

ESTABLISHING A PATIENT-PHARMACIST RELATIONSHIP: CLARIFYING
DUTIES AND IMPROVING PATIENT CARE

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This Article argues that a statutorily recognized patient-pharmacist relationship is necessary to clarify pharmacist duties and improve patient care. Courts continue to emphasize that pharmacists have no duty to warn patients about potential adverse drug effects or other dangers associated with prescription medications. In doing so, the judiciary potentially denies patients the benefits of pharmacists' expertise and the ability to successfully seek compensation from pharmacists if harmed by their failure to warn. Courts presuppose that if they hold pharmacists to account this might interfere with the patient-physician relationship, but this approach ignores the possibility that both patient-provider relationships may not only coexist but complement each other. This Article argues, first, that pharmacists should owe patients a duty to warn. Second, because such a duty will remain legally elusive until a patient-pharmacist relationship is universally acknowledged, state legislatures should correct the repeated failure by the courts to recognize this relationship by establishing a patient-pharmacist relationship better aligned with contemporary pharmacy practice's contributions to patient care and pharmacists' ability to do more than count pills and adhere prescription labels.

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INTRODUCTION

When you pick up your small white bag containing your antibiotic at your local drug store, have you created a relationship with the pharmacist in the same way you do when visiting your doctor for an infection? Perhaps it does not feel like a relationship with the pharmacist to the same degree as it does with the doctor, but designating it as such has important consequences for pharmacist liability. As patients take prescription anti-inflammatory drugs to recoup from their sports injuries or prescription hepatitis C medications to be cured, they establish relationships with pharmacists. As pharmacists move away from a lick, stick, count, and pour role,¹ they encourage patients' reliance on them for drug information, including the health risks of taking harmful drug combinations or excessive drug dosages. These patients may be surprised to learn pharmacists typically have no legal duty to warn of adverse effects, or other dangers, associated with a patient's medications. In most jurisdictions, pharmacists must only accurately fill a prescription; to further warn the patient is perceived as potentially disrupting the patient-physician relationship, the juggernaut of the American health care system.

Although most courts are reluctant to acknowledge it, in day-to-day practice pharmacists establish and maintain what appear, at least at first glance, to be patient relationships. In many instances, while both the patient and the pharmacist may believe they are in a patient care relationship, the law does not recognize the relationship. Long recognizing patient-physician

¹See generally Terence C. Green, *Licking, Sticking, Counting, and Pouring – Is That All Pharmacists Do?* McKee v. American Home Products Corp., 24 CREIGHTON L. REV. 1449 (1991).

relationships, the law is blind to patient-pharmacist relationships.² In medicine, the legally defined relationship provides patients and physicians a clearer understanding of the patient-centric nature of the relationship³ as well as a basis for any duties owed,⁴ such as continuing patient care.⁵ The lack of a similarly recognized patient-pharmacist relationship hinders clarification of pharmacist duties and fails to incentivize better patient care by pharmacists.

This Article advocates for legal recognition of patient-pharmacist relationships, similar to, but distinct from, patient-physician relationships. While many scholars agree pharmacists should owe patients a duty to warn, this Article argues that while this duty is important, it is secondary to the more preliminary issue of establishing a legally cognizable relationship. The existence and legal recognition of a patient-provider relationship⁶ gives rise to possible duties providers owe patients and perhaps third parties.⁷ The specific duty a provider owes may depend on the provider type, physician or pharmacist; but the analysis begins with an established relationship. Courts should facilitate responsible behavior by pharmacists, but as they fail to do

²Borrowing from the National Association of Boards of Pharmacy Task Force on the Definition of a Patient-Pharmacist Relationship, this article places the “patient” before “pharmacist” in order to maintain the patient as the primary focus of the relationship. NAT’L ASS’N OF BDS. OF PHARMACY, REPORT OF THE TASK FORCE ON THE DEFINITION OF A PATIENT-PHARMACIST RELATIONSHIP 2 (2017), <https://nabp.pharmacy/wp-content/uploads/2018/01/2017-Report-of-Task-Force-on-Definition-of-Patient-Pharmacist-Relationship.pdf>. For the same reason, this article also places “patient” before “physician” in the patient-physician relationship.

³See Christine Laine & Frank Davidoff, *Patient-Centered Medicine A Professional Evolution*, 275 JAMA 152, 152 (1996) (summarizing the professional shift in medicine from physician-centered to patient-centered care which is more closely aligned with patient preferences).

⁴See 46 AM. JUR. PROOF OF FACTS 2d 373 *Existence of Physician and Patient Relationship* § 4 (1986) (explaining that once a patient-physician relationship is established, a physician owes a duty to exercise the professional standard of care of the medical community where the physician practices).

⁵Meghan C. O’Connor, *The Physician-Patient Relationship and the Professional Standard of Care: Reevaluating Medical Negligence Principles to Achieve the Goals of Tort Reform*, 46 TORT TRIAL & INS. PRAC. L.J. 109, 113 (2010) (analyzing the physician’s duty under the patient-physician relationship).

⁶Although this article focuses on physician and pharmacist relationships with patients, other professional-patient relationships also exist, such as the patient-physician assistant relationship, MICH. COMP. LAWS ANN. § 691.1501 Sec. 1(1) (West 2016) (exempting providers with no pre-existing relationship from liability when providing emergency care without compensation at the scene of an emergency).

⁷See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 42, at 275 (5th ed. 1984).

so, this Article recommends legislatively establishing a patient-pharmacist relationship.

Part I begins by explaining why legally recognized patient-pharmacist relationships are necessary. It continues by asserting pharmacists are educated and trained to serve in our health care system as medication experts⁸ and demonstrating that the law has not kept pace with changes in pharmacy practice. Part II examines the patient-physician relationship as a model for patient-pharmacist relationships and analyzes the implications of using it as a model. Finally, Part III analyzes the key factors for legislatures to consider in crafting a legislative solution recognizing a patient-pharmacist relationship and to address the judiciary's repeated failure to explicitly and consistently recognize such a relationship. By treating pharmacists like other professionals, recognizing the patient-pharmacist relationship, and considering what duty, if any, arises because of the relationship, patients will likely benefit from improved health outcomes.

I. TOWARD BETTER ALIGNING THE LAW WITH CONTEMPORARY PHARMACY PRACTICE

In our current health care system, pharmacists do much more than lick, stick, count, and pour.⁹ Pharmacists' evolving responsibilities highlight a need to recognize and delimit their duties to patients. The pharmacist, often the last health care professional a patient sees before taking a medication, is well positioned to provide warnings about potential adverse events or dangers associated with the drug.¹⁰ By failing to recognize a patient-pharmacist relationship, the judiciary avoids finding duties owed because of the

⁸Michael P. Gabay, *The Evolution of Drug Information Centers and Specialists*, 52 HOSP. PHARMACY 452, 452 (2017) (explaining how pharmacists changed from drug providers to medication therapy experts who are an integral part of the patient care team).

⁹Green, *supra* note 1. Pharmacy is the third largest health care profession in the U.S. *About Us*, AM. ASS'N COLLS. PHARMACY, <https://www.aacp.org/about-aacp> (last visited January 23, 2020). Patients regularly rely on and interact with pharmacists to access their prescription medications at community pharmacies. According to the Kaiser Family Foundation, 3,792,051,418 prescriptions were filled at retail pharmacies in 2019. *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*, KAISER FAM. FOUND., <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22unitedstates%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited January 23, 2020).

¹⁰The U.S. health care system spends approximately \$300 billion a year on problems related to prescription medication use. *Improving Patient Care*, AM. PHARMACIST ASS'N, [https://www.pharmacist.com/sites/default/files/files/Making%20the%20Case%20\(2015\).pdf](https://www.pharmacist.com/sites/default/files/files/Making%20the%20Case%20(2015).pdf).

relationship, thereby missing an opportunity to improve patient medication safety. Without a clear pathway from the patient-pharmacist relationship to a duty to warn of potential prescription medication dangers, patients are often unable to successfully seek compensation from pharmacists, our medication experts. This Part explains why a legally recognized patient-pharmacist relationship is necessary. It also describes pharmacists' changing role in our health care system and analyzes the key reasons the law lags behind contemporary pharmacy practice.

A. Why Legally Acknowledged Patient-Pharmacist Relationships are Necessary

For a plaintiff to succeed in a professional negligence action, the plaintiff must prove a professional relationship exists.¹¹ It is the relationship that gives rise to the duty¹² to conform to an appropriate standard of conduct.¹³ If a health care provider and a patient have a professional relationship, such that the health care provider is obliged to act for the benefit of the patient, then the provider owes a legal duty. As demonstrated in Part I C, in limited instances the judiciary may find a pharmacist owes a patient a duty, but overwhelmingly courts avoid the critical first step of recognizing a patient-pharmacist relationship.

Liability under professional negligence is predicated on an existing relationship between the professional and the plaintiff,¹⁴ as is clear from two familiar types of liability cases, legal malpractice and medical malpractice.¹⁵ As one commentator summarizes, for a prima facie case of legal malpractice, courts require: (1) an attorney-client *relationship*; (2) a duty owed to the client because of the relationship; (3) breach of the duty; (4) the breach was

¹¹ *E.g.*, O'Connor, *supra* note 5, at 116.

¹² Ernest J. Weinrib, *Thinking About Tort Law*, 26 VAL. U. L. REV. 717, 717 (1992).

¹³ *AMS Salt Indus., Inc. v. Magnesium Corp. of Am.*, 942 P.2d 315, 320–21 (Utah 1997) (quoting W. Page Keeton et al., *PROSSER AND KEETON ON THE LAW OF TORTS* § 53 at 356 (5th ed. 1984)).

¹⁴ Weinrib, *supra* note 12, at 717.

¹⁵ Engineers and architects are also examples of nonmedical professionals whose relationship with a client is the first step in determining what, if any, legal duty the professional owes the client. See Philip Steven Horne, *Onita Pacific Corp. v. Trustees of Bronson: The Oregon Supreme Court Recognizes the Negligent Misrepresentation Tort*, 72 OR. L. REV. 753, 763 (1993) (summarizing the duty of care owed clients by engineers and architects).

the proximate cause of the client's injury; and, (5) damages.¹⁶ Similarly, for a medical malpractice action: the provider must be sued in her capacity as a medical professional, the alleged negligence must arise from the patient-professional *relationship*, and the alleged negligence must be substantially related to the medical diagnosis or treatment and involve the exercise of medical judgment.¹⁷ As this Article asserts, recognizing a patient-pharmacist relationship is primary; any duty owed because of the relationship is secondary.¹⁸

Similar to attorneys, architects, engineers, physicians, and other professionals, pharmacists have a code of ethics,¹⁹ advanced education,²⁰ continuing education requirements,²¹ and have earned the public's trust.²² Pharmacy is a profession and pharmacists are professionals.²³ If courts consistently recognize pharmacists as professionals, like other professionals, it will "end judicial paternalism toward pharmacists and their responsibilities toward patients."²⁴

¹⁶Nicola A. Boothe-Perry, *No Laughing Matter: The Intersection of Legal Malpractice and Professionalism*, 21 AM. U. J. GENDER SOC'Y POL'Y & L. 1, 21–22 (2012) (emphasis added).

¹⁷*Trimel v. Lawrence & Mem'l Hosp. Rehab. Ctr.*, 764 A.2d 203, 207 (Conn. App. Ct. 2001) (emphasis added).

¹⁸*See id.*

¹⁹Peter Dwyer, *Pharmacists & Pharmaceutical Manufacturers: Some Ethical Considerations*, 24 MED. & L. 437, 443 (2005) (discussing pharmacists' code of ethics in the U.S., Australia, and Canada).

²⁰*See id.* at 442.

²¹Continuing education for pharmacists is governed by state regulation, e.g., WASH. ADMIN. CODE § 246-861-090(1) (2017) (requiring fifteen contact hours of continuing education annually for Washington State pharmacists).

²²*Pharmacists Rank Second Again Among Gallup's Most Trusted Professionals*, NAT'L ASS'N CHAIN DRUG STORES (Dec. 21, 2016), <https://www.nacds.org/news/pharmacists-rank-second-again-among-gallups-most-trusted-professionals/>.

²³Ryanne Bush Dent, Comment, *No Duty to Warn of Drug Interactions: A Dangerous Prescription*, 46 J. MARSHALL L. REV. 533, 545–47 (explaining why pharmacists are professionals and must abide by the customs of their profession); *see also* Mark Lee Levine & Stephen Thode, *Is an Appraiser a Professional? Why Does it Matter?*, 44 REAL EST. REV. J., Winter 2015, at 6 (emphasizing that not all professionals want to be a professional within a profession because of the increase in liability exposure).

²⁴Lauren Fleischer, Comment, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 187 (1999).

Case law highlights potential patient harms that may occur when courts safeguard pharmacists from liability.²⁵ Prescription drugs are inherently unsafe, and patient death is possible.²⁶ Death may occur from off-label drug use,²⁷ drug-drug interactions of multiple prescriptions, including opioids,²⁸ and methadone intoxication.²⁹ Other harms may include: developing severe movement disorders such as tardive dyskinesia and dystonia,³⁰ birth defects,³¹ glaucoma,³² narcotic addiction,³³ and pulmonary hemorrhages.³⁴ Pharmacists, as medication experts, are well positioned in our health care system to be able to help prevent these and other patient drug risks.

Courts' emphasis on keeping pharmacists out of the patient-physician relationship suggests pharmacists might harm patients by warning them of a drug's risks. By being overly protective of the patient-physician relationship, these courts fail to recognize the role of other patient-provider relationships, such as the patient-pharmacist relationship, and the health care value pharmacists may provide to patients. The courts' perspective seems misaligned with a pharmacist's role as a medication expert or a health care

²⁵ See, e.g., *Tardy v. Eli Lilly & Co.*, No. CV-03-538, WL 1925536 (Me. Super. Ct. 2004); *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109 (Ark. 2011); *Hernandez v. Walgreen Co.*, 49 N.E.3d 453 (Ill. App. Ct. 2015).

²⁶ See generally *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166 (S.D.N.Y. 2016).

²⁷ *Tardy*, 2004 WL 1925536, at *1, *3 (holding a pharmacist does not owe a duty to warn about off-label drug use that could have serious health effects such as death).

²⁸ *Kowalski*, 378 S.W.3d at 112 (finding no general duty to warn patient or prescriber when patient prescribed numerous controlled substances); see also *DiGiovanni v. Albertson's, Inc.*, 940 N.E.2d 73, 77 (Ill. App. Ct. 2010) (finding no duty to warn patient of potential adverse drug when notified prescriber prior to filling prescription).

²⁹ *Hernandez*, 49 N.E.3d at 465 (Ill. App. Ct. 2015) (finding pharmacist owes no duty to monitor patient's prescription history to determine if methadone use was excessive or communicate a warning to the patient or the physician).

³⁰ *Urbaniak v. Am. Drug Stores, LLC*, 126 N.E.3d 561, 563 (Ill. App. Ct. 2019), *appeal denied*, 132 N.E.3d 373 (Ill. 2019).

³¹ *Nichols v. Cent. Merch., Inc.*, 817 P.2d 1131, 1132 (Kan. Ct. App. 1991) (shielding pharmacist, under the learned intermediary doctrine, from a duty to warn a pregnant patient that a drug may cause abnormalities in her child when pharmacist knew about drug warning and knew or suspected that patient was pregnant).

³² *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63, 67–68 (Ga. Ct. App. 1993) (finding no pharmacist duty to warn a patient or prescriber if a drug whose prolonged use may cause glaucoma; the physician bears the responsibility).

³³ *Adkins v. Mong*, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988) (finding pharmacy has no duty to warn of side effects, including narcotic addiction, if a prescription is valid).

³⁴ *Silves v. King*, 970 P.2d 790, 792 (Wash. Ct. App. 1999).

professional educated, trained, and licensed to help patients. For example, if a physician lacks critical knowledge about a drug she prescribes for her patient, and the pharmacist has that knowledge but is under no obligation to warn the patient, it is the patient who ultimately risks suffering unnecessary harm. The patient will be better served if the pharmacist uses her expertise to either warn the patient or the prescribing physician, and the physician will benefit from learning more about the medication from the pharmacist.

In our fragmented and time-pressured health care system, it is not sufficient to assume that physicians adequately inform patients about the potential side effects or risks of prescribed medications.³⁵ Physician care is the lynchpin of our health care system;³⁶ yet, as physicians have less time³⁷ for any individual patient, pharmacists can help improve patient care.³⁸ Pharmacists, as medication experts, can, at best, provide new drug warnings or, at worst, reinforce a physician's drug warning. Either way, the patient is more likely to have an improved medication outcome.

³⁵An FDA survey found that one-third of patients received prescription drug side effect information from their physicians. See Frederick Fern & Jordan Bergman, *Rising Professional Standards the Pharmacist's Evolving Intellectual Duty to Warn*, 47 FOR DEF., Nov. 2005, at 25 (citing Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27).

³⁶This is not the first time physician dominance of the health care system has been challenged by increased education and training of other health professions. Nursing shifting from hospital-based training to university-based education, including graduate programs for advanced practitioners, provides an example pharmacy may follow. Mary Anne Bobinski, *Law and Power in Health Care: Challenges to Physician Control*, 67 BUFF. L. REV. 595, 633–35 (2019).

³⁷Fern & Bergman, *supra* note 35, at 25 (discussing the deterioration of the patient-physician relationship, including the reduced time physicians have for each patient, impinging upon her ability to fully inform patients of drug risks and benefits).

³⁸In addition to helping improve patient quality of care, pharmacists can help improve population health and decrease health care costs. *The IHI Triple Aim*, INST. FOR HEALTHCARE IMPROVEMENT, <http://www.ihl.org/Engage/Initiatives/TripleAim/Pages/default.aspx> (last visited Jan. 24, 2020) (depicting the Triple Aim framework to optimize health system performance composed of improving patient quality of care, population health, and decreasing costs). According to the Centers for Disease Control and Prevention, when pharmacists are part of health care teams, patient quality of care increases, costs decrease, and patients have healthier outcomes. *How Pharmacists Can Improve Our Nation's Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/grand-rounds/pp/2014/20141021-pharmacist-role.html> (last visited Jan. 24, 2020).

Patient-physician and patient-pharmacist relationships can coexist,³⁹ both improving patient health care quality⁴⁰ by helping patients take the right dose of the right drug at the right time.⁴¹ By doing what she is educated and trained to do, a pharmacist does not “unduly interfere”⁴² with a patient-physician relationship; rather, she acts pursuant to her patient-pharmacist relationship. Perhaps more importantly, by applying her expertise and warning her patients, a pharmacist may prevent individual patient harms caused by drugs.⁴³ Yet, without a clear pathway from patient-pharmacist relationship to duty to warn of potential prescription medication dangers, patients are often unable to successfully seek compensation from pharmacists, the medication experts.⁴⁴ Ironically, a model for a patient-pharmacist relationship can be found in the relationship pharmacists are admonished not to interfere with: the patient-physician relationship.

B. Pharmacists’ Progression from Licking & Sticking to Medication Expertise Supports a Recognized Patient-Pharmacist Relationship

Traditionally, a pharmacist’s role in the American health care system was confined to accurately filling a prescription written by a physician.⁴⁵ This perspective that pharmacists “act as robots in all situations . . . to properly fill

³⁹ *But see* 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, 308–09 (2005) (asserting that a pharmacist duty to warn would likely encourage rivalry between physicians and pharmacists).

⁴⁰ *Horner v. Spalitto*, 1 S.W.3d 519, 523 (Mo. Ct. App. 1999).

⁴¹ Frank Federico, *The Five Rights of Medication Administration*, INST. FOR HEALTHCARE IMPROVEMENT, <http://www.ihi.org/resources/Pages/ImprovementStories/FiveRightsofMedicationAdministration.aspx> (last visited January 24, 2020) (listing the five rights: the right patient, the right drug, the right dose, the right route, and the right time).

⁴² *See Horner*, 1 S.W.3d at 523.

⁴³ *Id.* at 522 (health care providers cannot prevent all medication harms, as some unknown or rare events may occur, and patients may take the drugs in a manner contrary to the prescription directions).

⁴⁴ *See generally* *Nichols v. Cent. Merch., Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. Ct. App. 1993).

⁴⁵ *See, e.g.*, Alison G. Myhra, *The Pharmacist’s Duty to Warn in Texas*, 18 REV. LITIG. 27, 33 (1999) (defining dispensing drugs accurately and efficiently as the “bedrock function of the traditional pharmacy practice”).

and label prescriptions”⁴⁶ reflects a desire to prevent pharmacists from interfering with the patient-physician relationship.⁴⁷ Moreover, it presupposes pharmacists do not exercise “independent discretion, skill, or knowledge.”⁴⁸ While accurately filling a prescription remains an important role for pharmacists today, pharmacists’ expanding responsibilities should come with a legally recognizable patient-pharmacist relationship that may give rise to a duty to warn as well as other duties.⁴⁹

Regarding their profession, pharmacists have moved from only dispensing patient prescriptions to serving as a pharmaceutical care provider.⁵⁰ In addition to counseling patients,⁵¹ and other day-to-day tasks, pharmacists may refuse to fill and dispense a fraudulent-looking opioid

⁴⁶ *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109, 122 (Ark. 2011) (Brown, J., dissenting).

⁴⁷ *E.g., McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1055–56 (Wash. 1989) (pharmacists filling a patient’s prescription for an amphetamine appetite suppressant for ten years owe no duty to warn patient of adverse effects of long-time consumption of the medication).

⁴⁸ *Kohl v. Am. Home Prods., Corp.*, 78 F. Supp. 2d 885, 890 (W.D. Ark. 1999).

⁴⁹ *See* Claire A. Smearman, *Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 509–14 (2006) (examining the legal role of pharmacists, including their duty to warn and duty to fill prescriptions).

⁵⁰ Johanna L. Keely, *Pharmacist Scope of Practice*, 136 ANNALS INTERNAL MED. 79, 79 (2002) (relying on the American Pharmaceutical Association’s definition of pharmaceutical care as “patient-centered, outcomes-oriented, pharmacy practice,” *id.* at 80). As automation in prescription dispensing increases and pharmacy technicians expand their scope of practice, pharmacists are likely to have increased time to devote to providing patient care. *See id.* Pharmacy technicians are often utilized in pharmacies to complete limited tasks at a lower cost, permitting pharmacists to focus more on patient care. Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists’ Legal Responsibilities*, 24 AM. J.L. & MED. 417, 420 (1998) (summarizing the cost effectiveness of pharmacy technicians); Michael Andreski et al., *The Iowa New Practice Model: Advancing Technician Roles to Increase Pharmacists’ Time to Provide Patient Care Services*, 58 J AM. PHARMACISTS ASS’N 268 (2018). Pharmacy technicians are now being prepared to assume more advanced roles in the pharmacy, including managing robotics and assuming more supervisory roles. William A. Zellmer & Rafael Saenz, *Advanced Pharmacy Technician Roles: Professionalizing Pharmacy’s Technical Workforce*, 75 AM. J. HEALTH-SYS. PHARMACY 43, 43 (2018).

⁵¹ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388-151 (codified as amended at 42 U.S.C. § 1396r-8(g) (1994)) (requiring states to implement requirements that pharmacists offer to discuss medications with patients, screen for potential problems prior to dispensing, and maintain adequate documentation). *See generally* David B. Brushwood, *The Pharmacist’s Duty Under Obra-90 Standards*, 18 J. LEGAL MED. 475 (1997) (suggesting the state implementation of OBRA-90 should establish the standard of care that pharmacists must satisfy to discharge their duty to patients).

prescription,⁵² administer a flu vaccine,⁵³ order laboratory tests and modify a patient's anticoagulation medication,⁵⁴ and other patient care services. The paradigm of a pharmacist's duty being limited to verifying obvious prescription errors,⁵⁵ while not questioning a physician's judgment,⁵⁶ no longer applies to contemporary pharmacy practice or pharmacists' role in our health care system.

If a pharmacist's duty is limited to accurately filling prescriptions, then our entire health care system loses the full value of a pharmacist's knowledge and education,⁵⁷ and we fail to incentivize a pharmacist to use the full extent of her expertise on behalf of her patient. Pharmacists are experts in medication therapy,⁵⁸ drug toxicity,⁵⁹ negative drug-drug interactions,⁶⁰ and other risks associated with patients taking pharmaceuticals.⁶¹ Based on their

⁵²Under federal law, filling pharmacists have a corresponding responsibility to ensure controlled substance prescriptions are for a legitimate medical purpose, 21 C.F.R. § 1306.04 (2005). *See also* Karl G. Williams et al., *The Role of the Pharmacist in Addressing the Opioid Crisis*, 11 ALB. GOV'T L. REV. 174, 182–84 (2018) (analyzing case law addressing pharmacists' corresponding responsibility).

⁵³Pharmacist administration of vaccines is governed by state law. *See, e.g.*, WASH. REV. CODE § 18.64.011 (2016), WASH. ADMIN. CODE § 246-863-100 (2003). *See also Pharmacist Administered Vaccines* (January 2019) https://media.pharmacist.com/practice/IZ_Authority_012019.pdf (summarizing the types of vaccines pharmacists are authorized to administer in each state).

⁵⁴Pharmacist ordering of laboratory tests and modifying anticoagulation medications is governed by state law. *See, e.g.*, WASH. REV. CODE § 18.64.011; § 246-863-110.

⁵⁵*See, e.g.*, *Gassen v. E. Jefferson Gen. Hosp.*, 628 So. 2d 256, 259 (La. Ct. App. 1993) (failure of hospital pharmacist to clarify prescription with prescriber before changing it and filling it for intramuscular administration rather than intravenous administration).

⁵⁶*Id.* (citing *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1055–56 (Wash. 1989)).

⁵⁷*See* *Horner v. Spalitto*, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999).

⁵⁸Jon C. Schommer et al., *Pharmacist Contributions to the U.S. Health Care System*, 1 INNOVATIONS PHARMACY, June 1, 2010, at 1, 2 (citing James A. Owen & Anne Burns, *Medication Use, Related Problems and Medication Therapy Management*, in *THE PHARMACIST IN PUBLIC HEALTH: EDUCATION, APPLICATIONS, AND OPPORTUNITIES* 91 (Am. Pharmacists Ass'n 2010)).

⁵⁹*See* Accreditation Council for Pharmacy Educ., *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, Appendix 1, 19–21, <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf> (listing the required didactic elements of an accredited Doctor of Pharmacy curriculum including toxicology, pharmacology, and pharmaceuticals).

⁶⁰*Id.*

⁶¹*See* Jessica L. Van Beek, *The Future for Pharmacists: Does Physician-Pharmacist Collaborative Practice Mean Collaborative Liability?*, 36 J. LEGAL MED. 442, 444 (2015) (including failure of chronic disease patients to adhere to drug therapy).

education, a pharmacist's expertise in medication therapy management "exceeds any other health care provider's."⁶²

Before a pharmacist can care for patients, she must minimally earn a Doctor of Pharmacy (PharmD) professional degree,⁶³ requiring at least 6 years of education,⁶⁴ and pass a state licensure exam.⁶⁵ Moreover, many pharmacists complete advanced pharmacy training in the form of a residency,⁶⁶ and achieve specialty board certifications,⁶⁷ similar to

⁶²Schommer et al., *supra* note 58, at 2. When pharmacists round with physicians in intensive care units, reviewing medication orders when prescribed and making recommendations as necessary, preventable adverse drug events were reduced 66 percent, Lucian L. Leape et al., *Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit*, 282 JAMA 267, 267 (1999).

⁶³Yang-Yi Lin, *Evolution of PharmD Education and Patient Service in the USA*, 4 J. EXPERIMENTAL & CLINICAL MED. 227, 227 (2012). The Doctor of Pharmacy (PharmD) has been the entry level degree since 2000, Scott J. Knoer, et al., *A Review of American Pharmacy: Education, Training, Technology, and Practice*, 2 J. PHARM. HEALTH CARE & SCI. 32, 33 (2016). The Accreditation Council of Pharmacy Education (ACPE) accredits professional degree programs in pharmacy, *see generally* Accreditation Council for Pharmacy Educ., *supra* note 59 (categorizing the required elements, assessments, and expectations of PharmD programs). In order to earn a PharmD, students must complete didactic course work including "medication safety, pharmacy law and ethics, biostatistics, toxicology, epidemiology, hands-on skill-based labs, evidence-based practice, innovation, and business management," Knoer, *supra*.

⁶⁴*Frequently Asked Questions About Pharmacy Admissions*, AM. ASS'N OF COLLS. OF PHARMACY, <https://www.aacp.org/resource/frequently-asked-questions-faq-about-pharmacy-admissions> (last visited January 24, 2020).

⁶⁵All states require a competency-based pharmacy exam, the National Association of Boards of Pharmacy Licensure Examination (NABPLEX), applying knowledge to real-life situations, Knoer, *supra* note 63, and a federal and state law exam, *id.* For the law exam, most states use the Multistate Pharmacy Jurisprudence Examination (MPJE), *Which States Require the MPJE*, NAT'L ASS'N OF BDS. OF PHARMACY, <https://nabp.pharmacy/help/which-states-require-the-mpje/> (last visited January 24, 2020).

⁶⁶Pharmacy residencies are "widely recognized postgraduate training" opportunities enabling pharmacists to continue to develop their provider skills, S. Brandon Shannon, et al., *Pharmacy Residencies and Dual Degrees as Complementary or Competitive Advanced Training Opportunities*, AM. J. PHARM. EDUC. Oct. 2012 at 1, 2. Completion of a postgraduate residency is often required for entry into health-system pharmacy practice, Knoer, *supra* note 63.

⁶⁷The American Pharmaceutical Association established the Board of Pharmaceutical Specialties, recognizing specialty areas of pharmacy practice. Pharmacists can achieve board certification by earning a pharmacy degree, maintaining an active state license to practice pharmacy, completing additional training and experience in a specialty, and successfully passing the specialty examination. Keely, *supra* note 50. As of 2020, there are thirteen board specialties: ambulatory care pharmacy, cardiology pharmacy, compounded sterile preparations pharmacy, critical care

physicians.⁶⁸ By the time a typical pharmacist begins practicing, she will have studied medications for five to seven years.⁶⁹ A typical physician will have studied medications for three semesters.⁷⁰

As medication experts, pharmacists have a unique and critical role in our health care system. Trained to recognize a prescription dose outside normal ranges,⁷¹ pharmacists are well poised to communicate dosage concerns to the prescriber⁷² or the patient. Four reasons previously suggested by Professor David Brushwood why pharmacists may be the most appropriate health care practitioner to oversee a patient's prescription drug use are: (1) patients may have multiple physicians but one pharmacist or pharmacy; (2) pharmacists can monitor drug refill frequency and side effects occurring between physician visits; (3) pharmacists are more accessible to the community than physicians; and (4) the public trusts pharmacists.⁷³ While the first reason may no longer hold true as patients may choose to use a different pharmacy

pharmacy, geriatric pharmacy, infectious diseases pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, psychiatric pharmacy, and solid organ transplantation pharmacy, *BPS Specialties*, BD. OF PHARMACY SPECIALTIES, <https://www.bpsweb.org/bps-specialties/> (last visited January 24, 2020).

⁶⁸ See generally Knoer, *supra* note 63 (describing how pharmacist education, training, and practice models "closely mirror those of physicians"); Jennifer E. Spreng, *Pharmacists and the "Duty" to Dispense Emergency Contraceptives*, 23 ISSUES L. & MED. 215, 229–33 (2008) (summarizing the changes to pharmacy practice in the twentieth century); David B. Brushwood, *The Pharmacist's Duty to Warn: Toward A Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 16–17 (1991) (explaining the evolution of pharmacy practice from compounder pharmacist, technical pharmacist, clinical pharmacist, to advocacy pharmacist).

⁶⁹ Andrew F. Spillane, *Negligence Liability's Role in Changing Pharmacotherapy Responsibilities*, 12 MARQ. ELDER'S ADVISOR 453, 489 (2011) (citing Michele L. Hornish, *Just What the Doctor Ordered—Or Was It?: Missouri Pharmacists' Duty of Care in the 21st Century*, 65 MO. L. REV. 1075, 1099 (2000)).

⁷⁰ *Id.*

⁷¹ *Horner v. Spalitto*, 1 S.W.3d 519, 523 (Mo. App. Ct. 1999).

⁷² *Id.*

⁷³ David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439, 441–42 (1996).

because of changes in health insurance,⁷⁴ offers of in-store coupons,⁷⁵ convenience,⁷⁶ and pharmacy tourism,⁷⁷ the other reasons remain applicable today. Patients visit pharmacists more than any other health care professional; almost ten times as often as they visit primary care providers.⁷⁸ With 93% of Americans living 5 miles or less from a community pharmacy, pharmacists are very accessible to patients.⁷⁹

C. *The Law Lags Behind Pharmacists' Contemporary Role in Health Care*

This subsection explores existing common law addressing the patient-pharmacist relationship and a pharmacist's potential duty to warn. It asserts that the primary reason why most courts find pharmacists do not owe a duty to warn, regardless of how the rationale is phrased, is to maintain the patient-physician relationship's integrity.⁸⁰ While a small number of courts may be more willing to find that a pharmacist may owe a patient a duty, these

⁷⁴INST. FOR SAFE MEDICATION PRACS., *Transferring Prescriptions Between Pharmacies Requires Caution*, CONSUMERMED.ORG, <https://consumermedsafety.org/medication-safety-articles/item/853-transferring-prescriptions-between-pharmacies-requires-caution> (last visited January 24, 2020).

⁷⁵Compare Anthony T. Burda et al., *Prescription-Transfer Coupons*, 68 AM. J. HEALTH-SYS. PHARMACY 787, 787 (2011) (describing the practice of some community pharmacies increasing their number of patients by offering in-store coupons, valued up to \$25, to patients bringing in new or transferred prescriptions; because of these types of incentives, some patients continue to transfer their prescriptions to multiple pharmacies to achieve maximum financial benefit), with PBA HEALTH, *Transferring Prescriptions: Does Your State Ban Financial Incentives?*, ELEMENTS (June 15, 2017), <https://www.pbahealth.com/transferring-prescriptions-state-ban-financial-incentives/> (explaining Tennessee's rule banning the use of gift cards and other incentives for patients to transfer prescriptions).

⁷⁶INST. FOR SAFE MEDICATION PRACS., *supra* note 74.

⁷⁷*Pharmacy Tourism Program Savings on Prescription Medication Filled Abroad*, PEHP HEALTH & BENEFITS, <https://www.pehp.org/pharmacy/tourism> (last visited January 24, 2020) (establishing a pharmacy tourism program for public employees in Utah willing to fly to San Diego and cross into Mexico to receive a 90-day supply of specific high cost prescription drugs from a pharmacy in Tijuana).

⁷⁸Rebecca Gale, *In Patient Safety Efforts, Pharmacists Gain New Prominence*, 37 HEALTH AFFS. 1726, 1726 (2018).

⁷⁹NAT'L ASS'N OF CHAIN DRUG STORES, *Chain Pharmacy Industry Profile Illustrates Pharmacy Value*, DRUG TOPICS (September 21, 2010), <https://www.drugtopics.com/top-news/nacds-2010-2011-chain-pharmacy-industry-profile-illustrates-pharmacy-value>.

⁸⁰Kimberly A. Burns & Alan R. Spies, *A Pharmacist's Duty to Warn: Promoting the Acceptance of a Consistent Legal and Professional Standard*, 47 DUQ. L. REV. 1, 5 (2009).

jurisdictions have gained little traction over time.⁸¹ By focusing on the patient-pharmacist relationship, courts may better clarify pharmacists' liability, and pharmacists may better improve patient care.

1. Stop Protecting the Patient-Physician Relationship from Pharmacist Interference

Courts continuously fail to recognize a patient-pharmacist relationship, and duties owed because of the relationship, despite pharmacists' capabilities and important roles in clinical care. Most courts simply find that pharmacists owe no duty to warn patients.⁸² While limited exceptions exist, where pharmacists may owe a duty, the law does not keep pace with pharmacists' role as medication experts.⁸³ Table 1 depicts the likelihood of a court finding a pharmacist owes a duty to a patient based on a pharmacist's failure to act.

Table 1: Common Recognition of a Duty

Pharmacist's Failure to Act	Does a Pharmacist Owe a Duty?
Failure to accurately fill a prescription	Yes
Failure to warn patient of drug's hazardous side effects	No
Failure to warn patient of high dose outside normal range	No

a. With Limited Exceptions, Most Courts Find Pharmacists Owe No Duty to Warn

There are three dominant reasons most courts provide for why pharmacists lack a duty.⁸⁴ First, the patient-physician relationship is sacrosanct, and pharmacists should not interfere in that relationship.⁸⁵ Second, the learned-intermediary doctrine applies to physicians not

⁸¹ *See id.*

⁸² *Id.*

⁸³ *See id.* at 1–2.

⁸⁴ *Id.* at 5.

⁸⁵ *Id.*

pharmacists.⁸⁶ The learned intermediary doctrine obligates a drug manufacturer to inform the physician about prescription medication risks.⁸⁷ The physician has the education, training, and individual patient knowledge to determine what, if any, prescription medication is appropriate for her patient and advise the patient about the risks and benefits of treatment with that drug.⁸⁸ Third, a finding of pharmacist liability would contradict public policy.⁸⁹ All three of these reasons serve to protect the patient-physician relationship, potentially at the risk of patient harm.

i. Patient-Physician Relationships

First, courts defer to the patient-physician relationship and strive to keep it inviolable.⁹⁰ Courts fear the potential dangers, such as death or serious injury, that pharmacists might cause by “second guessing”⁹¹ physicians and misleading patients.⁹² Courts’ language emphasizes the judiciary’s perspective that the patient relationship belongs to the physician and is not shared across the health care team.⁹³ For instance, one court stresses that a pharmacist is not liable for harm to a “*physician’s patient*”⁹⁴ from medication prescribed by the physician. Furthermore, pharmacists lack a duty to warn patients of an excessive dosage of prescription drugs because doing so would interfere with the patient-physician relationship and the pharmacist would “practice medicine without a license.”⁹⁵

⁸⁶ See *id.* at 6.

⁸⁷ *Id.*

⁸⁸ Under this theory the physician should be liable for prescribing errors, such as the wrong medication, and dosing errors, such as prescribing an excessive amount that may cause patient harm, see *Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 519 (Ala. 2008).

⁸⁹ *Burns & Spies*, *supra* note 80, at 5.

⁹⁰ *Id.* at 5–6.

⁹¹ *Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985).

⁹² See *Hofherr v. Dart Indus., Inc.*, 853 F.2d 259, 264 (4th Cir. 1988) (warning a patient about ingesting diethylstilbestrol, DES, a drug initially considered safe, but later linked to vaginal cancer in female offspring, while pregnant might be the practice of medicine and “not a field in which we should even encourage [pharmacists] to engage [in]). See generally David B. Brushwood, *The Pharmacist’s Drug Information Responsibility After McKee v. American Home Products*, 48 FOOD & DRUG L.J. 377, 391 (1993) (discussing the second-guessing fear and suggesting that patient care should trump any conflicts between health care professionals).

⁹³ See *Hofherr*, 853 F.2d at 264.

⁹⁴ *Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 519 (Ala. 2008) (emphasis added).

⁹⁵ *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551, 553 (Ill. App. Ct. 1985).

ii. The Learned Intermediary Doctrine

Second, under the learned intermediary doctrine the physician is the learned intermediary between the manufacturer and the patient; the patient must rely on the physician for drug information.⁹⁶ As applied to pharmacists, the learned intermediary doctrine means a pharmacist is not liable for failing to warn a patient even though the pharmacist has the knowledge and skill to readily do so.⁹⁷ Courts applying this doctrine to pharmacists construct a “protective barrier between pharmacists and liability.”⁹⁸ As a result of this dominant judicial perspective, some physicians themselves view the law as distinguishing between a pharmacist’s duty to safely dispense medication and a prescribing physician’s duty to warn of medication side effects.⁹⁹

Dicta in *McKee v. American Home Prods., Corp.*,¹⁰⁰ a classic learned intermediary case from the late 1980s, states that pharmacists do not have a duty to warn of medication-related risks because such a duty would “interject the pharmacist into the physician-patient relationship.”¹⁰¹ The physician knows the patient’s medical history and medication needs, not the pharmacist.¹⁰² Most courts continue to follow *McKee*’s analysis, reasoning that if pharmacists do not provide patients with additional information about prescription medications, then patients will be less likely to question a physician’s prescription and more likely to comply with pharmaceutical

⁹⁶*E.g.*, *Urbaniak v. Am. Drug Stores, LLC*, 126 N.E.3d 561, 565 (Ill. App. Ct. 2019), *appeal denied*, 132 N.E.3d 373 (Ill. 2019) (providing an overview of the learned intermediary doctrine).

⁹⁷*Id.* at 565–66.

⁹⁸Jennifer L. Smith, Comment, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists’ Expanding Liability and Duty to Warn*, 2 HOUS. J. HEALTH L. & POL’Y 187, 195 (2002).

⁹⁹Joshua J. Moore & Aaron G. Matlock, *Shared Liability? Consultants, Pharmacists, and the Emergency Physician: Legal Cases and Caveats*, 46 J. EMERGENCY MED. 612, 615 (2014) (advising physicians to communicate common side effects to patients; “[I]t cannot be assumed that the pharmacist will do this, as they are not legally obligated to do so.” *Id.*).

¹⁰⁰782 P.2d 1045, 1048 (Wash. 1989) (stating “While we need go no further, it is appropriate that we discuss the merits of the primary issue raised because of the importance of the issue and the public interest therein.”).

¹⁰¹*Id.* at 1051; *see also* *Silves v. King*, 970 P.2d 790, 794 (Wash. Ct. App. 1999) (affirming summary judgment for hospital, holding the hospital pharmacist has no duty to warn a patient about potential adverse interactions between two prescribed medications).

¹⁰²*McKee*, 782 P.2d at 1051.

treatment.¹⁰³ Three recent cases,¹⁰⁴ analyzed below, highlight the entrenchment of the learned intermediary doctrine and how difficult it is for injured patients to overcome the learned intermediary barrier.

In 2019, an Illinois court uses the learned intermediary doctrine to ensure pharmacists “stay out of the physician-patient relationship.”¹⁰⁵ For six years¹⁰⁶ the patient takes a drug with a black box warning, the strongest form of FDA prescription warning.¹⁰⁷ The black box warning indicates the drug should rarely be used for more than twelve weeks because the risk of developing serious movement disorders increases with duration and cumulative dosage of the drug.¹⁰⁸ After developing incurable serious movement disorders, the patient sues the prescribing physician and the pharmacist, alleging failure to verbally warn of the drug’s risks.¹⁰⁹ The physician, unaware of the drug’s risk, settles.¹¹⁰ Relying on the learned intermediary doctrine, the court holds the pharmacist owes no duty to verbally tell the patient of the risks of taking a black box warning drug for 300 weeks longer than advised.¹¹¹ According to the court, the primary duty to warn of dangers associated with long-term drug usage lies with the physician, not the pharmacist.¹¹²

Also in 2019, a Washington case finds a pharmacy has no general common law or statutory duty to warn a patient of an antibiotic’s adverse side effects.¹¹³ A patient receiving an antibiotic prescription from a physician for

¹⁰³William G. Clowdis, Jr., *The Pharmacist’s Duty to Warn Beneficial Impact on Quality of Care, Economically Sound, and Commensurate with Federal Law*, 31 J. LEGAL MED. 287, 289 (2010).

¹⁰⁴*Urbaniak v. Am. Drug Stores, LLC*, 126 N.E.3d 561, 565, (Ill. App. Ct. 2019), *appeal denied*, 132 N.E.3d 373 (Ill. 2019); *Nail v. Publix Super Mkts., Inc.*, 72 So. 3d 608 (Ala. 2011); *Long v. Rite Aid Headquarters Corp.*, No. 77695-9-I, 2019 WL 1370442, at *3 (Wash. Ct. App. Mar. 25, 2019), *review denied sub nom.*, *Long v. Rite Aid Corp.*, 445 P.3d 560 (Wash. 2019).

¹⁰⁵*Urbaniak*, 126 N.E.3d at 567.

¹⁰⁶*Id.* at 563.

¹⁰⁷*Id.* at 564.

¹⁰⁸*Id.*

¹⁰⁹*Id.* (The pharmacist gave the patient written information about the drug but no verbal warnings).

¹¹⁰*Id.* at 563.

¹¹¹*Id.* at 570.

¹¹²*Id.* at 568–69.

¹¹³*Long v. Rite Aid Headquarters Corp.*, No. 77695-9-I, 2019 WL 1370442, at *3 (Wash. Ct. App. Mar. 25, 2019), *review denied sub nom.* *Long v. Rite Aid Corp.*, 445 P.3d 560 (Wash. 2019).

a tooth abscess, filled her prescription at a pharmacy.¹¹⁴ The pharmacist does not tell the patient to contact a physician immediately if she develops diarrhea or to not take antidiarrheal products while taking the antibiotic.¹¹⁵ Unaware of any potential adverse effects, the patient does take Imodium, an antidiarrheal product, and as a result has part of her large colon surgically removed.¹¹⁶ In denying the patient's motion for reconsideration, the court places all of the responsibility for warning a patient about a drug on the physician, because only "the physician, and not the pharmacist, has the relevant knowledge concerning the patient's medical history and the physician's intended use of the medication."¹¹⁷

An Alabama case indicates the difficulties injured patients face when trying to avoid pharmacist liability being cut off by the learned intermediary doctrine.¹¹⁸ After a physician changes a patient's anticoagulation medicine from one milligram to five milligram tablets, and after the patient takes the same number of tablets a day, the patient suffers serious side effects from the drugs toxicity.¹¹⁹ As Alabama applies the learned intermediary doctrine, the pharmacist owes no duty to the patient to warn of the drug's hazardous side effects, including severe bleeding.¹²⁰ The patient, therefore, argues that the pharmacist owes a duty to warn her of the *dosage change*, not the possible side effects like drug toxicity.¹²¹ Reversing summary judgment, the court leaves the door open for a possible claim based on failure to warn of dose changes, while confirming the pharmacist owes no duty to warn of side effects.¹²²

As demonstrated by these three recent cases, most courts maintain the medical model dominated by physicians, adhering to the rationale that the learned intermediary doctrine protects the patient-physician relationship from pharmacist interference.¹²³ Cutting off pharmacist liability based on the

¹¹⁴ *Id.* at *1.

¹¹⁵ *Id.* at *2.

¹¹⁶ *Id.* at *1.

¹¹⁷ *Id.* at *3.

¹¹⁸ *See* *Nail v. Publix Super Mkts., Inc.*, 72 So. 3d 608 (Ala. 2011).

¹¹⁹ *Id.* at 610.

¹²⁰ *Id.* at 616.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *E.g.*, *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 893 (W.D. Ark. 1999) (finding no pharmacist duty to warn of dangers of combining two diet drugs because such a duty would

learned intermediary doctrine may preserve the patient-physician relationship at the expense of the patient. Moreover, courts fear if the learned intermediary doctrine does not apply to pharmacists, then “[a] risk averse pharmacist would have every incentive to dispense cautions that may be uninformed, inapplicable to or misunderstood by the patient.”¹²⁴

iii. Public Policy

Finally, courts have also maintained that applying liability to pharmacists contradicts public policy.¹²⁵ These courts reason that if pharmacists owe a duty to warn patients, then pharmacist liability would expand and pharmacists may potentially confuse patients, deterring them from adhering to their physician-prescribed medication therapy.¹²⁶ These public policy reasons that pharmacists should not “second guess”¹²⁷ prescribing physicians, nor provide information about a drug that a prescribing physician may not have communicated to the patient, relate to keeping pharmacists from disrupting the patient-physician relationship.

All three rationales—prohibiting pharmacist interference in the patient-physician relationship, only recognizing the physician as the learned intermediary between a drug manufacturer and a patient, and construing public policy as a hard limit on pharmacist liability—preserve the patient-physician relationship at the risk of harm to the patient. For most courts, there is one dominant reason pharmacists do not owe a duty to warn patients of drug risks: it keeps pharmacists from interfering in patient-physician relationships.¹²⁸

undermine the patient-physician relationship and noting that there may be some exceptions to the no duty to warn rule, perhaps if the pharmacy compounded the drug or altered it after receiving it from the manufacturer). Some courts, such as Massachusetts and Mississippi, have only extended the learned intermediary doctrine to pharmacists within the last twenty years, *e.g.*, *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 821 (Mass. 2002) (holding that generally a pharmacy has no duty to warn patients about side effects of prescription drugs); *Moore ex rel. Moore v. Mem’l Hosp.*, 825 So. 2d 658, 664 (Miss. 2002) (explicitly extending the learned intermediary doctrine to pharmacists).

¹²⁴*In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 288 (S.D. N.Y. 2001).

¹²⁵*Burns & Spies*, *supra* note 80.

¹²⁶*See* *Brushwood*, *supra* note 92, at 386.

¹²⁷*Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985).

¹²⁸*Clowdis*, *supra* note 103.

b. Few Courts Recognize A Pharmacist's Duty to Warn

Courts recognizing a pharmacist's duty to warn typically do so by creating an exception to the no-duty-owed rule; a few courts reason that a pharmacist does owe a duty of ordinary care or a professional standard of care.¹²⁹ These opinions, however, occur rarely and there is no indication that more courts are likely to adopt these rationales, following the minority jurisdictions.

Some courts, while adhering to the view that pharmacists do not normally owe a duty to warn, have carved out exceptions where pharmacists may owe a duty. These exceptions include filling a prescription with a clear, or obvious, error,¹³⁰ voluntarily undertaking to warn the patient about a drug,¹³¹ and failing to act on specific patient knowledge.¹³²

Courts are comfortable finding a pharmacist owes a duty when the pharmacist errs in correctly filling a prescription, either by introducing an error or by not recognizing a prescriber's error. For example, a physician prescribes a drug dose pack and a new pharmacist, not knowing the dose pack has been discontinued, calls the physician's office for clarification on filling the prescription.¹³³ Based on the conversation, the pharmacist attempts to dispense the prescription correctly, but mistakenly uses higher strength drug tablets, harming the patient.¹³⁴ In this instance, the court holds the pharmacist breached her duty to the patient by dispensing an excessive dosage.¹³⁵ Another court finds a duty when a pharmacist dispenses a different more powerful chemotherapy drug than prescribed, injuring the patient.¹³⁶ The pharmacist admits he would have discovered the error if he had followed the standard error checking process and if he had counseled the patient.¹³⁷ In

¹²⁹*Id.* at 292.

¹³⁰*McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1053 (Wash. 1989).

¹³¹Also called the voluntary assumption of duty doctrine, *Sanderson v. Eckerd Corp.*, 780 So. 2d 930, 931 (Fla. Dist. Ct. App. 2001).

¹³²*Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650 (Ill. App. Ct. 2000), *aff'd*, 766 N.E.2d 1118 (Ill. 2002).

¹³³*Hollier v. Brookshire Grocery Co.*, 48 So. 3d 1129, 1131 (La. App. 2 Cir. 2010).

¹³⁴*Id.*

¹³⁵*Id.* at 1132–33.

¹³⁶*Walter v. Wal-Mart Stores, Inc.*, 2000 ME 63, ¶ 10, 748 A.2d 961, 966.

¹³⁷*Id.* at 967.

some states, such as Maryland, a pharmacist has a limited duty to warn a patient if a prescription is “obviously fatal or the dosage is unusual.”¹³⁸

A pharmacist voluntarily assuming a duty to warn a patient may create a duty where it did not otherwise exist.¹³⁹ For instance, a pharmacy adopts and advertises a computer system capable of identifying potentially dangerous drug-drug interactions.¹⁴⁰ When the pharmacy fails to prevent a patient’s harmful drug interaction, the pharmacy may have breached a voluntarily assumed duty.¹⁴¹ On the other hand, a pharmacist warning a patient of some, but not all possible drug side effects, may not voluntarily assume a duty to warn of all side effects.¹⁴² This theory is not frequently used by plaintiffs suing pharmacists and does not represent a viable solution to patient harm caused by pharmacists’ failure to warn.

By making the physician the learned intermediary between the manufacturer and the patient,¹⁴³ the learned intermediary doctrine forces the patient’s reliance on the physician for the drug information. While the learned intermediary doctrine extinguishes most pharmacist liability, a pharmacist’s patient specific knowledge may give rise to a duty to warn that is outside of the learned intermediary doctrine.¹⁴⁴ For instance, a pharmacist with specific

¹³⁸Podgurski v. United States, No. CIV.CCB-03-3180, 2005 WL 2338851, at *3 (D. Md. Sept. 21, 2005) (finding no evidence that pharmacy knew, or should have known, that the patient had a drug allergy). It remains to be seen what the outcome will be in *Franklin v. Wal-Mart, Inc.*, where the court dismissed the informed consent claim but not the failure to warn claim. No. GJH-18-3341, 2019 WL 2744624 (D. Md. July 1, 2019).

¹³⁹*E.g.*, Cottam v. CVS Pharmacy, 764 N.E.2d 814, 821–22 (Mass. 2002) (citing Restatement (Second) of Torts § 323 (1965)); Frye v. Medicare-Glaser Corp., 605 N.E.2d 557, 558 (Ill. 1992); see also Dora A. Gonzalez, Notes & Comments, *A Prescription for Litigation: In Pursuit of the Pharmacist’s “Duty to Warn” of the Adverse Effects of Prescription Drugs*, 1 J. LEGAL ADVOC. & PRAC. 53, 76–77 (1999) (categorizing pharmacist duty to warn cases based on type of duty owed); 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, § 4 (2011) (explaining the authority for a pharmacist’s voluntary assumption of a duty to warn); Fern & Bergman, *supra* note 35, at 25.

¹⁴⁰*Baker v. Arbor Drugs, Inc.*, 544 N.W.2d 727, 731 (Mich. Ct. App. 1996).

¹⁴¹*Id.*

¹⁴²*Kasin v. Osco Drug, Inc.*, 728 N.E.2d 77 (Ill. App. Ct. 2000) (limiting any pharmacist liability to the accuracy of the warnings provided; for all other warnings the patient depends on the prescriber).

¹⁴³See discussion *supra* Part II.C.

¹⁴⁴*E.g.*, *Brienze v. Casserly*, No. 01-1655-C, 2003 WL 23018810, at *2 (Mass. Super. Ct. Dec. 19, 2003) (holding pharmacist with patient specific knowledge of patient’s potential adverse drug

patient knowledge, such as a known drug allergy, may owe a duty to warn. For instance, in one case a patient has a documented sulfa allergy, the pharmacist dispenses a drug containing sulfa, and the patient unfortunately dies from an allergic reaction to the drug.¹⁴⁵ The Nevada Supreme Court, reversing summary judgment in favor of the pharmacy, holds a pharmacist with specific patient knowledge has a duty to exercise reasonable care by warning the patient or notifying the prescriber of the risk.¹⁴⁶ In doing so the court limits the scope of the learned intermediary doctrine to cases where the pharmacist lacks specific patient information.¹⁴⁷

Very few courts reason that pharmacists either owe a duty of ordinary care to patients¹⁴⁸ or a duty to comply with their professional standard of care.¹⁴⁹ The *Hooks SuperX* court further takes the unusual stance of recognizing a patient-pharmacist relationship.¹⁵⁰

In *Hooks SuperX*, a patient becomes addicted to two opioid medications for pain, filling and consuming the medications approximately two and a half times faster than the rate prescribed.¹⁵¹ The *Hooks SuperX* court finds a direct contractual relationship between the pharmacist and the patient, separate from the patient-physician relationship.¹⁵² Based on this relationship, the court continues, the pharmacist should refrain from filling prescriptions a patient is excessively consuming.¹⁵³ The court minimizes the potential tensions between pharmacists and physicians, asserting that recognizing a pharmacist's duty will improve physician and pharmacist teamwork.¹⁵⁴

interactions may have a duty to warn outside the learned intermediary doctrine's scope); *Klasch v. Walgreen Co.*, 264 P.3d 1155, 1158 (Nev. 2011) (finding possible exception to pharmacist's no duty to warn a patient about generalized prescription medication risks when a pharmacist has specific patient allergy).

¹⁴⁵ *Klasch*, 264 P.3d at 1156–57.

¹⁴⁶ *Id.* at 1156.

¹⁴⁷ *Id.* at 1158.

¹⁴⁸ *E.g.*, *Hooks SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514, 519 (Ind. 1994); *see also* Myhra, *supra* note 45, at 36 (explaining courts' various phrasings of pharmacists' duties, including a New York court defining a pharmacist's duty of ordinary care as "the highest practicable degree of prudence, thoughtfulness and vigilance commensurate with the dangers involved and the consequences which may attend inattention").

¹⁴⁹ Myhra, *supra* note 45, at 36.

¹⁵⁰ 642 N.E.2d at 517.

¹⁵¹ *Id.* at 516.

¹⁵² *Id.* at 517.

¹⁵³ *Id.* at 518.

¹⁵⁴ *Id.* at 519.

While this is a significant ruling, most courts do not find a distinct, yet separate, relationship.

Another court in the minority rules that a pharmacist's duty to warn a patient about a contraindication of a known drug allergy is part of a pharmacist's duty of ordinary care.¹⁵⁵ In analyzing the pharmacist's duty, the court considers: (1) the pharmacist knows the prescribed drug is contraindicated because of the patient's pre-existing drug allergies and it is reasonably foreseeable that the patient will be injured if the pharmacist does not warn the patient; (2) the injury's high likelihood of occurring; (3) the minimal burden on the pharmacist to call the physician or talk to the patient; and, (4) the pharmacist need only relay information to the patient or the physician, pursuant to the pharmacy's company policy.¹⁵⁶ Based on these considerations, the court places this case outside of the learned intermediary doctrine and emphasizes the pharmacist's duty will not interfere with the patient-physician relationship.¹⁵⁷ The pharmacist, according to the court, is not being asked to "exercise any modicum of medical judgment or to interject himself into the doctor-patient relationship,"¹⁵⁸ again maintaining the patient-physician relationship's integrity.

Moreover, in the small number of states where statutes clarify that pharmacists are covered by the state's malpractice act, pharmacists may owe a duty to comply with their professional standard of care.¹⁵⁹ In one case where the court adopts a professional negligence standard, a physician prescribes three times the recommended dose of a strong hypnotic drug, along with a central nervous system depressant.¹⁶⁰ Concerned about the high dosage, the pharmacist calls the physician's office and dispenses the prescriptions after someone in the office told him the prescription was "okay."¹⁶¹ The patient dies a few days later from the adverse effects of multiple medications, particularly a near toxic dose of the hypnotic drug.¹⁶² The court rationalizes that confining a pharmacist's liability to accurately filling a prescription as

¹⁵⁵Happel v. Wal-Mart Stores, Inc., 737 N.E.2d 650, 657 (Ill. App. Ct. 2000), *aff'd*, 766 N.E.2d 1118 (Ill. 2002).

¹⁵⁶*Id.* at 656.

¹⁵⁷*Id.* at 656–57.

¹⁵⁸*Id.* at 656.

¹⁵⁹Myhra, *supra* note 45, at 36.

¹⁶⁰Horner v. Spalitto, 1 S.W.3d 519, 520 (Mo. Ct. App. 1999).

¹⁶¹*Id.* at 521.

¹⁶²*Id.*

written denigrates the pharmacist's education.¹⁶³ Pharmacists are trained to recognize a prescription dose outside normal ranges and they are well poised to communicate dosage concerns to the prescriber.¹⁶⁴

If current litigation trends continue, most courts will protect the patient-physician relationship from pharmacist interference by finding pharmacists owe no duty and patients will continue to risk unnecessary medication harms. Furthermore, the exceptions to a pharmacist no-duty-to-warn rule emphasize technical components of a pharmacist's profession, namely accurately filling a prescription and acting on existing patient specific knowledge such as a drug allergy. While these exceptions may be appropriate, the courts' technical emphasis may inadvertently fail to recognize a pharmacist's use of professional judgment in filling and dispensing prescriptions,¹⁶⁵ as well as providing other patient care services.

2. Start Accounting for Pharmacists' Professional Judgment

In failing to recognize a patient-pharmacist relationship, the law also fails to sufficiently acknowledge the importance of a pharmacist's professional judgment and patient specific knowledge in promoting patient care. Both professional judgment and specific health care knowledge about a particular patient are distinct from a pharmacist's more technical responsibilities, such as avoiding filling and dispensing an obviously flawed and perhaps fatal prescription medication.

Currently, the law views pharmacists as hybrids, part technician and part professional.¹⁶⁶ Pharmacists are professionals, similar to physicians and lawyers.¹⁶⁷ But unlike physicians and lawyers, the common law categorizes pharmacists' actions into technical actions and actions requiring professional judgment.¹⁶⁸ If a physician affects a patient through the practice of medicine,

¹⁶³ *Id.* at 522.

¹⁶⁴ *Id.* at 523.

¹⁶⁵ The increasing use of robotics in filling prescriptions may encourage further analysis of precisely when in the filling and dispensing of a prescription medication, a pharmacist exercises professional judgment. See Fred Gebhart, *The Future of Pharmacy Automation*, DRUG TOPICS (July 4, 2019), <https://www.drugtopics.com/automation/future-pharmacy-automation> (describing the use of robots in a community pharmacy).

¹⁶⁶ This could be, in part, because pharmacists provide patient care services and products. See Elizabeth Chiarello, *Medical Versus Fiscal Gatekeeping: Navigating Professional Contingencies at the Pharmacy Counter*, 42 J.L. MED. & ETHICS 518, 520–21 (2014).

¹⁶⁷ Smearman, *supra* note 49, at 507.

¹⁶⁸ *Id.* at 509.

it is likely the physician's conduct will form the basis of a legal patient-physician relationship¹⁶⁹ and thus lead to specific duties. The judiciary, however, does not tend to make an analogous finding for pharmacists.¹⁷⁰ Yet, there is no reason that the same analytical framework should not hold true for pharmacists. If the pharmacist affects a patient through the practice of pharmacy, then the pharmacist's conduct should form the basis of a patient-pharmacist relationship and the pharmacist should then be liable for any harm she causes to the patient. Given their expanding capabilities, scope of practice, and provider status,¹⁷¹ it is reasonable to consider pharmacists' actions as requiring some degree of professional judgment. As a health care provider, a pharmacist's actions may occur along a continuum from lesser to greater degrees of professional judgment. Regardless of where the pharmacist's actions lie along this continuum, the actions all likely require the pharmacist to use some degree of professional judgment.

Cases carving out limited exceptions where a pharmacist may owe a duty to warn, such as when a prescribing physician errs in writing the prescription, suggest a nontraditional pharmacist role not well defined in law. Under the traditional pharmacist role, pharmacists must accurately fill a prescription as it is written.¹⁷² For instance, a pharmacist may not introduce a prescription error by dispensing a more powerful chemotherapy drug than prescribed.¹⁷³ This is a technical pharmacist function, requiring the pharmacist to verify that the drug dispensed corresponds perfectly to the prescription. When pharmacists fail to catch a prescriber's obvious error, some courts¹⁷⁴ will also find a pharmacist duty to warn. Such cases differ from the traditional pharmacist's role, as they require pharmacists to use their medication

¹⁶⁹John D. Blum, *Internet Medicine and the Evolving Legal Status of the Patient-Physician Relationship*, 24 J. LEGAL MED. 413, 438 (2003).

¹⁷⁰*See, e.g.*, Kohl v. Am. Home Prods. Corp., 78 F. Supp. 2d 885, 893 (W.D. Ark. 1999); Cottam v. CVS Pharmacy, 764 N.E.2d 814, 821 (Mass. 2002); DiGiovanni v. Albertson's, Inc., 940 N.E.2d 73, 77 (Ill. App. Ct. 2010).

¹⁷¹Although federal law does not recognize pharmacists as providers, several states have enacted legislation distinguishing pharmacists as providers, some also including discretionary or required reimbursement policies for pharmacists providing patient care services. *See* Thomas K. Hazlet et al., Commentary, *Pathway to Pharmacist Medical Provider Status in Washington State*, 57 J. AM. PHARMACISTS ASS'N 116 (2017).

¹⁷²Myhra, *supra* note 45.

¹⁷³Walter v. Wal-Mart Stores, Inc., 748 A.2d 961, 965 (Me. 2004).

¹⁷⁴*See* Podgurski v. United States, No. CIV.CCB-03-3180, 2005 WL 2338851, at *3 (D. Md. Sept. 21, 2005).

expertise, or professional judgment, to recognize and resolve a physician's prescription error, not simply technically fill a flawed prescription.

Even filling and dispensing a lawful prescription (the bulk of a community pharmacist's workload) may require professional judgment.¹⁷⁵ For instance in a Florida case,¹⁷⁶ a patient's physician prescribes an opioid fentanyl patch following her Cesarean section.¹⁷⁷ The patient does not fill the prescription, however, until four months later when she wants to self-treat the pain of a fractured ankle.¹⁷⁸ After using the patch, the patient dies of toxic overexposure to fentanyl.¹⁷⁹ Here the pharmacist needs to consider the patient's opioid naivety combined with a 4 month-old prescription to warn the patient and/or contact the prescriber for further information.¹⁸⁰ In other words, the pharmacist needs to exercise professional judgment.

Analyzing case fact patterns through a professional judgment lens, older cases might have different outcomes if decided today. For instance, the Illinois Court of Appeals¹⁸¹ found that pharmacists owed no duty to warn a physician that drugs are being prescribed in an excessive quantity because to do so would interfere with patient-physician relationships and pharmacists would "practice medicine without a license."¹⁸² Through a professional judgment lens, a pharmacist providing a warning about an excessive use of narcotic pain medications is not practicing medicine, but practicing pharmacy and using professional judgment.

The law already accounts for pharmacists' professional judgment in limited situations. For instance many state statutes require pharmacists to exercise professional judgment in deciding who and how much counseling a patient requires about prescription medications.¹⁸³ Furthermore, common law

¹⁷⁵ *But see* Brushwood, *supra* note 68, at 19 (suggesting dispensing errors are unacceptable, perhaps because dispensing is a technical task not requiring professional judgment). Now, with the use of biologics and polypharmacy, even dispensing may require some exercise of professional judgment.

¹⁷⁶ *Dee v. Wal-Mart Stores, Inc.*, 878 So. 2d 426 (Fla. Dist. Ct. App. 2004).

¹⁷⁷ *Id.* at 427.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 427–28.

¹⁸¹ *Eldridge v. Eli Lilly & Co.*, 485 N.E.2d 551 (Ill. App. Ct. 1985).

¹⁸² *Id.* at 553.

¹⁸³ *E.g.*, Richard C. Alvarez, *Mislabeled the Pharmacist Who Does More Than Just Mislabeled the Prescription: Pharmaceutical Liability Under Florida Law*, 81 FLA. BAR J. 53 (2007) (analyzing Florida's state counseling requirement).

suggests that pharmacists use professional judgment in deciding precisely which side effects to discuss with a particular patient.¹⁸⁴ In one case, when a patient suffers an extreme and rare allergic reaction to a prescription, a Georgia court finds that the learned intermediary doctrine protects the pharmacist from liability.¹⁸⁵ According to this court, a pharmacist does not owe a duty to warn of every potential side effect of a given drug.¹⁸⁶ This was a rare allergic reaction, and the court reasons that even if the pharmacist warns the patient about the medication's side effects, this rare side effect would not likely be included.¹⁸⁷

II. THE ANATOMY OF THE PATIENT-PHYSICIAN RELATIONSHIP AND ITS APPLICATION TO THE PATIENT-PHARMACIST RELATIONSHIP

This Part explores what a legally recognized patient-pharmacist relationship may look like. It considers the basic anatomy of a patient-physician relationship as a model for a patient-pharmacist relationship. Finally, it concludes by analyzing the impacts of applying this model, demonstrating how a patient-pharmacist relationship may improve patient safety and health care teamwork and provide a foundation for a duty to warn, and suggesting that any risk a pharmacist is not ready to assume a duty to warn based on a relationship may be real, but is outweighed by the patient benefits.

A. *The Anatomy of the Patient-Physician Relationship*

As in any other aspect of life, relationships are an important component of health care.¹⁸⁸ They contribute to improved patient outcomes by facilitating diagnoses, preventing medical errors, and ensuring patient compliance with treatment.¹⁸⁹ Legally, establishing a relationship is the critical first step in determining whether a health care provider owes a duty to a patient.¹⁹⁰ Today's physicians and patients are familiar with the

¹⁸⁴Chamblin v. K-Mart Corp., 612 S.E.2d 25 (Ga. Ct. App. 2005).

¹⁸⁵*Id.* at 26.

¹⁸⁶*Id.* at 27.

¹⁸⁷*Id.* at 29.

¹⁸⁸Sagit Mor & Orna Rabinovich Einy, *Quality of Health Care and the Role of Relationships: Bridging the Medico-Legal Divide*, 22 HEALTH MATRIX 123, 125 (2012).

¹⁸⁹*Id.* (advocating for a no-fault system designed to strengthen the patient-physician relationship).

¹⁹⁰Weinrib, *supra* note 12, at 717.

consensual patient-physician relationship created “when a patient knowingly seeks a physician’s professional services, the physician agrees to treat the patient, and the patient consents to have medical care provided.”¹⁹¹ The “glue”¹⁹² binding the patient-physician relationship is trust and the goal of the relationship is improved health.¹⁹³

The patient-physician relationship originates in common law. *Hurley v. Eddingfield*,¹⁹⁴ decided in 1901 by the Indiana Supreme Court, is a classic case defining the contractual nature of the patient-physician relationship.¹⁹⁵ For no apparent reason, the only physician available, Dr. Eddingfield, refuses to deliver a woman’s child, even though he is her family physician.¹⁹⁶ Both mother and baby die of birth complications, and the mother’s estate sues Dr. Eddingfield for wrongful death.¹⁹⁷ The Indiana Supreme Court holds that a physician is not required to enter a contract against his will; state laws governing the practice of medicine do not require physicians to treat anyone requesting services.¹⁹⁸ This court gives the physician unfettered discretion over whether to enter any given patient relationship.¹⁹⁹ With a few federal statutory exceptions,²⁰⁰ the common law rule remains that a physician may decline to enter into a patient-physician relationship for almost any reason. But, once a physician, such as Dr. Eddingfield, has a pre-existing relationship with a patient, that relationship will likely give rise to a duty.²⁰¹ If litigated today, Dr. Eddingfield’s existing family practitioner relationship with the patient would probably create a duty owed to the patient.

¹⁹¹ Tracy L. Zuckett & Rachel E. Ryckman, *No Patient-Physician Relationship Means No Duty, Right? Warning: Get a Second Opinion*, FOR DEF., Aug. 2014, at 12, 13.

¹⁹² Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 470 (2002).

¹⁹³ *Id.* at 521.

¹⁹⁴ 59 N.E. 1058 (Ind. 1901).

¹⁹⁵ See Eleanor D. Kinney & Myra C. Selby, *History and Jurisprudence of the Physician-Patient Relationship in Indiana*, 30 IND. L. REV. 263, 267 (1997) (describing the cyclical pathway of how a strong patient-physician relationship is necessary for successful treatment and legal rules marking the boundaries of that relationship are needed to develop the relationship).

¹⁹⁶ *Hurley*, 59 N.E. at 1058.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ See Kinney & Selby, *supra* note 195, at 268.

²⁰⁰ See Jessica Mantel, *Refusing to Treat Noncompliant Patients Is Bad Medicine*, 39 CARDOZO L. REV. 127, 140–41 (2017) (discussing the nondiscrimination and other laws applicable to terminating a patient-physician relationship).

²⁰¹ *Id.* at 141.

1. The Beginning of a Relationship

Since a duty may arise from a patient-physician relationship, the relationship must have a clear beginning. Typically, the relationship begins when the patient visits the physician.²⁰² Once the physician agrees to treat the patient, the relationship is established, and the physician has an ongoing duty to provide care for the patient.²⁰³

2. The End of a Relationship

Similar to having a clear starting point for a patient-physician relationship, any such relationship needs to be clearly terminated in order to end any liability flowing from the relationship. Often the relationship terminates when no further treatment is needed or either party unilaterally ends the relationship.²⁰⁴ Patients may terminate the relationship for any reason.²⁰⁵ The physician, as long as she does not violate any anti-discrimination law or abandon the patient,²⁰⁶ may also sever the relationship. In some states, statutes or medical boards provide further guidance on terminating a patient-physician relationship,²⁰⁷ giving physicians clarity on when they may have a relationship entailing a duty owed a patient.

3. Testing Relationship Boundaries

Patient-physician relationship boundaries are not static. Changes in our health care delivery system, as well as technology changes,²⁰⁸ create new questions of when a relationship may begin or end and to whom a physician

²⁰² Am. Health Laws. Ass'n, *Creation of the Provider-Patient Relationship*, 1 HEALTH L. PRAC. GUIDE § 11:2 (2019).

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Dennis Auckley, *When the Patient-Physician Relationship Is Broken*, 10 AM. MED. ASS'N J. ETHICS 548, 550 (2008).

²⁰⁶ See Barry R. Furrow, *Forcing Rescue: The Landscape of Health Care Provider Obligations to Treat Patients*, 3 HEALTH MATRIX 31, 43–44 (1993) (explaining the tort of abandonment which may be invoked when a treating physician severs the relationship without giving the patient sufficient time to find another physician and the patient suffers injury because of the delay or lack of treatment).

²⁰⁷ Am. Health Laws. Ass'n, *supra* note 202.

²⁰⁸ See Michael A. McCann, *Message Deleted? Resolving Physician-Patient E-Mail Through Contract Law*, 5 YALE J. L. & TECH. 103, 104 (2003) (discussing whether email creates a patient-physician relationship).

owes a duty based on a patient relationship. The proliferation of medical consultations,²⁰⁹ the adoption of telemedicine,²¹⁰ the expansion of fertility clinics,²¹¹ and the transition to multidisciplinary care²¹² renew the matter of when a patient-physician relationship exists for purposes of malpractice cases and the apportionment of liability.²¹³ For example, in the fertility clinic context courts are called on to parse out when a physician has a relationship with the mother versus the embryo.²¹⁴ A duty may also arise where the physician never meets the patient face to face such as physician consultants.²¹⁵ In response to these changes in our health care system, patient-physician relationships are increasingly defined in state statute. For instance, Oklahoma,²¹⁶ Missouri,²¹⁷ New Hampshire,²¹⁸ and West Virginia,²¹⁹ describe in statute how a patient-physician relationship may be established. On the other hand, some state statutes, such as Idaho's²²⁰ and Utah's,²²¹ specify situations where a patient-physician relationship is not created.²²² The increasing number of statutes focusing on when a patient-physician relationship is or is not established demonstrates the legal importance of this relationship and the need to clarify the confines of its existence.

²⁰⁹E.g., *State ex rel. Red Cross Pharmacy, Inc. v. Harman*, 423 S.W.3d 258 (Mo. Ct. App. 2013); Teresa Baird, Notes, *Who Is Actually Calling the Shots? Watch Out, They May Not Be Liable: Irvin v. Smith*, 22 ST. LOUIS U. PUB. L. REV. 185 (2003).

²¹⁰Blum, *supra* note 169, at 414; Phyllis Forrester Granade, *Medical Malpractice Issues Related to the Use of Telemedicine- An Analysis of the Ways in Which Telecommunications Affects the Principles of Medical Malpractice*, 73 N.D. L. REV. 65, 67 (1997).

²¹¹G. Edward Powell, III, *Embryos as Patients? Medical Provider Duties in the Age of CRISPR/Cas9*, 15 DUKE L. & TECH. REV. 344, 354–55 (2017).

²¹²Zuckett & Ryckman, *supra* note 191.

²¹³Allyson N. Thompson, *Is This Really Over? 45 C.F.R. S 164.506(C)(4) and Determining When the Physician-Patient Relationship Ends*, 27 ANNALS HEALTH L. ADVANCE DIRECTIVE 23, 31 (2017) (highlighting the challenges of modern technology and its impact on the temporal boundaries of the patient-physician relationship).

²¹⁴Powell, *supra* note 211.

²¹⁵Zita Lazzarini, *An Analysis of Ethical Issues in Prescribing and Dispensing Syringes to Injection Drug Users*, 11 HEALTH MATRIX 85, 89 (2001).

²¹⁶OKLA. STAT. ANN. tit. 59, § 478.1 (West 2017).

²¹⁷MO. ANN. STAT. § 191.1146 (West 2016).

²¹⁸N.H. REV. STAT. ANN. § 329:1-c (2015).

²¹⁹W. VA. CODE ANN. § 30-14-12d (West 2019).

²²⁰IDAHO CODE ANN. § 72-1714 (West 2019).

²²¹UTAH CODE ANN. § 34-38-15 (West 2019).

²²²IDAHO CODE ANN. § 72-1714; UTAH CODE ANN. § 34-38-15 (no relationship in a workplace drug or alcohol testing program).

Understandably physicians, and other health providers, seek clear legal guidance regarding relationships and corresponding duties. A physician's understanding of her legal obligations to a patient not only affects the type of care a patient receives but even if a patient can successfully access care. Washington State's experience following a 2016 State Supreme Court decision²²³ changing a mental health professional's duty and confusing providers about when the duty begins, whether it ever ends, and how to satisfy the duty, illustrates the potential impact unclear common law may have on patient care.²²⁴ Confused by the new and vague duty owed by mental health professionals to patients and third parties,²²⁵ providers responded by considering retiring from practicing medicine or no longer caring for certain patients.²²⁶

The patient-physician relationship, central to the provision of health care, is unlikely to be lessened by recognizing a pharmacist-patient relationship. As a resilient relationship, able to adapt to changes in the law, the health care system, and medical technology, it provides a useful model applicable to pharmacy. As addressed below, the patient-physician relationship boundary questions may translate well to pharmacy.

B. Applying the Professional Medical Model to Pharmacy

For several reasons it is logical to apply the professional medical model of patient-physician relationships to pharmacy. First, they are both health care professionals. Second, both relationships have similar challenges, such as clarifying the relationships' termini, and responding to health care system and technology changes. The law's limited experience with patient-pharmacist relationships already demonstrates a natural analogy to the medical model which should be further developed. This is not to suggest, however, that medicine and pharmacy are identical; they are not, as

²²³Volk v. DeMeerleer, 386 P.3d 254 (Wash. 2016) (holding that once a special relationship is formed, a mental health professional has a duty to act with reasonable care, consistent with the standards of the mental health profession, and to protect the foreseeable victims endangered by the patient).

²²⁴Patricia C. Kuszler & Terry J. Price, *Volk v. DeMeerleer Study*, UNIV. WASH. CTR. L., SCI. & GLOB. HEALTH, Dec. 1, 2017, at 41.

²²⁵Volk, 386 P.3d at 254.

²²⁶Kuszler & Price, *supra* note 224, at 38–39.

evidenced by their differing scopes of practice²²⁷ and different training and experience.²²⁸

Following the patient-physician relationship model, three necessary elements of the patient-pharmacist relationship²²⁹ are a clear beginning, a clear end, and an ability to adapt to changes brought about by our health care system or technology. This subsection explores the law's current approach to these issues and how a patient-physician relationship model might apply in the pharmacy practice environment.

1. The Beginning of a Relationship

Limited pharmacy case law suggests that a patient-pharmacist relationship may at least begin when a patient requests a pharmacist fill and dispense a prescription. In one case a transplant patient sues a pharmacy alleging the pharmacy negligently substituted a generic rejection medication for the brand name drug prescribed.²³⁰ In its analysis, the court specifies that the pharmacist-patient relationship consists “of a patient asking the pharmacist to fill a prescription, and the pharmacist doing so.”²³¹ Moreover, a Maryland court clarifies that the learned intermediary doctrine applies in an “ordinary pharmacist-patient relationship wherein the pharmacist merely fills

²²⁷ Scope-of practice laws define the boundaries between different health care professions based on who can and cannot practice. See Joy Luchico Austria, *Urging a Practical Beginning: Reimbursement Reform, Nurse-Managed Health Clinics, and Complete Professional Autonomy for Primary Care Nurse Practitioners*, 17 DEPAUL J. HEALTH CARE L. 121, 130 (2015) (explaining scope-of-practice regulations in the context of nurse practitioners advocating for full professional autonomy).

²²⁸ As physicians assert, “Decisions about the most appropriate drug for a patient’s condition are often subtle and require a level of experience and training that is not provided in obtaining a PharmD degree.” Keely, *supra* note 50, at 81.

²²⁹ Although few courts have explicitly used the term “patient-pharmacist relationship,” the term appears to be more prevalent since 2012. This may suggest that courts, or at least parties’ attorneys, are more receptive to using the term. More importantly these meager cases demonstrate that even when the judiciary addresses a patient-pharmacist relationship, the term lacks a common definition and clear beginning and ending boundaries. In part, this may be because these opinions are often at the summary judgment or similar stage, so there is no further development of the issue as it progresses through litigation.

²³⁰ *Zoblotsky v. Tenet Choices, Inc.*, No. CIV. A. 03-2957, 2007 WL 2008506, at *1 (E.D. La. July 6, 2007) (plaintiff claiming that after her kidney transplant, she filled her prescription for Gengraf, a brand name transplant rejection medicine, and the pharmacy substituted a generic drug resulting in her suffering liver problems).

²³¹ *Id.* at *2.

the prescription as ordered by the physician.”²³² In doing so, the court acknowledges the pharmacist-patient relationship, implies that it begins when a prescription is presented for filling, and then finds that any duty to warn the patient about the medications attaches only to the physician, not the pharmacist.²³³

Other cases, however, consistently squash any suggestion of such a relationship. For instance, in Alabama, a pregnant woman and her husband are treated for scabies by the same physician but with different drugs.²³⁴ When the woman’s prescribed drug fails to cure her scabies, the physician tells her to use her husband’s prescribed medication.²³⁵ Her child is born with medical conditions allegedly caused by using her husband’s medication.²³⁶ Having previously determined that the mother and daughter’s claims against the pharmacies are not covered by the Alabama Medical Liability Act because there is no patient-provider relationship, the court further holds that the learned intermediary doctrine terminates any pharmacist’s duty to warn.²³⁷ According to this Alabama court, the pharmacist only needs to accurately fill the couple’s prescriptions and does not owe any duty to warn.²³⁸

In order to apply a patient-physician relationship model to pharmacy, patient-pharmacist relationships must have an agreed upon and readily recognizable starting point.

2. The End of a Relationship

In an Ohio case, Judge O’Toole’s dissent suggests the simplistic way some courts and experts may view terminating a patient-pharmacist relationship.²³⁹ This case arose when a pregnant patient sued a Walgreens

²³²Rite Aid Corp. v. Levy-Gray, 894 A.2d 563, 579 (Md. 2006).

²³³*Id.* (citing *People’s Serv. Drug Stores, Inc. v. Somerville*, 158 A. 12 (1932) (declining to extend the learned intermediary doctrine to fact patterns where the pharmacy affirmatively distributes medication information and instructions not legally required; in such cases the pharmacy may be liable for breach of express warranty)).

²³⁴*Walls v. Alparma USPD, Inc.*, 887 So. 2d 881, 882 (Ala. 2004).

²³⁵*Id.*

²³⁶*Id.*

²³⁷*Id.*

²³⁸*Id.* at 886.

²³⁹*DelleCurti v. Walgreen Co.*, 70 N.E.3d 111, 117 (Ohio Ct. App. 2016). Moreover, it must provide guidance for when and how a pharmacist-patient relationship is renewed rather than

pharmacy alleging breach of privacy under the Health Insurance Portability and Accountability Act.²⁴⁰ After the patient's obstetrician/gynecologist (OB/GYN) prescribed Adderall,²⁴¹ the patient attempted to fill the prescription at Walgreens.²⁴² The Walgreens pharmacist did not fill the prescription, considering it beyond the scope of an OB/GYN's practice.²⁴³ The patient subsequently filled her prescription at a CVS pharmacy.²⁴⁴ The plaintiff's pharmacist expert's report, referenced by the dissent, states that once the Walgreens pharmacist returned the Adderall prescription to the patient without filling it, the *patient-pharmacist relationship was terminated*.²⁴⁵ As the expert indicated, Adderall was part of the patient's continuation of care, so it was feasible that the patient filled other prescriptions at Walgreens.²⁴⁶ Whether not filling one prescription for a patient terminates any relationship with that patient may depend on the duration and breadth of the patient's relationship with the pharmacist. If for years this patient receives all of her prescription medications from Walgreens, except for the Adderall prescription, then it is unlikely her pharmacy relationship ended abruptly when her pharmacist did not fill her Adderall prescription.

Similar to terminating a patient-physician relationship, a patient-pharmacist relationship also needs a clear end point so that potential liability does not extend indefinitely. Following the patient-physician model, the patient-pharmacist relationship also terminates when no further treatment is needed or either party unilaterally ends the relationship.

continued. O'Donnell v. Siegel, 854 N.Y.S.2d 45, 47 (App. Div. 2008) (a patient who went five years between physician visits renewed the relationship at that time and so did not toll the statute of limitations).

²⁴⁰*DelleCurti*, 70 N.E.3d at 112 (the HIPAA claim arising from the Walgreens pharmacist calling CVS and telling a pharmacy technician not to fill the prescription because "it's wrong to give a pregnant woman Adderall"). *Id.* at 113 (the pharmacist told CVS the patient's name and other information).

²⁴¹*Id.* at 112.

²⁴²*Id.*

²⁴³*Id.* at 113.

²⁴⁴*Id.*

²⁴⁵Plaintiff's expert refers to this possibility of a long-term relationship with Walgreens since the Adderall was part of the patient's continuation of care. *Id.* at 117 (O'Toole, J., dissenting).

²⁴⁶*Id.*

3. Testing Relationship Boundaries

Medicine's experience with changing patient relationships also carries over to pharmacy where pharmacists and patients interact in a wide variety of health care environments. For instance, a consulting physician's relationship with an unmet patient provides guidance to a pharmacist providing care to a patient she does not meet in person,²⁴⁷ like many hospital pharmacists. Furthermore, just like medicine, pharmacy will encounter changing patient relationships brought on by technology changes such as social media.²⁴⁸ As pharmacy specific apps are developed, they too will likely challenge our understanding of a patient-pharmacist relationship.²⁴⁹

C. The Implications of Applying the Medical Model to Pharmacy

Applying a model, even one well-suited to the task, has implications. The major implications of applying a medical model to pharmacy are evaluated in this subsection.

1. Improving Patient Safety and Promoting Health Care Teamwork Through Coexisting Patient Relationships

Looking at patient-pharmacist relationships unclouded by a patient-physician relationship lens, it is apparent that pharmacists, like other health care providers, can form professional relationships with their patients.²⁵⁰ By

²⁴⁷ See *State ex rel. Red Cross Pharmacy, Inc. v. Harman*, 423 S.W.3d 258, 266 (Mo. Ct. App. 2013) (analogizing to a consulting patient-physician relationship, such as a radiologist or pathologist may have, and finding a pharmacist-patient relationship between a pharmacy and a patient, even though the pharmacy has no direct patient contact).

²⁴⁸ Pharmacists, who previously defined the pharmacist-patient relationship as "a series of face-to-face meetings between a patient and a pharmacist," now question the boundaries of that relationship in the social media era. Kevin A. Clauson, Matthew J. Seamon & Brent I. Fox, *Pharmacists' Duty to Warn in the Age of Social Media*, 67 AM. J. HEALTH-SYS. PHARM. 1290, 1290 (2010).

²⁴⁹ See Meghan Ross, *Gadget Guide: Spark Health App Empowers Pharmacists*, PHARMACY TIMES (Nov. 17, 2015), https://www.pharmacytimes.com/publications/career/2015/PharmacyCareers_November2015/gadget-guide-spark-health-app-empowers-pharmacists.

²⁵⁰ Jenna Pizzi, *Industry Analysis: Preparing for the Future of Healthcare and Pharmacy*, US SCIENCES (Apr. 16, 2019), <https://www.usciences.edu/news/2019/industry-analysis-preparing-for-the-future-of-healthcare-and-pharmacy.html> (explaining that pharmacists "create personalized, professional relationships that are extremely impactful, and . . . [are] more focused than ever on helping our patients achieve positive outcomes").

casting pharmacists as “assistants to physicians,”²⁵¹ and focusing on the technical aspects of pharmacy practice, courts have continually deferred to the patient-physician relationship.²⁵² Yet, there is no reason the two cannot coexist and even collaborate to promote better patient outcomes.²⁵³ In fact, studies indicate that physicians and pharmacist can work collaboratively to better patient care²⁵⁴ and the two professions have experience working together under collaborative practice agreements.²⁵⁵

As the U.S. continues striving for a team-based and value-based interdisciplinary health care system, professional responsibilities of prescribers and pharmacists will overlap when informing patients about prescription medications.²⁵⁶ All health care professionals, including pharmacists, are regulated through licensure to protect the public.²⁵⁷ At a minimum, the prescriber and pharmacist each contribute to a shared goal of a patient taking the right drug, in the right dose, at the right time.²⁵⁸ If the duty to warn a patient of drug risks belongs to both the prescriber and the pharmacist, then the patient receives the maximum benefit and should experience better health care outcomes.

²⁵¹ See Philip G. Peters, Jr., *Breaking Down the Boundaries of Malpractice Law*, 65 MO. L. REV. 1047, 1049 (2000).

²⁵² See *id.* at 1048.

²⁵³ For instance, this already occurs through collaborative practice agreements where a physician and pharmacist collaborate on patient care. See CTRS. FOR DISEASE CONTROL & PREVENTION, *Advancing Team-Based Care Through Collaborative Practice Agreements*, DEP'T OF HEALTH AND HUMAN SERVS., (2017), <https://www.cdc.gov/dhdsppubs/docs/cpa-team-based-care.pdf>.

²⁵⁴ See Clowdis, *supra* note 103, at 291 (a collaborative study in the care of transplant patients showed significant improvement in patient outcomes).

²⁵⁵ CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 253.

²⁵⁶ The United States' health care system is moving toward an interdisciplinary model where mid-level providers, such as pharmacists and nurses, are valuable health care team members. Janette A. Bertness, *Rhode Island Nurse Practitioners: Are They Legally Practicing Medicine Without a License?*, 14 ROGER WILLIAMS U. L. REV. 215, 252 (2009); David B. Brushwood, *Rounding with a Medical Team may Expand Pharmacist Liability*, PHARMACY TODAY, June 2016, at 56 (discussing the court's conclusion in *Gallegos v. Wood*, No. CIV 13-1055 JB/KBM, 2016 U.S. Dist. LEXIS 48150 (D.N.M. Mar. 31, 2016), that a pharmacist's close proximity to the patient and the patient's chart when rounding with a medical team may give rise to pharmacist liability).

²⁵⁷ Gil Siegal, *Enabling Globalization of Health Care in the Information Technology Era: Telemedicine and the Medical World Wide Web*, 17 VA. J.L. & TECH. 1, 13 (2012).

²⁵⁸ Federico, *supra* note 41.

By deferring to physicians,²⁵⁹ the judiciary keeps the patient-physician relationship inviolate from impingement by pharmacists and forces the patient-pharmacist relationship to remain undeveloped.²⁶⁰ As discussed in Part I C, courts primarily use the learned intermediary doctrine, as well as other theories, to prevent pharmacists from meddling in a patient-physician relationship and potentially leading a patient astray by providing drug information.²⁶¹ Although courts sometimes, in cases concerning contraindications²⁶² and changes in drug dosages,²⁶³ consider a pharmacist who notifies the patient or prescriber to not be interfering in the patient-physician relationship, if separate, or even overlapping provider duties, rather than interference, were the focus of the analysis patients and health care teams may benefit.

Although the judiciary is reluctant to expressly acknowledge patient-pharmacist relationships in law, growing health sciences research investigating the patient-pharmacist relationship demonstrates its existence in our health care system. Examples of practice settings where the patient-pharmacist relationship has been studied include: anticoagulation clinics,²⁶⁴ ambulatory clinics,²⁶⁵ independent pharmacies,²⁶⁶ and community pharmacies.²⁶⁷ Independent pharmacists rely on their strong patient

²⁵⁹Brushwood, *supra* note 92, at 409.

²⁶⁰*See id.* at 405 (explaining that focusing on the patient-physician relationship underestimates the patient-pharmacist relationship).

²⁶¹Urbaniak v. Am. Drug Stores, LLC, 126 N.E.3d 561, 567 (Ill. App. Ct.), *appeal denied*, 132 N.E.3d 373 (Ill. 2019); *In re Rezulin Prod. Liab. Litig.*, 133 F. Supp. 2d 272, 288 (S.D.N.Y. 2001).

²⁶²Keffer v. Lorenz, No. 2012-CA-1563-M, 2012 WL 3235398, at *10 (D.C. Super. Ct. 2012) (finding that even if the learned intermediary doctrine applied to pharmacists, it would not apply in this case because a pharmacist warning about contraindicated medications prescribed by a physician would not interfere with patient access to care or the patient-physician relationship, nor would such a pharmacist be practicing medicine without a license).

²⁶³Nail v. Publix Super Mkts., Inc., 72 So. 3d 608, 616 (Ala. 2011) (learned intermediary doctrine does not bar plaintiff's claim against pharmacist for failing to warn of dosage change in anticoagulation medicine from one-milligram to five-milligrams).

²⁶⁴Megan B. McCullough et al., *Knowing the Patient: A Qualitative Study on Care-Taking and the Clinical Pharmacist-Patient Relationship*, 12 RES. IN SOC. & ADMIN. PHARMACY 78, 79 (2016).

²⁶⁵Carol J. Hermansen & Joseph B. Wiederholt, *Pharmacist-Patient Relationship Development in an Ambulatory Clinic Setting*, 13 HEALTH COMM. 307, 308 (2001).

²⁶⁶Carmin J. Gade, *Understanding and Defining Roles in the Pharmacist-Patient Relationship*, 1 J. COMM. IN HEALTHCARE 88, 89 (2007).

²⁶⁷Marcia M. Worely-Louis et al., *Construct Identification and Measure Development for Investigating Pharmacist-Patient Relationships*, 51 PATIENT EDUC. & COUNSELING 229, 229

relationships to suggest that their care of patients is superior to that of chain and mail-order pharmacists.²⁶⁸ With greater availability outside of traditional working hours and closeness to a patient's home, pharmacists are well situated, geographically and temporally, to enter into and maintain patient relationships. Patient protections through drug warnings can be increased by holding pharmacists liable based on a patient-pharmacist relationship. As pharmacists use their expertise and professional judgment for patients' benefit, health care quality in terms of medication safety will most likely improve.²⁶⁹

2. A Relationship May Give Rise to a Duty to Warn

A small number of cases consider the next required question under tort law, does a patient-pharmacist relationship give rise to a duty?²⁷⁰ In *Aldrich v. Ohm Specialty Pharmacy, LLC*, the court finds that the patient-pharmacist relationship does not give rise to a duty to warn third parties.²⁷¹ In this case, the patient fills two Fentanyl prescriptions, leaves the pharmacy, places one Fentanyl patch in his mouth, and drives his car across the road's center line, striking another car, killing its two passengers, and injuring the driver.²⁷² The trial court finds a special relationship between the pharmacy and the patient rooted in the patient-pharmacist relationship.²⁷³ After finding a relationship, the trial court addresses the question of duty, finding the pharmacy owes a duty to the car accident victims, in part because the pharmacy was in a

(2003); Joshua J. Spooner et al., *A Nationwide Study of Pharmacists' Perception of the Impact of Medicare Part D on the Pharmacist-Patient Relationship*, 32 CONSULTANT PHARMACIST 629, 629 (2017).

²⁶⁸Danielle Beth Rosenthal, Note, *Are Independent Pharmacies in Need of Special Care? An Argument Against an Antitrust Exemption for Collective Negotiations of Pharmacists*, 13 YALE J. HEALTH POL'Y, L. & ETHICS 198, 238 (2013).

²⁶⁹See *Saukas v. Walker St. Pharmacy, Inc.*, No. 260560, 2005 WL 1846289, at *5 (2005) (Murphy, J., dissenting). Moreover, a pharmacist using her expertise will not likely interfere with the patient-physician relationship. *Id.* at *3.

²⁷⁰Some of these cases do not provide an analysis of the issue. For instance, in *Lemons v. Abbott Labs., Inc.*, the court in overruling the demurrers merely recites the plaintiff's allegation that the pharmacists filling her child's prescription failed to comply with their legal duties to fully and accurately warn of the drug's risks as required by the pharmacist-patient relationship. No. CL98-97, 1999 WL 33726950 (Va. Cir. Ct. 1999).

²⁷¹No. 338140, 2018 WL 5276416, at *1 (Mich. Ct. App. Oct. 23, 2018), *appeal denied*, 927 N.W.2d 257 (Mich. 2019) (Mem.).

²⁷²*Id.* at *1.

²⁷³*Id.* at *2.

position to prevent the harm.²⁷⁴ The court of appeals reverses the trial court, finding a pharmacist owes no duty to third parties.²⁷⁵

More significantly, the *Correa v. Schoeck* court finds the patient-pharmacist relationship contributes to a limited duty to notify the patient and the prescriber of the need for prior authorization each time the patient attempts to fill her prescription.²⁷⁶ In *Correa*, a young woman, Yarushka Rivera, dies after suffering an epileptic seizure.²⁷⁷ She was unable to take her prescription anti-seizure medication because her insurer requires prior authorization that the prescribing physician does not submit.²⁷⁸ The insurer only notifies the pharmacy, which submits the claim for coverage of the drug, of the needed prior authorization, not the patient nor the prescriber.²⁷⁹ The pharmacy's computer system alerts the pharmacist when prescription coverage is denied because of the need for a prior authorization.²⁸⁰ This same computer system permits the pharmacist to send a facsimile with a single "click" to the prescriber, notifying her of the prior authorization requirement and providing the necessary patient and medication information.²⁸¹ There is no evidence, however, that even though Rivera repeatedly tries to fill her

²⁷⁴ *Id.*

²⁷⁵ While the duty to warn third parties is beyond the scope of this article, this issue is beginning to percolate through the courts and will likely continue to be litigated as plaintiffs attempt to hold pharmacists liable for dispensing drugs without sufficient warnings. *See Dent v. Dennis Pharmacy, Inc.*, 924 So. 2d 927, 928 (Fla. Dist. Ct. App. 2006) (third party motorist injured when pharmacy patient drove after consuming a prescription drug with a "use caution driving" label"); *Kirk v. Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 391 (Ill. 1987) (passenger injured when patient/driver hit tree after taking prescription medications without being adequately warned that drugs would diminish physical and mental abilities); *Kinney v. Hutchinson*, 449 So. 2d 696, 697 (La. Ct. App. 1984) (Kinney was shot by Hutchinson and alleged that pharmacist failed to warn Hutchinson of possible adverse effects and dangers of the prescriptions. The court holds that the learned intermediary doctrine protects pharmacists); *Sanchez ex rel. Sanchez v. Wal-Mart Stores, Inc.*, 125 Nev. 818, 221 P.3d 1276, 1278–79 (2009) (holding no duty owed to third-party when pharmacy patient injures third parties while driving under the influence of prescription medications).

²⁷⁶ 98 N.E.3d 191, 194 (Mass. 2018).

²⁷⁷ *Id.* at 197.

²⁷⁸ Without insurance coverage of the medication, Rivera would have to pay \$399.99 out of pocket for the drug, which she and her family could not afford. *Id.* at 196.

²⁷⁹ *Id.* at 195. Prior authorization remains a difficult issue for health care providers. *See Shelby Livingston & Susannah Luthi, House Committee Throws Spotlight on Prior Authorization Burden*, MODERN HEALTHCARE (Sept. 11, 2019, 04:36 PM), <https://www.modernhealthcare.com/politics-policy/house-committee-throws-spotlight-prior-authorization-burden>.

²⁸⁰ *Correa*, 98 N.E.3d at 195.

²⁸¹ *Id.*

prescription at Walgreens, the pharmacist ever notifies the prescriber of the prior authorization requirement.²⁸²

In finding Walgreens owes a duty to notify the patient and the prescriber about the needed prior authorization,²⁸³ the *Correa* court considers the “evolving nature of the pharmacist-patient relationship,”²⁸⁴ Walgreens’s specific knowledge of the prior authorization necessity, the pharmacy industry’s customs and practices regarding prior authorization requests, and the foreseeability of the harm to the patient.²⁸⁵ The court’s explanation of the patient-pharmacist relationship embraces a contemporary view of the relationship and the role of pharmacists in the U.S. health care system. Specifically, the court notes that the relationship is “unlike that of a typical store vendor and customer.”²⁸⁶ Moreover, the court relies on the state statute and regulation language referring to “those obtaining prescriptions as ‘patients’ rather than ‘customers’” as an indication that the patient-pharmacist relationship is broader than a standard commercial relationship²⁸⁷ and that the pharmacist profession has moved beyond that of mere dispensing.²⁸⁸ Under Massachusetts law, pharmacists must complete a prospective drug review before dispensing a new prescription,²⁸⁹ including identifying drug contraindications, incorrect drug dosages or durations, and drug allergies.²⁹⁰ To take proper care of the patient, state law contemplates that the pharmacist may consult with the prescriber and/or the patient.²⁹¹ In essence, the *Correa* court recognizes that pharmacists have a role in improving patients’ well-being and they are well poised within the health care system to help patients with specific medication issues.²⁹²

²⁸² *Id.* at 196.

²⁸³ This duty is limited; pharmacies must take reasonable steps to notify patients and prescribers about the need to complete prior authorization paperwork; they do not need to control the prescriber’s actions. *Id.* at 203.

²⁸⁴ *Id.* at 198.

²⁸⁵ *Id.*

²⁸⁶ *Id.*

²⁸⁷ *Id.* at 199.

²⁸⁸ *Id.*

²⁸⁹ *Id.* at 198–99.

²⁹⁰ *Id.* at 199.

²⁹¹ *Id.*

²⁹² *Id.*

Correa, a case of first impression, finds a patient-pharmacist relationship gives rise to a duty.²⁹³ This type of duty to contact a prescriber and patient about prior authorization is an example of a pharmacist's more technical function. The *Correa* court makes note of how easy it is for the pharmacist to notify the provider; with one click the computer will send the notification with all the necessary information.²⁹⁴ The more challenging question remains, will the court be willing to find the relationship gives rise to a duty to exercise professional judgment?

Any duty to warn owed by pharmacists should be broad enough to avoid unhelpful distinctions among narrow types of duties. As indicated by the Alabama anticoagulation dose change case discussed in Part I C,²⁹⁵ the court perceives a pharmacist's duty to warn of a dose change, unlike the duty to warn of side effects, as not "infring[ing] upon the patient-physician relationship."²⁹⁶ It is unclear why the Alabama court considers one type of duty, the duty to warn about dosage changes not to infringe on the patient-physician relationship,²⁹⁷ while the duty to warn of side effects does infringe on the patient-physician relationship.²⁹⁸ This distinction between a duty to warn of a dose change versus a duty to warn of side effects may be useful now in providing patients a means of avoiding a dead end under the learned intermediary doctrine; but, it does so by creating a seemingly artificial distinction. In Alabama, a pharmacist, noting the dosage change, cannot warn a patient to avoid taking an excessive anticoagulation dose because of the risk of severe bleeding. That same pharmacist can, however, warn a patient her anticoagulation dose changed, presumably leaving it to the patient, based on the patient-physician relationship, to contact her physician and clarify any dose toxicity issues. This distinction without meaning, further blurs how and when a pharmacist safely remains outside the patient-physician relationship.

3. Not All Pharmacists May Be Ready to Assume Duties Flowing from a Defined Relationship

Pharmacy organizations rely on aspirational references to the patient-pharmacist relationship to promote pharmacists' role in improving patient

²⁹³ *Id.* at 198.

²⁹⁴ *Id.* at 195.

²⁹⁵ *Nail v. Publix Super Mkts., Inc.*, 72 So. 3d 608, 616 (Ala. 2011).

²⁹⁶ *Id.*

²⁹⁷ *Id.*

²⁹⁸ *Id.*

outcomes, although the law fails to formally recognize one. As a profession, pharmacists support a patient-pharmacist relationship through a variety of aspirational references, none of which have the force of law. Similar to attorneys, architects, engineers, physicians, and other professionals, pharmacists adhere to a code of ethics. In 1994, the American Pharmaceutical Association adopted a Code of Ethics for pharmacists emphasizing the pharmacist's relationship with patients.²⁹⁹ A pharmacist's relationship with a patient imposes a moral obligation on the pharmacist to help patients obtain the optimum benefit from medications and maintain patients' trust.³⁰⁰ Moreover, the Joint Commission of Pharmacy Practitioners (JCPP), a forum for national organizations of pharmacy practitioners, focuses on achieving the JCPP Vision for Pharmacists' Practice, of which the patient-pharmacist relationship is central.³⁰¹ JCPP further developed a Pharmacists' Patient Care Process dependent on an established patient-pharmacist relationship.³⁰² In this process, the pharmacist works with prescribers and other health care practitioners to optimize patient health and medication outcomes.³⁰³ JCPP's efforts are another example of the pharmacy profession's aspirational goals explicitly referencing the patient-pharmacist relationship. While such aspirational goals may provide guidance to some pharmacists, until the relationship is consistently legally recognized, injured patients will not fully benefit.

The existing view that pharmacists owe no duty to warn patients may cause some pharmacists to feel protected from an obligation to warn patients.

²⁹⁹AM. PHARMACIST ASS'N, CODE OF ETHICS (Oct. 27, 1994), <https://www.pharmacist.com/code-ethics>.

³⁰⁰*Id.*

³⁰¹"Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare." *About JCPP*, JOINT COMM'N PHARMACY PRAC., <https://jcnp.net/about/> (last visited January 27, 2020). (JCPP members include: the Academy of Managed Care Pharmacy, the Accreditation Council for Pharmacy Education, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Pharmacists Association, the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, the National Alliance of State Pharmacy Associations, the National Association of Boards of Pharmacy, and the National Community Pharmacists Association).

³⁰²JOINT COMM'N PHARMACY PRAC., PHARMACISTS' PATIENT CARE PROCESS (May 29, 2014), <https://jcnp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf> (in this process pharmacists collect, assess, plan, implement, monitor and evaluate a patient centered care plan).

³⁰³*Id.*

Such pharmacists may be unwilling or unable to assume the duty to warn. In 2017, the National Association of Boards of Pharmacy (NABP), an association that assists its member boards in ensuring the protection of public health,³⁰⁴ established a task force to examine the lack of a pharmacist-patient relationship definition.³⁰⁵ The Task Force explored the boundaries of any such relationship, such as when it may begin or end, and considered input from NABP's outside legal counsel, highlighting that defining the relationship may further define liability.³⁰⁶ Ultimately, the task force recommended that NABP not amend the Model Act, an act created by NABP, providing State Boards of Pharmacy with model language to use when developing state statutes or board rules,³⁰⁷ to include a patient-pharmacist relationship definition.³⁰⁸

The Task Force, comprised of experts in pharmacy regulation, was concerned that some pharmacists, particularly community pharmacists, may not be ready to satisfy a standard of care flowing from a legally defined patient-pharmacist relationship.³⁰⁹ As demonstrated in Part I C, the duty to

³⁰⁴ *About*, NAT'L ASS'N OF BDS. OF PHARMACY, <https://nabp.pharmacy/about> (last visited January 27, 2020).

³⁰⁵ *See Definition of a Patient-Pharmacist Relationship (Resolution 113-2-17)*, NAT'L ASS'N OF BDS. OF PHARMACY, (May 25, 2017), <https://nabp.pharmacy/news/news-releases/definition-patient-pharmacist-relationship/>.

³⁰⁶ NAT'L ASS'N OF BDS. OF PHARMACY, REPORT OF THE TASK FORCE ON THE DEFINITION OF A PATIENT-PHARMACIST RELATIONSHIP, 2 (2017), <https://nabp.pharmacy/wp-content/uploads/2018/01/2017-Report-of-Task-Force-on-Definition-of-Patient-Pharmacist-Relationship.pdf>. The Task Force determined that if states adopted a definition, it should put "patient" before "pharmacist" in order to maintain the patient as the primary focus of the relationship. *Id.*

³⁰⁷ NAT'L ASS'N OF BDS. OF PHARMACY, THE MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (Aug. 2019), <https://nabp.pharmacy/wp-content/uploads/2019/01/NABP-Model-Act-August-2020.docx>.

³⁰⁸ NABP, *supra* note 306.

³⁰⁹ NABP, *supra* note 306, at 3. *Compare* Spreng, *supra* note 68 (discussing the potential disconnect between community pharmacists, who predominantly dispense and occasionally counsel patients, and the aspirations of the pharmacy profession. *Id.* at 232. As pharmacy practice lives up to its aspirations, it will open itself up to additional liabilities. *Id.* at 233), *with* Brushwood, *supra* note 73 (acknowledging that once liability exists it would not be unexpected for the judiciary to impose such liability on all pharmacists, regardless of practice settings. *Id.* at 458). Additionally, the National Association of Chain Drug Stores does not support imposing civil liability on pharmacists. *See* Burns & Spies, *supra* note 80, at 13. Moreover, the NABP Task Force was fearful that a defined pharmacist-patient relationship might provide payers with a mechanism for denying

warn issue arises and is litigated primarily in the community pharmacy setting. Most courts, by shielding pharmacists from a duty to warn, may encourage pharmacists not to warn since no liability attaches for failing to warn. However, community pharmacists with patient-pharmacist relationships, should be able to comply with a duty to warn, based on their role as medication experts. Or, if not, additional training may enable them to be able to meet such a standard.

III. RELATIONSHIPS MATTER: IT IS TIME FOR LEGISLATURES TO ACT

Practically, the professional patient-pharmacist relationship exists, at least for some pharmacists and patients, but the law is reluctant to recognize it. For over thirty years, academics have identified the judiciary's failure to recognize pharmacists' duties to patients and proposed solutions,³¹⁰ yet the disconnect between the law's perception of pharmacy practice and pharmacy practice reality continues to grow.³¹¹ There is significant consensus that courts "should do away with the antiquated limits on [pharmacist] liability."³¹² These commentators are correct, "a solution needs to be reached and adopted by state courts and the [pharmacy] profession."³¹³ Normative recommendations, no matter how frequently asserted, recommending courts recognize a duty to warn have proven ineffective and insufficient in convincing the judiciary. This failure of courts to be persuaded to change course suggests that state legislatures may be better able to correct the situation by providing a statutory solution. Establishing a patient-pharmacist relationship in statute, cognizable by courts, will provide the first step toward finding a duty owed by pharmacists to patients. By focusing on the patient-

reimbursement claims. It is often said in health care, if you did not document it, it did not happen. If the relationship was not properly documented the payer might determine it does not exist and thus the services do not qualify for reimbursement, NABP, *supra* note 309, at 3.

³¹⁰See Brushwood, *supra* notes 73, 73, and 92; (an expert in pharmacy law, addressing pharmacist's legally unrecognized expanding liability in several articles); Burns & Spies, *supra* note 80, at 7 (two pharmacy law scholars, advocating for courts and the pharmacy profession to adopt a consistent duty to warn standard). Moreover, many scholars and commentators have thoroughly addressed the general failure of courts to recognize OBRA 90's mandates regarding pharmacists, Brushwood, *supra* note 73. Others have called for an end to the learned intermediary doctrine. Burns & Spies, *supra* note 80, at 14.

³¹¹See Myhra, *supra* note 45, at 82 (asserting that the common law has been slow to recognize pharmacists' expertise).

³¹²Spillane, *supra* note 69, at 503.

³¹³Burns & Spies, *supra* note 80, at 2.

pharmacist relationship, the gap between the court's rulings on pharmacist liability and the contributions pharmacists can make toward improving patient care can be narrowed.

A legislative solution will encourage pharmacists to act on their patient-centered responsibilities.³¹⁴ Pharmacists will not be liable for all preventable prescription drug injuries,³¹⁵ but they may be liable for harms resulting from their failure to comply with their duties owed to patients as a result of their patient-pharmacist relationships. It will provide guidance to courts that are reluctant to acknowledge contemporary pharmacy practice. If a patient-pharmacist relationship, giving rise to a duty, is clearly articulated in statute then courts will be more likely to recognize it and subsequently analyze whether a duty exists based on the relationship. This simple act of recognizing a relationship and potential duty will permit more litigation to proceed past the summary judgment, which is often the stopping point today.³¹⁶ When courts consistently treat pharmacists like other professionals, recognizing the patient-pharmacist relationship, and considering what duties arise because of the relationship, patients will likely benefit.³¹⁷

Any legislative solution must accommodate state variability in pharmacy practice. Different pharmacy practice settings must also be accounted for in any legislation.³¹⁸ Initiating a patient-pharmacist relationship in a community practice likely differs from initiating a patient-pharmacist relationship in a geriatric practice.³¹⁹ While this Article ultimately argues for greater pharmacist liability based on a patient-pharmacist relationship, any legislative solution should not create unlimited liability for pharmacists.

³¹⁴ See AM. PHARMACISTS ASS'N, *supra* note 299.

³¹⁵ See Brushwood, *supra* note 73, at 451–52 (asserting that from moral perspective, pharmacists should be accountable only for unnecessary medication harms that they could have known would occur).

³¹⁶ Burns & Spies, *supra* note 80, at 16.

³¹⁷ See Hornish, *supra* note 69, at 1084–85 (discussing the modern view of pharmaceutical duties of care).

³¹⁸ For instance, pharmacists practice in hospitals, outpatient clinics, emergency departments, community pharmacies, physicians' offices, community-based clinics, nursing homes, and managed care organizations. *About Clinical Pharmacists*, AM. COLL. CLINICAL PHARMACY, <https://www.accp.com/about/clinicalpharmacists.aspx> (last visited January 28, 2020). Pharmacists also practice in the pharmaceutical industry, pharmacy mail service, managed care, and the government. Keely, *supra* note 50, at 79.

³¹⁹ See Brenda Jones Quick, *The Cost of the Omnibus Budget Reconciliation Act of 1990*, 2 J. PHARMACY & L. 145, 153–54 (1994) (discussing differences in relationship formation in urban and rural settings).

Pharmacists, like all health care providers, cannot guarantee a good pharmaceutical outcome, sometimes injuries occur without the fault of a provider. The prescriber and the patient also share outcome responsibility with the pharmacist.³²⁰

This Part identifies the major factors state legislatures must consider in proposing a statutory patient-pharmacist relationship. At a minimum, legislatures should clarify the existence and boundaries of a patient-pharmacist relationship forming a basis for potential duties owed to a patient. This Article's intent is not to recommend specific statutory language but to catalyze further discussion by policymakers, as well as providers, patients, and other policy stakeholders.

A. *Defining and Clarifying Boundaries*

1. Factors in Defining a Patient-Pharmacist Relationship

A legislative solution must define a patient-pharmacist relationship if parties are to share a common understanding of the term. Future legislation should learn from existing state statutes that fail to define the patient-pharmacist relationship.

In Arkansas³²¹ and Kentucky,³²² state statutes refer to patient-pharmacist relationships without defining such a relationship.³²³ In Arkansas, a pharmacist must use professional judgment to determine if a person attempting to purchase a behind-the-counter medication,³²⁴ without a valid prescription, has a legitimate medical and pharmaceutical need for the product.³²⁵ Based on their professional judgment, pharmacists may dispense the behind-the-counter medication to a person who rarely uses pharmacist services³²⁶ or who has not *established a patient-pharmacist relationship* with the dispensing pharmacist.³²⁷ The critical element is the exercise of the

³²⁰Brushwood, *supra* note 73, at 459.

³²¹ARK. CODE ANN. § 5-64-1103(c)(1)(A) (West 2015).

³²²KY. REV. STAT. ANN. § 315.121(2)(i) (West 2019).

³²³Other midlevel provider patient relationships are also in state statute. MICH. COMP. LAWS ANN. § 691.1501 Sec. 1(1) (West 2016).

³²⁴ARK. CODE ANN. § 5-64-1103(c)(1)(A) (regulating the sale of ephedrine and related products including pseudoephedrine or phenylpropanolamine).

³²⁵*Id.*

³²⁶*Id.* § 5-64-1103(c)(3)(A).

³²⁷*Id.* § 5-64-1103(c)(3)(B) (emphasis added).

pharmacist's professional judgment in deciding whether or not to dispense a behind-the-counter medication. In Kentucky, a pharmacist accessing confidential information about a patient with whom the pharmacist does not have a *current patient-pharmacist relationship*³²⁸ may face an administrative agency action for unprofessional conduct.³²⁹ It is unclear from these statutes how a patient-pharmacist relationship is defined or established, or when it qualifies as a current relationship.

In at least five states, Georgia,³³⁰ North Dakota,³³¹ Louisiana,³³² Texas,³³³ and Washington,³³⁴ a patient-pharmacist relationship is required, but again undefined, for certain pharmaceutical therapies,³³⁵ including home health care services,³³⁶ sterile compounding,³³⁷ collaborative drug therapy management,³³⁸ and parenteral therapy,³³⁹ pursuant to state regulations. Pharmacists providing home health care services in Georgia³⁴⁰ and North Dakota³⁴¹ must establish and maintain a patient-pharmacist relationship throughout the patient's course of therapy.³⁴² As part of this relationship in Georgia, the pharmacist should contact the patient at least quarterly and

³²⁸KY. REV. STAT. ANN. § 315.121(2)(i) (West 2019) (emphasis added).

³²⁹*Id.* § 315.121(1)(a).

³³⁰GA. COMP. R. & REGS. § 480-21-.07(3) (2019).

³³¹N.D. ADMIN. CODE § 61-06-01-07(3) (1988).

³³²LA. ADMIN. CODE tit. 46, § 523(D)(1)(b)(ii) (2019).

³³³22 TEX. ADMIN. CODE § 291.133(d)(11)I (2019) (Tex. State Bd. of Pharmacy, Pharmacies Compounding Sterile Preparations).

³³⁴WASH. ADMIN. CODE § 246-871-070(3) (2019).

³³⁵State regulations addressing practitioner-pharmacist-patient relationships are not included in this discussion because these regulations address the general requirement of a triad relationship between prescriber, pharmacist, and patient. In this type of relationship, the pharmacist typically knows the physician and/or the patient and is well poised to verify any concerns with the prescription. *See* 21 N.C. ADMIN. CODE § 46.1804(a) (2019) (governing who can receive a prescription order within the pharmacy); *Id.* § 46.2504(f) (2019) (requiring counseling for mail order prescriptions where the practitioner-pharmacist-patient relationship does not exist); N.H. CODE ADMIN. R. PH. 704.10 (2020) (prescriptions written by a non-New Hampshire physician may be dispensed only if a traditional physician-pharmacist-patient relationship exists).

³³⁶GA. COMP. R. & REGS. § 480-21-.07(3) (2019); N.D. ADMIN. CODE § 61-06-01-07(3).

³³⁷22 TEX. ADMIN. CODE § 291.133 (2019).

³³⁸LA. ADMIN. CODE tit. 46 § 523 (2019).

³³⁹WASH. ADMIN. CODE § 246-871-070(3) (2019).

³⁴⁰GA. COMP. R. & REGS. § 480-21-.07(3) (2019).

³⁴¹N.D. ADMIN. CODE § 61-06-01-07(3) (1988).

³⁴²GA. COMP. R. & REGS. § 480-21-.07(3) (2019); N.D. ADMIN. CODE § 61-06-01-07(3)) (1988).

document the contact in the patient's profile.³⁴³ In North Dakota, the pharmacist should visit the patient in person; telephone contact is not sufficient to satisfy the regulation.³⁴⁴ Louisiana pharmacists engaged in collaborative drug therapy management must establish and maintain a patient-pharmacist relationship with each participating patient.³⁴⁵ A patient-pharmacist relationship must be "established and maintained"³⁴⁶ throughout a patient's course of therapy requiring compounded sterile preparations in Texas.³⁴⁷ This patient-pharmacist relationship must be documented in the patient's medication record.³⁴⁸ And, Texas physicians delegating drug therapy management to a pharmacist must determine that the pharmacist establishes and maintains a patient-pharmacist relationship.³⁴⁹ Finally, Washington holds pharmacists responsible for non-hospitalized patient compliance with parenteral products based on a patient-pharmacist relationship.³⁵⁰

None of these state statutes or regulations define or provide guidance for how or when a patient-pharmacist relationship is established, maintained, or kept current. While it is theoretically possible that courts, pharmacists, physicians, patients, and others simply know a patient-pharmacist relationship when they see it,³⁵¹ future legislation should provide an explicit definition so that all parties understand the terminology. State-level stakeholder input can aid in developing a definition that accounts for state variation in pharmacy practice.

³⁴³GA. COMP. R. & REGS. § 480-21-.07(3) (2019).

³⁴⁴N.D. ADMIN. CODE § 61-06-01-07(3) (1988).

³⁴⁵LA. ADMIN. CODE tit. 46 § 523(D)(1)(b)(ii) (2019).

³⁴⁶22 TEX. ADMIN. CODE § 291.133(d)(11)(C) (2019) (Tex. State Bd. of Pharmacy, Pharmacies Compounding Sterile Preparations).

³⁴⁷*Id.* § 291.133(d)(11).

³⁴⁸*Id.* § 291.133(d)(11)(C). Moreover, in Texas, insurers providing pharmacist professional liability insurance are not required to report instances "where a licensee invented a medical device which may have injured a patient but the licensee has no personal pharmacist-patient relationship with the specific patient claiming injury by the device," 22 TEX. ADMIN. CODE § 281.18(d)(1) (2019) (Tex. State Bd. of Pharmacy, Reporting Professional Liability Claims).

³⁴⁹22 TEX. ADMIN. CODE § 295.13(e)(6) (2019) (Tex. State Bd. of Pharmacy, Drug Therapy Management by a Pharmacist under Written Protocol of a Physician).

³⁵⁰WASH. ADMIN. CODE § 246-871-070(3) (2019).

³⁵¹Similar to Justice Stewart's comment "I know it when I see it" regarding pornography. *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

2. Factors in Establishing Boundaries on a Patient-Pharmacist Relationship

As discussed in Part II B, case law suggests that a pharmacist-patient relationship may at least begin when a patient requests a pharmacist fill and dispense a prescription and end when a pharmacist declines to fill a patient's prescription.³⁵² This is not, however, a convincing group of well-reasoned cases based on commonly occurring fact patterns from which a legislature may draw upon in developing boundaries on the patient-pharmacist relationship. To resolve the issue of when a patient-pharmacist relationship is formed, a necessary component of any legislative solution, legislatures should consider applying a medical model to pharmacy, modifying it to adjust for practice differences. Like medicine, a patient-pharmacist relationship may begin once a patient requests and a pharmacist agrees to provide care. Additional consideration will need to be given to when and how a patient-pharmacist relationship is renewed rather than continued³⁵³ and whether a patient has a relationship with a particular pharmacist or the pharmacy.

a. The Beginning of a Relationship

Physicians with patient office visits provide a model for pharmacists providing clinical services to patients in person. For instance, a patient visits a pharmacist to receive services such as monitoring and adjustment of anticoagulation medication. The patient presents themselves to the pharmacist, implicitly or explicitly, requesting specific health care services, the monitoring and adjustment of anticoagulation medication. If the pharmacist agrees to provide these services to the patient, then a patient-pharmacist relationship begins. Like the physician model, the pharmacist, or pharmacy, now has an ongoing duty to care for the patient.

This analysis could also apply to community pharmacists interacting with patients³⁵⁴ filling prescription drugs, receiving vaccines, or accessing

³⁵² See *supra* Part III.B.

³⁵³ See *O'Donnell v. Siegel*, 854 N.Y.S.2d, 45, 47–48 (N.Y. App. Div. 2008) (finding a patient who went five years between physician visits renewed the relationship at that time and so did not toll the statute of limitations).

³⁵⁴ Pharmacists are also beginning to provide health coaching to patients, John M. Lonie et al., *Pharmacist-based Health Coaching: A New Model of Pharmacist-patient Care*, 13 RSCH. SOC. & ADMIN. PHARMACY 644, 644 (2017).

nonprescription drugs.³⁵⁵ A patient consistently filling prescriptions at one pharmacy, likely indicates a patient-pharmacist relationship. A patient receiving a vaccination from a community pharmacist will also likely create a patient-pharmacist relationship. In the case of nonprescription drugs available from a pharmacist, such as codeine cough syrup³⁵⁶ and decongestant pseudoephedrine,³⁵⁷ pharmacists are the only health care professional a patient needs to communicate with in order to receive the drug. When a patient speaks with the pharmacist about purchasing one of these nonprescription drugs from behind the counter, and the pharmacist, using her professional judgment, decides to sell it to the patient, a patient-pharmacist relationship should be formed.

b. The End of a Relationship

A patient who transfers her prescriptions to a new pharmacy will likely terminate her patient-pharmacist relationship. For a patient receiving her vaccines from a community pharmacist, when, if at all, the relationship terminates may depend on whether the patient also receives her prescriptions from the pharmacy or whether the patient only received her vaccines from the pharmacist. In the first instance, the relationship will likely remain intact; in the latter instance, the relationship may end after receiving the last vaccine.³⁵⁸ Finally, when a patient purchases a behind-the-counter

³⁵⁵ *But see* *Burgess v. Sewerage & Water Bd. of New Orleans*, 225 So. 3d 1020, 1027 (La. 2017) (stating that unlike “a patient’s personal relationship with his doctor,” there is “no meaningful difference” regarding which pharmacy dispenses a patient’s prescription drug that would mandate an employee’s choice under workers’ compensation law).

³⁵⁶ *Kintigh v. Abbott Pharmacy*, 503 N.W.2d 657 (Mich. Ct. App. 1993) (as the plaintiff could obtain, without a prescription, the codeine cough syrup, a Schedule V controlled substance, from a licensed pharmacist, the pharmacist is the sole “gatekeeper” for this drug and thus the only health care provider that can bear any liability. *Id.* at 660, 662 (Shelton, J, dissenting)).

³⁵⁷ *See* Patricia Stanley, Comment, *The Combat Methamphetamine Epidemic Act: New Protection or New Intrusion?*, 39 TEX. TECH L. REV. 379, 395 (2007) (discussing placement of pseudoephedrine within a pharmacy). The USA Patriot Improvement & Reauthorization Act of 2005 containing the Combat Methamphetamine Epidemic Act of 2005 established pseudoephedrine and related products as behind-the-counter drugs, requiring the pharmacist to act as a gatekeeper. Customers may purchase such products without a prescription, but access is controlled by the pharmacist, 21 U.S.C. § 801.

³⁵⁸ In some cases, like Shingrix, the shingles vaccine, this will require two separate vaccinations about two to six months apart. *Administering Shingrix*, CTR. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/administering-vaccine.html> (last visited January 27, 2020).

medication from a pharmacist, it is likely that the relationship terminates upon purchase and is renewed if subsequently purchased.

B. Establishing an Exception to the Learned Intermediary Doctrine

As discussed in Part I C, a few courts carve out an exception to a pharmacist's no-duty-to-warn rule when a pharmacist has specific health care knowledge about a patient.³⁵⁹ In these limited instances, the judiciary finds an exception to the learned intermediary doctrine.³⁶⁰ The pharmacist's specific knowledge may arise from several sources, including a computer alert, or a pharmacist's knowledge, training, and expertise.³⁶¹ Regardless of the basis of a pharmacist's patient-specific knowledge, once a pharmacist has the knowledge she may need to act. In addition to defining and establishing boundaries for a patient-pharmacist relationship, legislatures should also consider establishing an exception to the learned intermediary doctrine.

In *Saukus v. Walker*,³⁶² a patient suffers a life-threatening drug interaction after ingesting a large dose of seizure medications, Depakote, combined with another anticonvulsant prescription drug, Lamictal.³⁶³ The patient fills the Lamictal prescription at the same brick and mortar pharmacy where she had filled her Depakote prescription six months earlier.³⁶⁴ Subsequently, unbeknownst to the brick and mortar pharmacy, the patient fills her Depakote at a mail-order pharmacy.³⁶⁵ Confirming summary judgment for the pharmacy, the Michigan Court finds a pharmacist cannot warn without specific patient knowledge, and the pharmacist does not know the patient remains on Depakote, which she receives through a mail-order pharmacy.³⁶⁶ As the dissent writes, checking the computer system should alert the pharmacist to ask about the potential drug conflict.³⁶⁷

³⁵⁹ See *supra* Part II.C.

³⁶⁰ See discussion *supra* Section II.C.1.b.

³⁶¹ Often a pharmacist's knowledge may be complemented by a computer alert. For instance, in *Brienze v. Casserly*, the pharmacist knew the patient was prescribed two drugs simultaneously, the pharmacy computer system alerted the pharmacist of the potential adverse interaction of these two drugs, and the pharmacist also knew of the potential adverse interaction based on his training and experience, No. CIV.A. 01-1655-C, 2003 WL 23018810, at *1 (Mass. Super. Ct. Dec. 19, 2003).

³⁶² No. 260560, 2005 WL 1846289 (Mich. Ct. App. Aug. 4, 2005).

³⁶³ *Id.* at *1.

³⁶⁴ *Id.* at *2.

³⁶⁵ *Id.*

³⁶⁶ *Id.*

³⁶⁷ *Id.* at *3 (Murphy, J., dissenting).

In a bizarre twist, from a patient protection perspective, at least one court opines that a patient's specific knowledge negates a pharmacist's specific knowledge.³⁶⁸ A Connecticut patient dies of acute drug toxicity, and the estate alleges the pharmacist failed to warn about the potentially dangerous combinations of the approximately 149 prescriptions filled and dispensed to the patient.³⁶⁹ The Connecticut court extends the learned intermediary doctrine to pharmacists unless an exception applies, such as specific knowledge.³⁷⁰ Without specific knowledge, a pharmacist has no duty to warn, even if a patient is overmedicated or overdoses.³⁷¹ The estate-plaintiff alleges that the number and quantity of prescriptions presented by the patient to the pharmacist should have given rise to a duty, based on specific patient knowledge.³⁷² The court, however, finds that because the patient knew the medications she was taking, why she was taking them, and how frequently she was to take them, the pharmacist did not have any special knowledge.³⁷³

While a number of sources may contribute to a pharmacist's special patient knowledge, once they have that knowledge, it seems illogical that another person's knowledge, such as a patient's, could simply render the pharmacist's knowledge no longer special. Patients' medication therapy knowledge should be encouraged as it improves outcomes; it should not be used as another means of shielding pharmacists from liability. If a patient's knowledge trumps a pharmacist's knowledge, it may prompt a new type of pharmacy health care documentation. If the patient sufficiently indicates on the document the drugs they are taking, why they are taking them, and how often they take them, then the pharmacist can robotically dispense, safe in the knowledge that the patient's knowledge shields the pharmacist from liability. Regardless of the patient's knowledge, the pharmacist retains her special knowledge and should be obligated to act. At the very least, the pharmacist, by acting on her special knowledge, reinforces the patient's knowledge and aids in improving health outcomes.

Courts continue to use the learned intermediary doctrine to shield pharmacists from liability, even going so far as to find that a knowledgeable patient forecloses an exception to the learned liability doctrine based on a

³⁶⁸ *Deed v. Walgreen Co.*, 927 A.2d 1001, 1004 (Conn. Super. Ct. 2007).

³⁶⁹ *Id.* at 1002.

³⁷⁰ *Id.* at 1002–03.

³⁷¹ *Id.* at 1003 (citing *Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985)).

³⁷² *Id.* at 1004.

³⁷³ *Id.*

pharmacist's specific knowledge.³⁷⁴ Eventually, the law's acceptance of pharmacists as medication therapy experts may foster reconsideration of the learned intermediary doctrine's utility since physicians may not be the best health care provider to warn a patient. Until then, a legislative solution should acknowledge that a patient-pharmacist relationship combined with pharmacist's professional judgment may serve as a specific knowledge exception to the learned intermediary doctrine.

C. Limitations of a Legislative Solution

Legislatures' willingness to consider establishing a statutory patient-pharmacist relationship may vary according to the progressive nature of pharmacy practice in a given state. For instance, Washington State, touted by some pharmacy educators as having the "most progressive practice environment in the country,"³⁷⁵ may be more inclined to consider a legislative solution than a state with a more traditional pharmacy practice. Even the more traditional pharmacy practice states may, however, be encouraged to pursue this type of statute to improve patient prescription medication outcomes.

Any legislative solution requires political will.³⁷⁶ This is particularly true in health care regulation with turf battles between different licensed health care professionals.³⁷⁷ While turf battles typically focus on scope of practice issues such as diagnosis, evaluation, and treatment,³⁷⁸ legal recognition of a patient-pharmacist relationship will likely trigger a reaction by some physicians and physician organizations to protect patient-physician relationships from pharmacist interference. Pharmacists can help by advocating for a legislative solution. Advocacy is a required element of pharmacy education and so pharmacists should have basic advocacy skills to

³⁷⁴ See, e.g., *Id.*

³⁷⁵ *Dean's Welcome*, U. WASH., <https://sop.washington.edu/about/deans-welcome/> (last visited January 28, 2020).

³⁷⁶ See Taled El-Sabawi, *What Motivates Legislators to Act: Problem Definition & the Opioid Epidemic, A Case Study*, 15 IND. HEALTH L. REV. 188, 193 (2018) (analyzing the components of legislative decision making, including local needs, voter preferences, interest group and administrative preferences).

³⁷⁷ Christopher Ogolla, *Litigating Hypocrisy: Turf Wars Between Health Care Professionals Regarding Diagnosis, Evaluation, and Treatment*, 50 U. TOL. L. REV. 67, 69 (2018).

³⁷⁸ *Id.* (detailing how health care professionals, organizations, and state-sanctioned licensure boards litigate against each other regarding issues of diagnosis, evaluation, and treatment).

apply to this issue.³⁷⁹ Pharmacists will also need to collaborate with other health care professionals, such as physicians, because without physician support, any bill establishing a patient-pharmacist relationship is likely to fail.³⁸⁰

A legislative solution may also require reconsideration of the pharmacists' work conditions, particularly in the community setting where company policies may cause pharmacists to experience workflow tensions with patient care.³⁸¹

IV. CONCLUSION

While patient-physician relationships are a critical component of our health care system, they are not worth protecting to the detriment of improved patient care. Pharmacists are part of our complicated health care system³⁸² and their role and responsibilities in this system warrant legislative and judicial recognition. A patient's relationship with a pharmacist does not necessarily harm the patient-physician relationship. Rather it may support and complement it.

The judiciary's failure to explicitly and consistently recognize a pharmacist-patient relationship is the root cause of most courts' inability to find that pharmacists owe a duty to warn patients of the potential adverse effects or risks associated with their prescriptions. A pharmacist's duty to

³⁷⁹ ACCREDITATION COUNCIL FOR PHARMACY EDUC., ACCREDITATION STANDARDS AND KEY ELEMENTS FOR THE PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR OF PHARMACY DEGREE 22 (2015), <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf>.

³⁸⁰ Physician support, or at least neutrality, has been necessary for pharmacists to achieve state-level provider status and will be necessary in establishing a patient-pharmacist relationship, *see* B. Joseph Guglielmo & Sean D. Sullivan, *Pharmacists as Health Care Providers: Lessons from California and Washington*, 1 J. AM. CLIN. PHARMACY 39, 40 (2018) (describing how once the California Medical Association accepted a neutral stance toward California pharmacist's provider status bill, all organized opposition to the bill dissipated).

³⁸¹ Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, NY TIMES (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html> (warning that pharmacists in chain drug stores may be making mistakes because of company policies regarding productivity). *See also* Smith, *supra* note 98 at 224–25 (discussing the heavy workload of pharmacists, particularly community pharmacists, potentially impacting these pharmacists' professionalism).

³⁸² As Bill Gates, co-founder of Microsoft, and President Trump have commented, health care is "complicated," and pharmacy is no exception. Nicolas P. Terry, *"Prime Health" and the Regulation of Hybrid Healthcare*, 8 NYU J. INTELL. PROP. & ENT. L. 42, 88 (2018).

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warn arises because the pharmacist has a provider-patient relationship with her patient. Clear recognition and analysis of the relationship is the first step in the analysis, from there, courts can move on to the next steps, determining if the pharmacist owes a duty to warn and the scope of any such duty.