphold this covenantal relationship by competently serving their patients to ensure that the "optimal therapeutic outcomes are attained." ¹⁵⁷

Further, the profession recognizes that knowledge of the science of pharmacy is not the only responsibility of the profession; equally as important is maintaining high ethics while treating patients. This includes striving for "optimal patient care." It makes sense that to ensure "optimal patient care," the drugs being dispensed must not interact with one another.

Moreover, the language in the Code of Ethics for Pharmacists displays the intent of the profession to take on responsibilities, regardless of the protection of the learned intermediary doctrine. Two phrases in particular are applicable to drug interactions.

First, that "[a] pharmacist promotes the good of every patient" This statement fits with the proposed requirement that a pharmacist must warn the patient of drug interactions. The possible consequences of not informing a patient of a potential drug interaction could be deadly. Warning a patient of a drug interaction and possibly avoiding the interaction would absolutely "promote the good of [that] patient." Opposite this, not informing the patient, could have disastrous consequences and does not serve the best interest of the patient.

Second, "[a] pharmacist respects the autonomy and dignity of each patient." This second phrase entails that the patient is allowed to make his own decisions, furthering the need to warn of drug interactions. When a patient is not notified of potential drug interactions, he does not make a conscious choice. The patient, if given a choice, may risk taking the medication, notify the doctor to get a replacement medication that does not create an interaction, or not take the medication at all. In effect, by not informing the patient of the possible drug interaction, the pharmacist is making this decision for the patient: the pharmacist is making the decision that the patient should take the drug and risk an interaction. This is not the best way to serve the patient and it certainly does not

^{157.} Id. at 101.

^{158.} Id.

^{159.} Id. at 102.

^{160.} Code of Ethics, supra note 6.

^{161.} *Id*.

^{162.} See Coll. of Am. Pathologists & Am. Assoc. of Clinical Chemistry, Toxicology Information (July 17, 2009), http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=home (follow "Reference Resources and Publications" link; then follow "Disease Diagnosis and Prevention" link; then follow "Toxicology Information" link) (stating that mixing prescription drugs can have severe consequences, even fatal ones).

^{163.} Code of Ethics, supra note 6.

^{164.} *Id*.

appear to comport with the Code of Ethics for Pharmacists.

Pharmacists already voluntarily follow these standards of conduct, ethics, and oaths, ¹⁶⁵ and they were created after the inception of the learned intermediary doctrine. ¹⁶⁶ Pharmacists should understand that not following their own profession's codes could have consequences on their patients and result in liability. ¹⁶⁷ It is reasonable, then, to require pharmacists to abide by these codes or suffer the consequences in court.

The pharmacy profession has made it clear what standards they intend to uphold. The courts must now recognize that under both the purpose and the language of these professional standards there is a duty to warn of drug interactions that should not be abridged by the learned intermediary doctrine.

V. CONCLUSION

Through the years, pharmacists have embraced additional roles and responsibilities.¹⁶⁹ Regardless of the fact that some of these duties were mandated with the imposition of OBRA and subsequent state legislation,¹⁷⁰ the pharmacy profession has embraced its new role in health care. As such, pharmacists must now accept the legal liability that comes with their redefined health care role.

By imposing on pharmacists a duty to warn of drug interactions, not only are patients further protected from harm, but also the goals of the pharmacy profession are upheld. The learned intermediary doctrine should no longer shield pharmacists from liability; doing so only undermines the very oaths the pharmacist has sworn to uphold. A pharmacist's duty to warn of drug interactions will more adequately protect the patient and should be embraced by all courts.

^{165.} See AphA-ASP/AACP COD, supra note 7, at 101-02 (stating at the end of both the Oath of a Pharmacist and the Pledge of Professionalism that the person taking the oath/pledge does so voluntarily).

^{166.} See Sterling, 370 F.2d at 85 (articulating the learned intermediary doctrine for the first time in 1966). The Code of Ethics and Oath of the Pharmacist, were not adopted until 1994. AphA-ASP/AACP COD, supra note 7, at 101-02. Looking at the timeline, the learned intermediary doctrine was created first.

^{167.} See Carpenter & Baker, supra note 154, at 1 (explaining that pharmacists are dissatisfied and believe it undermines the profession when a court decides not to impose a higher duty on pharmacists by determining that they are practically mere order fillers).

^{168.} See AphA-ASP/AACP COD, supra note 7, at 101-02 (duplicating the standards of ethics and oaths that the pharmacy profession has adopted).

^{169.} Cacciatore, *supra* note 16, at 104.

^{170.} See supra notes 55-57 and accompanying text (explaining further OBRA and subsequent state regulation).