"PILLING" THEM SOFTLY: LEGISLATIVE EXPANSION OF PHARMACIST DUTY OF CARE AND IMPENDING NEGLIGENCE LIABILITY IN THE ERA OF THE OPIOID CRISIS

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INTRODUCTION

Legal theorists have predicted for decades that a pharmacist's role in patient care is evolving into one more reflective of healthcare professional than mere dispensers of medication.[1] The broadening scope of professional duties and responsibilities imposed upon pharmacists by both the legislature and medical community has placed them squarely in the crosshairs of tort law and has opened them up to negligence liability where they were historically shielded.[2] While a majority of jurisdictions either adopted the learned intermediary doctrine[3], or simply applied its rationale to excuse pharmacists from civil liability for filling facially-valid prescriptions,[4] the current technological and cultural landscape of availability of patient medical and prescriptive history is eroding the justifications for adherence to the doctrine and its underlying theory.[5] While public policy and statutory schemes[6] impose a special relationship between

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1. Lauren Fleischer, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 FORDHAM L. REV. 165, 168-72 (1999); Alison G. Myhra, *The Pharmacist's Duty to Warn in Texas Reconsidered Within a National Framework*, 27 REV. LITIG. 607, 611-17 (2008).

2. Ryanne Bush Dent, *No Duty to Warn of Drug Interactions: A Dangerous Prescription*, 46 J. MARSHALL L. REV. 533, 553-54 (2013); James Barney, *Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists' Duty to Warn*, 39 GONZ. L. REV. 399, 405-07 (2004).

3. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. e (AM. LAW INST. 1998).

4. Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387 (Mich. Ct. App. 1987).

5. Baker v. Arbor Drugs, Inc., 544 N.W.2d 727, 730 (Mich. Ct. App. 1996) (imposing liability on pharmacy for implementing and advertising a computer system known as Arbortech Plus to monitor medication profiles and adverse drug interactions because pharmacy voluntarily assumed a duty to the patient); *See generally* Moore v. Covenant Care Ohio, Inc., 2014-Ohio-4113, 18 N.E.3d 1260 (6th Dist.) (finding the pharmacy owed a duty to the customer because it utilized a computerized system to verify prescriptions and to review any potential risks).

6. 21 C.F.R. § 1306.04 (2020) (does not implicitly define a relationship between a pharmacist and a patient, but proscribes upon the pharmacist a "corresponding responsibility" to that of the

pharmacist and patient, one that carries with it a "duty to act with due, ordinary, care and diligence in compounding and selling drugs,"[7] courts have generally declined to hold pharmacists strictly liable without fault.[8] Even where a pharmacist is shown to have actual and documented knowledge of a patient's addiction to alcohol, and over a period of time fills 728 units of a prescription known to contraindicate with the use of alcohol, a duty to the patient is not automatically created, and consequently, the pharmacist is not automatically liable for resulting injuries.[9]

This paper will explore three factors giving rise to this shift in public consciousness and will examine how judiciaries traditionally applying the learned intermediary doctrine to pharmacists are abandoning old rules in favor of diversifying liability. This diversification presents an implicit warning to the pharmacy community that the once impermeable shield from negligence liability for failure to warn is dissolving, and pharmacists should be aware that emerging public policy considerations, legislative decisions, and judicial interpretations all serve to expose the modern pharmacist to negligence liability.

I. HISTORICAL FOUNDATION

A. Legislative Authority

To be sure, pharmacist standards of care are statutorily assigned and they must adhere to both federal and state regulations.[10] The Food and Drug Administration (FDA), among other actions, governs the approval, manufacturing, and regulations of medications, while the Drug Enforcement Administration (DEA) monitors and enforces certain aspects of the practice of pharmacy.[11] This is all authorized under the Federal Controlled Substances Act of 1970 (Title II).[12] The federal government's involvement in the practice of pharmacy, and its primary concern with all pharmaceuticals, is substantially centered on the "manufacturing, distribution, dispensing, and delivery of drugs or substances that are subject to, or have the potential for, abuse or physical or psychological dependence" – aka "controlled substances."[13] The regulation, monitoring, and enforcement of these

physician); MICH. ADMIN. CODE. r. 338.490 (2019) (does not implicitly define the relationship between a pharmacist and patient as a "special relationship," but implies that there is such a relationship that creates a "professional responsibility" owed to the patient by a pharmacist. The pharmacist's breach of her professional responsibility is, in essence, a breach of her duty owed to the patient.).

7. Batiste v. Am. Home Prods. Corp., 231 S.E.2d, 269, 273-74 (N.C. Ct. App. 1977).

8. 25 AM. JUR. 2D *Drugs and Controlled Substances* § 247 (2020).

9. Hand v. Krakowski, 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982).

10. MICH. COMP. LAWS ANN. § 333.17741 (West 2020) (providing a relevant example).

11. DAVID C. KOSEGARTEN & DOUGLAS J. PISANO, PHARMACY & FEDERAL DRUG LAW REVIEW: A PATIENT PROFILE APPROACH 1 (David C. Kosegarten & Douglas J. Pisano eds., 2006).

12. *Id*.

13. *Id.* at 7.

has been delegated to the states. As is typical with state regulation in any category, there are variations in legislation.[14]

For a touch of local flavor, compare Ohio Administrative Code §4729-5-21 and Section 17751 of Act 368 of the Michigan Public Health Code of 1978, codified at Michigan Compiled Laws § 333.17751 ("Act 368"),[15] concerning the manner and procedure for dispensing prescription drugs. Both require that the prescription be written for a proper purpose – OAC uses "legitimate medical purpose"[16] while Act 368 uses "prescribed drug is appropriate and necessary for the treatment of an acute, chronic, or recurrent condition."[17] Both require that the prescription be issued by an authorized prescriber – OAC uses "[a] prescription, to be valid, must be issued…by an individual prescriber acting in the usual course of his/her professional practice,"[18] while Act 368 uses "if the prescriber is a physician or dentist…pursuant to an existing physician-patient…relationship"[19] and "the prescription falls within the scope of practice of the prescriber."[20] The OAC and Act 368 also indicate variations in the acceptable forms and methods of receipt of the prescription, the proper recording of dispensing controlled substance medications, and the authority of a pharmacist to modify the quantity of a patient's medication under certain circumstances.[21]

For all their definitional similarities and complimentary requirements, the OAC and Act 368 differ in at least one important way for purposes of this analysis: the OAC imparts a knowledge component as a prerequisite to assigning liability to pharmacists who fill invalid prescriptions, while Act 368 requires that a pharmacist use his or her professional judgment to determine that a prescription is valid.[22] The Act enumerates the requirements that a pharmacist must satisfy (using his professional judgment) prior to dispensing a medication, including that the "prescription is authentic,"[23] that it be communicated by a "physician prescriber, dentist prescriber, or veterinarian prescriber,"[24] that the pharmacist determine that there is an "existing physician-patient…relationship,"[25] and the medication is "appropriate and necessary."[26] The OAC simply requires that the prescription be

14. *Compare* MICH. COMP. LAWS ANN. § 333.17751 (West 2020), *with* OHIO ADMIN. CODE 4729-5-21(A) (2015).

15. *See* MICH. COMP. LAWS ANN. § 333.17751.

16. OHIO ADMIN. CODE 4729-5-21(A) (2015).

17. MICH. COMP. LAWS ANN. § 333.17751(2)(c) (West 2020).

18. OHIO ADMIN. CODE 4729-5-21(A) (2015).

19. MICH. COMP. LAWS ANN. § 333.17751(2)(a) West 2020) .

20. MICH. COMP. LAWS ANN. § 333.17751(3) (West 2020).

21. *See generally* MICH. COMP. LAWS ANN. § 333.17751 (West 2020); OHIO ADMIN. CODE 4729-5-21(A) (2015).

22. *Compare* OHIO ADMIN. CODE 4729-5-21(A) (2015) ("a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a prescription, as well as the person issuing it, shall be subject to the penalties of law."), *with* MICH. COMP. LAWS ANN. § 333.17751(2) (West 2020).

23. MICH. COMP. LAWS ANN. § 333.17751(2)(b) (West 2020).

24. MICH. COMP. LAWS ANN. § 333.17751(2) (West 2020).

25. MICH. COMP. LAWS ANN. § 333.17751(2)(a) (West 2020).

26. MICH. COMP. LAWS ANN. § 333.17751(2)(c) (West 2020).

written in the usual course of bona fide treatment of a patient, and a pharmacist who fills a prescription with knowledge to the contrary, is liable (along with the prescriber) for damages.[27] This slight difference in level of awareness, required to show a failure on the part of the pharmacist, becomes an important consideration for the courts in whether or not to assign liability for resulting injuries.

Medical malpractice claims still require a showing of a "proximate causal connection between the … act or omission constituting the breach and the injury sustained . . . ."[28] Thus, the statutory schemes in Ohio and Michigan, whether imparting knowledge of filling an invalid prescription, or failure to use professional judgment in determining a prescription valid, are not unique. Even absent such statutory requirements, a claim for negligence necessarily includes some component of the actor's awareness of the risk of harm or the foreseeability of the risk of harm.[29] Therefore, it is no surprise that a pharmacist's clear knowledge of a customer-specific risk related to the prescribed medication opens up a vein to liability, and courts have taken advantage of the opportunity when available.[30]

Generally, however, state regulations assign only a minimal duty to pharmacists beyond simply ensuring that a prescription is facially valid – meaning that the prescription is written by a licensed physician and there are no "clear errors" with respect to the medication prescribed.[31] Some indicators of clear error have been identified as: (a) prescription appears to be improperly written; (b) prescription is ambiguous; (c) pharmacist has reason to believe the prescription could cause harm to the patient; or (d) pharmacist has reason to believe that the prescription will be used for non-legitimate purposes.[32] While a prescription's facial validity historically was the only question asked when assessing a pharmacist's culpability in dispensing a prescription, as illustrated in the examined authorities in Ohio and Michigan, the "legitimate medical purpose" of a prescription is the true threshold question for pharmacist liability; a prescription that is not issued for a legitimate medical purpose is not a prescription and a pharmacist who fills such a prescription is open to liability for resulting injuries.

With respect to controlled substances, federal and state law has been rapidly changing, and continues to change, in response to the opioid epidemic infecting a substantial portion of the U.S. population.[33] The United States Department of

27. OHIO ADMIN. CODE 4729-5-21(A) (2015).

28. Nail v. Publix Super Mkts., 72 So. 3d 608, 613 (Ala. 2011).

29. RESTATEMENT (SECOND) OF TORTS § 432-33 (AM. LAW INST. 1965).

30. Hand v. Krakowski, 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1982) (finding a duty where pharmacist failed to warn a customer of a drug's adverse interaction with alcohol where the pharmacist knew the customer to be an alcoholic); Klasch v. Walgreen Co., 264 P.3d 1155, 1157-58 (Nev. 2011) ("Following the modern trend of case law…the learned-intermediary doctrine does not foreclose a pharmacist's potential for liability when the pharmacist has knowledge of a customer-specific risk").

31. 25 AM. JUR. 2D *Drugs and Controlled Substances* § 256 (2002).

32. MICH. ADMIN. CODE r. 338.490 (2020).

33. Francis Collins, *The Federal Response to the Opioid Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE (Oct. 5, 2017), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-

Health and Human Services' (HHS) five-point Opioid Strategy to mitigate the opioid epidemic includes "strengthen[ing] public health data reporting and collection to improve timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves…"[34] Consequently, state regulations concerning the dispensing of controlled substances typically have far more rigid guidelines than those simply defining the general scope of a pharmacist's professional responsibility in dispensing medications.[35] It is within the language of these stricter regulations that proponents, who seek to broaden the pharmacy landscape to hold pharmacists, at a minimum, to the same standard of care as the prescribing physician, sow their seeds.

B. The Learned Intermediary Doctrine

The most mountainous obstacle in the path of those advocating for expansion of pharmacist liability is judicial hesitancy to break from tradition. Enter the learned intermediary doctrine ("LID"): a common law doctrine first coined by the Eighth Circuit in a 1966 decision where the court reasoned that "the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer."[36] As noted, the doctrine originally functioned as a shield for drug manufacturers from a duty to warn a patient of side effects, or foreseeable risks of a particular medication, using the theory that the physician was the "learned intermediary" between the manufacturer and the patient.[37] Provided that the manufacturer delivered adequate warnings to the physician, the manufacturer was then relieved from general liability to the patient.[38]

As the pharmacy profession became more integrated with patient healthcare, and pharmacists became defendants in negligence actions alongside prescribing physicians, the doctrine was extended by the courts to protect pharmacists from general liability.[39] The primary rationale used by the court in applying the doctrine

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congress/2017/federal-response-to-opioid-crisis; *See generally* Opioid Crisis Response Act of 2018, S. 2680, 115th Congress (2018).

34. *Id*.

35. *Compare* MICH. COMP. LAWS ANN. § 333.7333 (West 2020), *with* OHIO ADMIN. CODE 4729-5-20 (2017) (also applies to the general filling of prescriptions).

36. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

37. Roseann B. Termini, *The Pharmacist Duty to Warn Revisited: The Changing Role of Pharmacy in Health Care and the Resultant Impact on the Obligation of a Pharmacist to Warn*, 24 OHIO N.U. L. REV. 551, 552 (1998); James Barney, *Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists' Duty to Warn*, 39 GONZ. L. REV. 399, 404-05 (2003).

38. Barney, *supra* note 37; Larkin v. Pfizer, Inc., 153 S.W.3d 758, 765 (Ky. 2004).

39. *See e.g.* Adkins v. Mong, 425 N.W.2d 151, 152-54 (Mich. Ct. App. 1988) (holding that "there exists no legal duty on the part of a pharmacist to monitor and intervene with a customer's reliance on drugs prescribed by a licensed treating physician."); Kintigh v. Abbott Pharmacy, 503 N.W.2d 657, 658 (Mich. Ct. App. 1993) (rejecting theory that pharmacist owed a customer a legal duty to monitor drug usage, that there exists no duty on the pharmacist to discover a customer's addicted status, and the pharmacist, having no knowledge of such addiction, had no duty to refuse to sell the prescribed medication); Moore *ex rel* v. Mem'l Hosp. of Gulfport, 825 So. 2d 658 (Miss. 2002); Walls v. Alpharma USPD, Inc., 887 So. 2d 881 (Ala. 2004); Allberry v. Parkmor Drug, Inc.,

was the same: the physician or prescriber is the person in the best position to make decisions with respect to patient care and should be the most knowledgeable when it comes to prescribing a specific medication.[40] Thus, in theory, courts applying LID are suggesting that in the physician-pharmacist-patient relationship model, the physician is still the learned *intermediary* between the pharmacist and patient. This logic is problematic. From an aerial view, it simply seems disjointed to rectify the two applications: in the manufacturer-physician-patient relationship model, the physician is the person in the last and best position to protect the patient, so transversely it seems that in the physician-pharmacist-patient relationship model, the pharmacist would be in the last and best position to protect the patient. This concept has clearly complicated the courts and is one of the underlying public policy bases for moving away from application of the LID, in favor of imposing liability on pharmacists.[41]

The learned intermediary doctrine is "more than just a narrow rule of law regarding a manufacturer's or pharmacist's limited duty to warn."[42] It considers the "relationships between the parties involved in the distribution, prescribing, and use of prescription drugs"[43] when there is a breach of the duty to warn a patient of dangerous or contraindicated propensities of medication, because "[i]t is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy."[44] Even where a pharmacist informs a physician that, in the pharmacist's professional judgment, the prescription written by the physician contains the incorrect loading dosage of a medication and provides incomplete dosage information to the physician, the pharmacist will escape any liability to an injured patient under an LID theory.[45] The traditional application of LID – shielding drug manufacturers from a duty to warn patients of drug risks, has been officially adopted by only about half of the state supreme courts or legislatures in the United States, but the theory and underlying considerations of the doctrine have been applied by courts in 48 states, Puerto Rico, and the District of Columbia.[46]

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834 N.E.2d 199 (Ind. Ct. App. 2005); Carista v. Valuck, 2016 OK CIV APP 66, 394 P.3d 253; Urbaniak v. Am. Drug Stores, LLC., 126 N.E.3d 561 (Ill. App. 1 Dist. 2019).

40. Ingram v. Hook's Drugs Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985); *Allberry*, 834 N.E.2d at 199 (applying LID); *Walls*, 887 So.2d at 884-85 (finding that holding pharmacist liable would intrude upon the doctor-patient relationship and would force pharmacists to practice medicine without a license); *Moore*, 825 So. 2d at 664 (holding that a physician is in the best position to determine what is best for the patient and by extending such responsibility to the pharmacist, it places the pharmacist between the physician and the patient).

41. *See generally* Karina Fox, *A Weighty Issue: Will Pharmacists Survive the Fen-Phen Feeding Frenzy: Kohl v. American Home Prod. Corporation and a Pharmacist's Duty to Warn of the Dangers of Prescription Drugs*, 2001 BYU L. REV. 1349; Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 767 (1976).

42. Springhill Hosp. Inc. v. Larrimore, 5 So.3d 513, 518 (Ala. 2008).

43. *Id.*

44. W. KEETON, R. KEETON & D. OWEN, PROSSER AND KEETON ON TORTS § 96, 688 (5th ed. 1984).

45. *Springhill Hosp. Inc.*, 5 So.3d at 521.

46. Chris A. Johnson, Alicia J. Donahue, & Paula Sarti, *Inside the Learned Intermediary Doctrine*,AB.A.(July29,2013), https://www.americanbar.org/groups/litigation/committees/products-

Michigan is one such state that has adopted the LID and has also applied it to relieve pharmacists of liability,[47] as have jurisdictions including Alabama[48], Illinois[49], Indiana,[50] Massachusetts,[51] Mississippi[52], Oklahoma[53], and Texas.[54]

Some states, such as Ohio, have adopted LID with respect to drug manufacturers and prescribers,[55] and has also applied the theory outside of the medical realm to cases involving chemical suppliers[56] and manufacturers of welding products,[57] but has declined to apply the doctrine to pharmacist liability.[58] In fact, in *Thompson v. Knobeloch*,[59] the court proclaimed "Ohio has never adopted nor applied the learned intermediary doctrine[60]…This Court disagrees with the

liability/articles/2013/inside-learned-intermediary-doctrine/; *See also* Larkin v. Pfizer, Inc., 153 S.W.3d 758, 767 fn. 3 (Ky. 2004) (providing list of states who have adopted LID in the context of drug manufacturer-physician-patient relationship model).

47. Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387-88 (Mich. Ct. App. 1987); Adkins v. Mong, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988); Lemire v. Garrard Drugs, 291 N.W.2d 103, 105 (Mich. Ct. App. 1980).

48. Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 884-85 (Ala. 2004); *Springhill Hosp. Inc.*, 5 So.3d at 513.

49. Urbaniak v. Am. Drug Stores, LLC., 126 N.E.3d 570 (Ill. App. 1 Dist. 2019); Happel v. Wal-Mart Stores, Inc., , 766 N.E.2d 1118, 1129 (Ill. 2002) (assigning an exception to LID where a pharmacist has undertaken a duty to warn a patient such as collecting patient information and prescriptive history).

50. Allberry v. Parkmor Drug, Inc., 834 N.E.2d 199, 202-03 (Ind. Ct. App. 2005).

51. Cottam v. CVS Pharmacy, 764 N.E.2d 814, 819-21 (Mass. 2002).

52. Moore *ex rel* v. Mem'l Hosp. of Gulfport, 825 So. 2d 658, 664 (Miss. 2002).

53. Carista v. Valuck, 2016 OK CIV APP 66, ¶ 5, 394 P.3d 253, 256.

54. Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 173 (Tex. 2012); *See* DECHERT LLP, *The Closing of the Learned Intermediary Frontier*, JD SUPRA (June 2, 2011), https://www.jdsupra.com/legalnews/the-closing-of-the-learned-intermediary-97921/ (identifying additional jurisdictions where experts see a trend toward applying LID, or where experts predict that if the court were presented with a LID question, would apply LID in favor of the pharmacist).

55. OHIO REV. CODE ANN. § 2307.75(D) (West 2020) (An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect); OHIO REV. CODE ANN. § 2307.76(C) (West 2020) (An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it); *See also* Seley v. G.D. Searle & Co., 423 N.E.2d 831, 836-37 (Ohio 1981).

56. Doane v. Givaudan Flavors Corp., 184 Ohio App.3d 26, 2009-Ohio-4989, 919 N.E.2d 290, 297 (1st Dist.).

57. Boyd v. Lincoln Elec. Co., 179 Ohio App.3d 559, 2008-Ohio-6143, 902 N.E.2d 1023, 1035 (8th Dist.).

58. Thompson v. Knobeloch, 10th Dist. Franklin No. 14CVA05-4879, 2017 WL 90606, at *10.

59. *Id.*

60. The court is incorrect in stating that Ohio has never adopted LID. Ohio has in fact adopted LID (both legislatively and judicially) with respect to drug manufacturers and prescribers, but has declined to extend the doctrine to pharmacist liability. Likely, the Court intended to make this distinction but the chosen language makes it ambiguous. *See* Layne v. GAF Corp., 537 N.E.2d 252 (Ohio Com. Pl. 1988); Roberts v. George V. Hamilton, Inc., No. 99 JE 26, 2000 WL 875324 at *3 (Ohio Ct. App. June 30, 2000).

logic and policy espoused by the doctrine…"[61] The court justifies its declination to apply LID to pharmacist liability by theorizing that the "better public policy argument for imposing a duty to warn is the pharmacist's role as a 'safety net.' Pharmacists have an equal (if not greater knowledge) of the pharmacology and contraindications of drugs than many physicians."[62] The court goes on to firmly reject the underlying rationale of LID that, in the court's view, serves to relegate a pharmacist to nothing more than a "pill-counter."[63] While *Thompson* is not binding authority in Ohio, what it does provide is confirmation that Ohio declines to adopt or apply LID to protect pharmacists from liability, and sets out clear parameters for what Ohio courts are likely to consider when an issue arises concerning a pharmacist's failure to warn a patient: "[i]n this Court's opinion, the better public policy is to impose a duty on the pharmacist to call the physician and warn both the physician and the patient of the potential harm."[64]

Ohio is not alone in rejecting the LID. Some states that have adopted the doctrine with respect to drug manufacturers and prescribers, have refused to extend its protection to pharmacists, and this judicial rejection is spreading throughout state courts.[65] The primary underlying theory for such judicial resistance is based in large part on shifting public policy concerns, which seek to hold pharmacists at least as culpable as physicians when injuries are sustained as a result of a failure to warn patients concerning the risks and dangerous propensities of a dispensed medication. This Note explores various factors giving rise to this shift in public consciousness and will examine how judiciaries traditionally applying the LID to pharmacists are abandoning old rules in favor of diversifying liability.

II. THE *ALDRICH* CONCURRENCE

The central catalyst for purposes of this research comes from Justice Tukel's concurring opinion in *Aldrich v. Ohm Spec. Pharm.*[66] *Aldrich* is an important illustration from which we can observe an active, developing shift away from adherence to the LID, through public policy, legislative intent, and judicial response, toward a more modern approach for imposing pharmacist liability. The *Aldrich* court, while following established precedent in Michigan, by holding that a pharmacist has no general duty to refuse a facially-valid prescription,[67] presents an implicit warning to the pharmacy community that the once impermeable shield

61. *Thompson*, 2017 WL 90606 at *10 (the court is incorrect in stating that Ohio has never adopted LID. Ohio has in fact adopted LID with respect to drug manufacturers and prescribers, but has declined to apply the doctrine to pharmacist liability.); *Layne*, 42 Ohio Misc.2d 19, 537 N.E.2d 252; *Roberts*, 2000 WL 875324 at *3.

62. *Thompson*, 2017 WL 90606 at *11.

63. *Id.* at *11-14 (citing cases from Maryland, New York, Pennsylvania, and Texas that discuss a duty to warn or duty to inquire owed by the pharmacist).

64. *Id.* at *12.

65. Fox, *supra* note 41, at 1358-60.

66. Aldrich v. Ohm Spec. Pharm., LLC, 2018 WL 5276416, at *6-11 (Mich. Ct. App. 2018) (Tukel, J., concurring).

67. *Id.* at *7 (Tukel, J. concurring).

from negligence liability for failure to warn is dissolving.[68] In fact, the opinion in *Aldrich*, although ultimately finding in favor of the pharmacy, does not suggest that the Court maintains the traditional opinion that pharmacists are generally relieved of liability. Rather, because of the fact pattern in *Aldrich*, the Court had no other choice but to adhere to precedent,[69] thus granting much more insight into Justice Tukel's concurrence. Indeed, the *Aldrich* opinion should not be viewed as a simple adherence to precedent, but rather should be analyzed as an implicit warning of impending judicial movement toward imposing liability upon pharmacists for a failure of the duty to warn.[70]

The facts of *Aldrich* are of particular importance because of the various mitigating factors that likely impacted the Court's refusal to deviate from precedent. The suit arises from a 2013 motor vehicle accident in which the driver, Kevin Haynes ("Haynes"), drove his vehicle across the center line of traffic causing a collision with a vehicle driven by Plaintiff Aldrich.[71] Aldrich's two sisters were passengers in the vehicle, and both suffered fatal injuries.[72] Aldrich filed the negligence action[73] seeking judgment, in part against the defendant, Ohm Specialty Pharm., LLC d/b/a Downs Pharmacy ("Downs"), based upon three legal theories: (1) Downs filled a prescription for Fentanyl for Haynes in violation of administrative rules requiring that pharmacists decline to dispense medications if she has reason to believe that the medication is not for legitimate medical purposes;[74] (2) that Downs' negligent filling of Haynes' prescription created a special relationship between Downs and Aldrich;[75] and that (3) Haynes' abuse of the medication was foreseeable.[76] Aldrich argues that the presence of these factors created a duty on the part of Downs to refuse to fill Haynes' prescription, and because Downs breached that duty by dispensing the Fentanyl to Haynes, it caused the injuries to Plaintiffs.[77] The trial court agreed that, based upon the special pharmacist-patient relationship between Haynes and Downs, that there existed a "causal connection" between Downs' "conduct in dispensing Fentanyl to Haynes and plaintiffs' damages," and denied Downs' motion for summary judgment.[78]

The Michigan Court of Appeals reversed based on precedent in Michigan that generally rejects the imposition of a duty on a pharmacist beyond the filling of

68. *Id.* at *11 (Tukel, J. concurring).

69. Interestingly, Justice Tukel points out that the Michigan Court of Appeals is "obligated under the Michigan Court Rules to follow cases published since 1990…" The statutory authority for this requirement is provided for at MICH. COMP. LAWS ANN. § 7.215(J)(1) (West 2019).

70. I use "duty to warn" like a pill box and intend for it to encompass the narrower categories of pharmacist duties such as a duty to refuse to fill a prescription or a duty to report contraindications to the prescriber. While these are specific instances concerning a pharmacist's professional responsibility, or rather, breach of that responsibility, "duty to warn" is used herein generally.

71. *Aldrich*, 2018 WL 5276416 at *1.

72. *Id.*

73. The estate for Aldrich's sister, Judith Ann Kelly, is also a plaintiff to the suit.

74. *Aldrich*, 2018 WL 5276416 at *2.

75. *Id.*

76. Aldrich v. Ohm Spec. Pharm., LLC, 2018 WL 5276416, at *3-4 (Mich. Ct. App. 2018).

77. *Id.*

78. *Id.* at *5.

facially-valid prescriptions, or rather, based on its adoption of the LID.[79] While this holding is less than controversial on its face, as Justice Tukel provides in his concurrence, "the underlying principle on which those cases relied, that a pharmacist is not required to look beyond the facial validity of a prescription for a controlled substance is not correct, and was not correct at the time those cases were decided…"[80] He elaborates that both federal and state law require that pharmacists consider whether prescriptions [for controlled substances] are issued "in the usual course of professional practice…in good faith and for a legitimate medical purpose."[81] While Justice Tukel ultimately agrees with the holding in *Aldrich* relieving the pharmacy from liability for reasons which this research will explore, he pointedly calls out for revision of the current stasis:

> [O]ur Supreme Court or Legislature might wish to revisit this issue to bring current law more in line with recent developments…. As the pharmacy had a corresponding responsibility to that of the pharmacist, a very significant burden, if we were writing on a blank slate in considering a pharmacist's potential duty, we might well determine that our definition of duty would permit a jury to find that the pharmacy was liable.[82]

Justice Tukel provides three reasonings for his distaste of the current state of Michigan precedent used in pharmacist-liability cases: (1) under MCR 7.215(J)(1), the Court was not required to apply two of the three precedential cases upon which it relied for its holding;[83] (2) the precedential cases were in contravention with the law at the time they were decided and thus, the Court should no longer apply them to pharmacist-liability actions;[84] and (3) recent changes in Michigan law per 2017 PA 251 (effective March 27, 2018) and codified at MCL § 333.7333 tightened standards for dispensing of controlled substances and included a "good faith" element.[85] I will address each in turn.

A. MCR § 7.215(J)(1)

MCR § 7.215(J)(1) states, in pertinent part, that "[a] panel of the Court of Appeals must follow the rule of law established by a prior published decision of the Court of Appeals issued on or after November 1, 1990, that has not been reversed or modified by the Supreme Court, or by a special panel of the Court of Appeals."[86] Interestingly, while Justice Tukel criticizes the court for applying cases prior to November 1, 1990 as precedent in this case,[87] he specifically indicates that

79. *Id.* at *6.
80. *Id.* at *7-11 (Tukel, J., concurring).
81. *Id.* (Tukel, J., concurring).
82. *Id.* at *25. (Tukel, J., concurring).
83. *Id.* at *18 (Tukel, J., concurring).
84. *Id.* at *15-16. (Tukel, J., concurring).
85. *Id.* at *8-9.
86. MICH. CT. R. 7.215(J)(1).
87. *See* Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381 (Mich. Ct. App. 1987); *See also* Adkins v. Mong, 425 N.W.2d 151 (Mich. Ct. App. 1988); *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *15-16 (Tukel, J., concurring).

he is not "calling for a conflict panel."[88] This comment stems from MCR § 7.215(J)(2) which states, in pertinent part, that if the Court of Appeals "follows a prior published decision only because it is required to do so by subrule (1) [the court] must so indicate in the text of its opinion, citing this rule and explaining its disagreement with the prior decision."[89] Under the specific facts of the *Aldrich* case, Justice Tukel is not convinced, "without the benefit of full briefing on the parties' behalf" that he would diverge from the court's ultimate holding.[90] I would argue that the court's analysis of only three analogous,[91] precedential cases, two of which were decided prior to November of 1990, and the one remainder in 1993, coupled with its statement that "Michigan caselaw does not allow for the imposition of a duty under the circumstances presented,"[92] rides dangerously close to following prior published opinions only because it is statutorily required to do so under MCR § 7.215(J)(2).

Justice Tukel's concurrence has the effect of a conflicting opinion sufficient to warrant convening a special panel as provided for in MCR § 7.215(J)(3).[93] Regardless, such a panel was not requested, likely because of the attenuating circumstances of the Aldrich case: The action was filed by a third-party rather than by the patient who received the medication from the pharmacy. It is my theory that because of these attenuating circumstances, the court was reluctant to inject liability for injuries caused to *third-parties* in a jurisdiction that has historically refused to assign liability to a pharmacist for injuries to the *patient*.

B. Precedential Cases in Contravention with Law

The court primarily rests its analysis and holding in *Aldrich* upon its own decisions in *Stebbins v. Concord Wrigley Drugs, Inc.,*[94] *Adkins v. Mong,*[95] and *Kintigh v. Abbott Pharmacy.*[96] Justice Tukel argues that the holdings in *Stebbins* and *Adkins*, despite the fact that they could be excluded based upon MCR § 7.215(J)(1), were erroneous at the time they were decided and should not be applied in *Aldrich*.

1. Stebbins v. Concord Wrigley Drugs, Inc.

This case stems from a motor vehicle accident in which the driver, Joseph Zagone, ran a red light striking a vehicle driven by Plaintiff Bonnie Stebbins and causing serious injuries.[97] The Plaintiff filed suit against Zagone's treating

88. *Aldrich*, 2018 WL 5276416 at *11 (Tukel, J. concurring).
89. MCR. 7.215(J)(2).
90. *Aldrich*, 2018 WL 5276416 at *11 (Tukel, J. concurring).
91. Justice Tukel argues that the cases are not analogous – another component to his call for revising the current precedent.
92. *Aldrich*, 2018 WL 5276416 at *6.
93. MCR § 7.215(J)(3).
94. Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381 (Mich. Ct. App. 1987.
95. Adkins v. Mong, 425 N.W.2d 151 (Mich. Ct. App. 1988).
96. Kintigh v. Abbott Pharm., 503 N.W.2d 657 (Mich. Ct. App. 1993).
97. *Stebbins*, 416 N.W.2d at 383.

physician and Defendant Concord Wrigley Drugs ("Concord") for failing to warn Zagone to not drive while taking Tofranil, an anti-depressant (a non-controlled substance) prescribed by Zagone's physician and dispensed by Concord, that Plaintiff claims caused "'psychological as well as physical impairments' in Zagone's driving ability."[98] The trial court granted summary disposition in favor of Concord under the traditional theory that the "general rule in Michigan is that a pharmacist…may be held liable for negligently dispensing a drug other than that prescribed" and that "[a] pharmacist is generally not held liable for damages resulting from a correctly filled prescription."[99] The trial court found that "it is the physician who has the duty to know the drug that he is prescribing and to properly monitor the patient."[100] The *Stebbins* court went so far as to assign a duty upon the patient to "notify the physician of other drugs the patient is taking."[101] The Court of Appeals affirmed the trial court's position and added that "a pharmacist has no duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face and neither the physician nor the manufacturer has required that any warning be given to the patient by the pharmacist."[102] While the holding here is representative of the norm, Justice Tukel disagreed with the *Stebbins* holding because it "treated prescriptions for controlled substances and non-controlled substances interchangeably," and as a result, the court "overlooked state statutory and federal regulatory authority regarding controlled substances."[103] As *Aldrich* involved a prescription for a controlled substance – Fentanyl, Justice Tukel found the *Stebbins* decision unpersuasive and inapplicable to the facts in *Aldrich*.[104]

2. Adkins v. Mong

Controlled substances were at issue in the *Adkins* case. The Plaintiffs filed a negligence and malpractice action against several physicians and pharmacies, including defendant Motor City Prescription Centers ("Motor City"), for supplying plaintiff, Lincoln Adkins, Jr. ("Adkins") with excessive amounts of controlled substances totaling 116 prescriptions over a span of six years.[105] Plaintiff claimed that as a result of defendants' negligence, Adkins became addicted to several narcotic substances.[106] The trial court denied summary disposition to Motor City, and the Court of Appeals reversed and remanded for a grant of summary disposition in favor of Motor City.[107] The Court of Appeals relied primarily on its holding in *Stebbins* to find that "there exists no legal duty on the part of a

98. *Id.*
99. *Id.* at 387.
100. *Id.*
101. *Id.*
102. *Id.* at 387-88.
103. Aldrich v. Ohm Spec. Pharmacy., LLC, 2018 WL 5276416, at *8, *9 (Mich. Ct. App. 2018) (Tukel, J., concurring).
104. *Id.* at *18.
105. Adkins v. Mong, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988).
106. *Id.*
107. *Id.* at 151-52, 154.

pharmacist to monitor and intervene with a customer's reliance on drugs prescribed by a licensed treating physician."[108] The court's adherence to the same logic in reaching its decision in *Adkins* is unsurprising since the matter was presented to the court less than six months after the ruling in *Stebbins*.[109] In his concurrence, Justice Tukel criticized the court's use of *Adkins* primarily because it relied on, according to Tukel, the erroneous reasoning in *Stebbins*,[110] suggesting that both holdings have become outdated nesting dolls of legal precedent. Consequently, Justice Tukel found *Adkins* at a minimum inapplicable to *Aldrich* and at a maximum bad law.[111]

C. MCL § 333.7333

After reasoning away the applicability of *Adkins* and *Stebbins*, what remained was *Kintigh v. Abbott Pharmacy*.[112] This action is similar to *Adkins* in that Plaintiff David Kintigh brought a negligence suit against twelve pharmacies and twenty-two pharmacists for selling to him certain Schedule V, nonprescription controlled substances,[113] which Plaintiff alleged perpetuated his preexisting substance abuse problem.[114] However, *Kintigh* differed from *Adkins* in that it did not involve the physician-prescriber, thus not necessarily invoking the physician-pharmacist-patient relationship model. Nonetheless, in a 1-page opinion wherein the court relied entirely upon *Adkins*, it affirmed the trial court's grant of summary disposition against the collective defendants, holding that "[t]his Court has previously rejected the theory that a pharmacist owes a customer a legal duty to monitor drug usage . . . . [T]he pharmacists owed no duty to plaintiff to discover his addicted status.[115]

Justice Shelton's dissent in *Kintigh* contained a far more conscientious discussion of the substantive law than did the majority opinion. In his dissent, Justice Shelton considered the pharmacist's ultimate responsibility as a "gatekeeper" to protect the public from potentially harmful drugs such as the Schedule V substances sold to the plaintiff,[116] and he criticized the court's "cavalier reliance"[117] on the *Adkins* decision because it involved the pharmacist's relationship with the prescribing physician which is clearly not at issue in *Kintigh*. Ironically, contemporary public policy considerations placing the pharmacist in the position of the last "safety net" closely resemble Justice Shelton's arguments.

Justice Tukel disagreed with applying *Kintigh* to *Aldrich* not only because of its reliance on *Adkins* (which Justice Tukel finds inapplicable to *Aldrich*), but also

108. *Id.* at 154.
109. *Stebbins* was decided November 2, 1987 and *Adkins* was decided March 2, 1988.
110. *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *15-18 (Tukel, J. concurring).
111. *Id.* at *15, *18, *20.
112. Kintigh v. Abbott Pharmacy., 503 N.W.2d 657 (Mich. Ct. App. 1993).
113. Codeine-based cough syrup. *See id.* at 658.
114. *Kintigh*, 503 N.W.2d at 658.
115. *Id.*
116. *Id.* at 660 (Shelton, J. dissenting).
117. *Id.*

because the primary focus of *Kintigh's* instability relates to a 1974 federal regulation which provides that the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescription.*"[118] This language opened the door for imposition of physician criminal liability for breach of duty, and consequently, for the pharmacist who bears a corresponding responsibility to ensure the propriety of the prescription.[119] Because Michigan law expressly incorporated federal law in this regard in 1978,[120] Justice Tukel argued that the duty to monitor or warn with respect to controlled substances has, in fact, been required of a pharmacist since that time.[121] Effectually, this confirms that the *Adkins* court was incorrect when it held that "there exists no legal duty on the part of a pharmacist to monitor and intervene with a customer's reliance on drugs prescribed by a licensed treating physician."[122] Consequently, the holding in *Kintigh* is also incorrect.

Even if the incorporation of federal regulation did not persuade the Michigan Supreme Court or the Legislature to take a second look at the intersection of these cases, Justice Tukel notes that the Michigan Legislature recently tightened standards for dispensing controlled substances in the 2017 PA 251 Act, applying a "good faith" standard upon pharmacists in the dispensing of controlled substances.[123] The statute defines "good faith" as it applies to a pharmacist to mean "the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful."[124] The rule goes on to enumerate factors that should guide the pharmacist in making his "good faith" determination including: (a) lack of consistency in the doctor-patient relationship; (b) frequency of prescriptions for the same drug; (c) quantities beyond those normally prescribed for that drug; (d) unusual dosages; and (e) unusual geographic distances between the patient, pharmacist, and prescriber.[125]

Justice Tukel applied this "good faith" standard to the *Aldrich* case and questioned if, under this standard, it can be found that the physician did not act in good faith in prescribing and thus, liability could attach to the pharmacist under the "corresponding responsibility" duty.[126] And while Justice Tukel admitted that the federal and state statutes really allow for criminal liability, the court can and should utilize the legislature's rationale and purpose for imposing the

118. 36 Fed. Reg. 80, § 306.04 (April 24, 1971), codified thereafter and currently at 21 C.F.R. § 1306.04(a) (2018). Aldrich v. Ohm Spec Pharm., No. 338140 LEXIS 3364, at *19-20 (Mich. Ct. App. 2018) (Tukel, J. concurring) (emphasis added).

119. *Aldrich*, 2018 WL 5276416, at *?? (Mich. Ct. App. 2018) (Tukel, J. concurring).

120. MICH. COMP. LAWS ANN. § 333.17741(2) (West 2018).

121. *Aldrich*, 2018 WL 5276416, at *7 (Tukel, J. concurring).

122. *Id.*

123. MICH. COMP. LAWS ANN. § 333.7333(2) (West 2018). *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *21-22 (Tukel, J. concurring).

124. MICH. COMP. LAWS ANN. § 333.7333(1) (West 2018). *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *22-23 (Tukel, J. concurring).

125. MICH. COMP. LAWS ANN. § 333.7333(1) (West 2018). *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *21-23 (Tukel, J. concurring).

126. *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *24-25 (Tukel, J. concurring).

"corresponding responsibility" and "good faith" duties on pharmacists in its own considerations as to whether a pharmacist should be found liable for breaching those duties, whether in criminal or civil actions.[127]

The Michigan Court of Appeals, presented with its first opportunity in *Aldrich* to decide a pharmacist-liability case in light of the 2017 statutory amendment, seems to have recoiled at the last minute in an effort to avoid opening a precedential floodgate for pharmacist-centered negligence litigation. Certainly, there were factual circumstances present in this case that warranted an analysis considering the evolving legislative intent to assign a "good faith" duty upon the pharmacist, as well as a "corresponding duty" to the physician. I suggest that there are four reasons which might help explain why the *Aldrich* court decided the case based on precedent rather than the revised statutory scheme.

1. Physician Warning

In *Aldrich*, it is undisputed that Haynes's prescribing physician, Dr. Ononuju advised Haynes not to drive while taking the Fentanyl medication.[128] Under a traditional LID application, this is a responsibility of the physician, and if the warning was in fact given by the physician, it serves almost as a complete bar to pharmacist liability.[129] It is unsurprising that the *Aldrich* court would take advantage of the physician's warning to distance the pharmacist's responsibility. Indeed, the question of who holds the duty to warn only arises when there is an alleged failure of the duty. Whether it is the physician or the pharmacist who delivers the warning to the patient is of less concern than the actual receipt of the warning by the patient. Had the facts shown that the physician did not caution Haynes regarding the possible risks of ingesting the medication and operating a motor vehicle, the *Aldrich* court may have had opportunity to question whether the pharmacist acted in "good faith" and met her "corresponding duty" to the physician.

2. Patient Misuse

Haynes misused the medication by placing the Fentanyl patch in his mouth.[130] Even under traditional products-liability theory, a customer's misuse of a product, if not reasonably foreseeable, bars the manufacturer from liability.[131] It would be in direct contradiction with well-settled law to excuse the manufacturer when a customer misuses a product yet hold a pharmacist liable when a patient misuses a medication absent a pharmacist's failure to provide instructions for the proper administration of the medication. Haynes's had filled this prescription many times and was well-versed in the correct methods for use.[132] Certainly, a patient's misuse

127. *Id.* at *25-28.
128. Aldrich v. Ohm Spec. Pharmacy., LLC, 2018 WL 5276416, at *2 (Mich. Ct. App. 2018).
129. Allberry v. Parkmor Drug, 834 N.E.2d 199, 202 (Ind. Ct. App. 2005).
130. *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *3.
131. A CONCISE RESTATEMENT OF TORTS, 3D ED., § 17 cmt. h (2013).
132. *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *1-3.

of a properly prescribed and dispensed medication—where instructions for proper administration were either given or there is a showing that the patient was familiar enough with the medication to know the proper administration—would mitigate pharmacist negligence, if not completely bar liability because of pharmacist negligence.[133]

3. Prescriber Misfeasance

In 2012, prior to the date of the Haynes incident, Haynes's prescribing physician, Dr. Ononuju, was the subject of a disciplinary proceeding arising from an issue concerning Ononuju's practice of prescribing controlled substances for "reasons other than lawful diagnostic or therapeutic purposes."[134] As a result, Ononuju's authority to prescribe controlled substances was suspended from his medical license.[135] The record does not provide whether or not Ononuju was still under such restrictions at the time that he prescribed Fentanyl to Haynes or whether Downs knew of Ononuju's prior discipline.

This is an illustration of the complications that arise with broadening the duties of a pharmacist to act in "good faith" to ensure the propriety of a prescription. The *Aldrich* opinion does not discuss Ononuju's role in the litigation, but suppose Ononuju's prescription for Fentanyl was invalid because he did not possess requisite authority to prescribe such medication. Would the pharmacist's "good faith" effort include verifying that Ononuju in fact had the proper prescriptive authority for the medication that Downs is dispensing? Suppose Ononuju's prescription was not written for a legitimate medical purpose; how would the pharmacist ascertain whether a physician's purpose is legitimate? These questions do not have clear responses, and just as they frustrate the reader, they frustrated the court. Rather than delve into a deep analysis of *Aldrich* and explore a narrow instance where a pharmacist could be held liable due to a prescriber's misfeasance, the court simply applied its traditional LID considerations that placed the primary responsibility upon the physician, and so all liability of misfeasance by the physician remains with the physician.

4. Third Party Tort Liability

Courts do not typically enjoy imposing duties on persons for injuries caused to third parties as it complicates the chain of causation and thus must be considered carefully. A special relationship between the defendant and the third-party must first be established.[136] The relationship between a pharmacist and a customer is a direct one based upon contract and is independent of the relationship between

133. See David J. Marchitelli, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R.5th 393 Art. 2 (2020) ("[C]ourts … will not hold a pharmacist liable for injuries not sufficiently shown to have been proximately caused by a pharmacist's failure to follow the appropriate standard of care.")

134. *Aldrich*, 2018 Mich. Ct. App. LEXIS 3364, at *3 n.2.

135. *Id.* at n.2

136. Samson v. Saginaw Prof'l Bldg., 224 N.W.2d 843, 849 (Mich. 1975).

physician and patient; customers rely upon pharmacists for their expertise.[137] The court in *Hooks SuperX v. McLaughlin* promulgated this pharmacist-customer relationship, adding that the "relationship between pharmacist and customer is sufficiently close to justify imposing a duty."[138]

In *Aldrich*, the Court relied on various cases that refused to impose a duty on a defendant unless there existed a special relationship between the defendant and the plaintiff or the defendant and the third party.[139] Ultimately, the *Aldrich* court did not find a special relationship or resulting duty owed by the defendant to the third party, primarily because it historically has not found a special relationship between the patient and the pharmacist sufficient to impose a duty on the pharmacist. The *Aldrich* court refused to rule contrary to precedent likely because such a ruling would impose a duty upon a pharmacist to a third-party where it has not imposed the same duty owed to the patient.

Three implications—public policy, legislative, and judicial—are embedded within this global movement away from physician-centered liability and toward imposition of a share of culpability upon medical professionals who dispense medications. Each implication may be seen in *Aldrich*. First, the relationship between the pharmacist and the physician is no longer one of clear subordination, and consequently, the pharmacist's relationship with the patient no longer arbitrary. Second, the relationship between the pharmacist and the legislature is no longer intended to exculpate. Third, the relationship between the pharmacist and the court is no longer predictable.

III. STATE LEGISLATURES SHRINK THE GAP BETWEEN PHARMACIST AND PHYSICIAN INVOLVEMENT IN PATIENT CARE

The pharmacist's role in patient care has been in transition from mere dispenser of medication to quasi-physician. Traditionally, pharmacists were viewed as technicians – mere pill-counters whose responsibilities focused on the accuracy and efficiency in dispensing drugs.[140] A pharmacist was to remain "nonjudgmental" and interference with the physician-patient relationship was discouraged as pharmacists were not recognized by legislatures as healthcare professionals.[141] The modern approach to pharmacist liability – a move away from the learned intermediary doctrine – is firmly rooted in both legislative recognition of the pharmacist's increased role in patient healthcare[142] as well as the pharmacist's voluntary assumption of a duty to the patient by offering expanded

137. 25 AM. JUR. 2D *Drugs and Controlled Substances: Basis for Liability* § 247 (2002).

138. Hooks SuperX v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994).

139. Aldrich v. Ohm Spec. Pharmacy., LLC, 2018 WL 5276416, at *8 (Mich. Ct. App. 2018) (citing Graves v. Warner Bros., 656 N.W.2d 195 (Mich. Ct. App. 2002)).

140. Fleischer, *supra* note 1, at 168.

141. *Id.*

142. The Omnibus Budget Reconciliation Act of 1990 began the trend toward requiring pharmacists to perform duties beyond mere pill counting for Medicaid patients by imposing an obligation that pharmacists provide better information to patients concerning dispensed prescription medications, maintain a patient's prescriptive history, and offer to discuss medications.

services such as prescription drug screening for possible drug contraindications.[143] In fact, state codes often require that pharmacies implement drug utilization reviews ("DUR") in order to screen for possible warnings associated with the filling and dispensing of a prescribed medication and the patient's health profile.

> Ohio Administrative Code § 4729-5-20 provides as follows:
> (A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
> (1) Over-utilization or under-utilization;
> ….
> (3) Drug-disease state contraindications;
> (4) Drug-drug interactions;
> ….
> (7) Abuse/misuse…[144]

On its face, the DUR obligation assigned by state legislatures imposes additional potential negligence liability on pharmacists, as it provides another avenue for allegations of breach of the proscribed standard of care. In *Baker v. Arbor Drugs, Inc.*, the court found that the defendant voluntarily assumed a duty to the patient because Arbor had implemented a computer system known as "Arbortech Plus" to monitor patient medication profiles and adverse drug interactions.[145]

The learned intermediary doctrine is also nested under a DUR obligation. In *Happel v. Wal-Mart Stores*, an Illinois court found that the learned intermediary doctrine does not apply where a pharmacist has undertaken a duty to warn the patient, such as collecting patient information and prescriptive history.[146] This serves as a mitigating factor to applicability of the LID to pharmacist liability.[147] Thus, the more legislatures that mandate usage of DUR systems, the weaker the LID shield becomes.

In Michigan, the legislature expanded the duty of care by imposing a "good faith" standard on a pharmacist to fill lawful prescriptions for controlled substances pursuant to a licensed prescriber's order.[148] MCL § 333.7333(1) suggests that a pharmacist, in making the determination whether a prescription is lawful, should be guided by nationally accepted professional standards as well as the enumerated requirements provided for under the statute.[149] These considerations also individually serve to broaden the scope of pharmacist duty of care, including

143. Fleischer, *supra* note 1, at 169-70.

144. OHIO ADMIN. CODE § 4729-5-20(A) (2017).

145. Baker v. Arbor Drugs, Inc., 544 N.W.2d 727, 731 (Mich. Ct. App. 1996). *See also* Moore v. Covenant Care of Ohio 18 N.E.3d 1260 (Ohio Ct. App. 2014); Oakey v. May Maple Pharm., 2017-NMCA-054, ¶ 34-35, 2017 N.M. Ct. App. LEXIS 21, 399 P.3d 939 (2017) (New Mexico imposes additional responsibilities on pharmacists such as viewing patient profiles and identifying abuse or misuse of medications.).

146. Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1119 (Ill. 2002).

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

148. MICH. COMP. LAWS ANN. § 333.7333(1) (West 2018).

149. *Id.*

"[l]ack of consistency in the doctor-patient relationship," "[f]requency of prescriptions for the same drug by 1 prescriber," and "[u]nusual dosages."[150] Some of these factors require a fact-specific analysis that may be unrealistically outside the reach of the pharmacist's knowledge such as the nature of the doctor-patient relationship. While other factors, such as the frequency of prescriptions issued by a single prescriber, may be more easily assessed. Such questioning of a physician's medical judgment creates distrust between the pharmacist and the physician that healthcare professionals have argued is detrimental to the patient and the sanctity of the highly protected doctor-patient relationship.

IV. COURTS REMAIN PENSIVELY RELUCTANT TO APPLY STATUTORY DEVICES OR ASSIGN CIVIL LIABILITY TO PHARMACISTS WHO FILL FACIALLY VALID PRESCRIPTIONS.

In general, courts remain reluctant to impose liability on pharmacists absent a showing of knowledge of a customer-specific risk.[151] In *Klasch*, the court considered the learned intermediary doctrine under first impression. The court adopted the doctrine in general in the context of the pharmacist/customer relationship, holding that "pharmacists have no duty to warn of a prescribed medication's generalized risks."[152] However, the court ultimately declined to apply the doctrine, holding that "[f]ollowing the modern trend of case law, we conclude that the learned-intermediary doctrine does not foreclose a pharmacist's potential for liability when the pharmacist has knowledge of a customer-specific risk."[153] Even where a duty to the patient is imposed upon the pharmacist, whether or not the pharmacist had the requisite knowledge to expose himself to negligence liability, in the court's view, is a "classic question of fact" for a jury.[154]

In *Aldrich*, the court did not get to the question of whether a pharmacist's knowledge of a patient's drug addiction or misuse would open a pharmacist up to liability for resulting injuries; it did not believe that the pharmacist's knowledge that the patient was taking a prescription commonly prescribed to drug addicts supplied sufficient suspicion to the pharmacist that the patient was a drug addict, such that the pharmacist should have refused to fill the prescription.[155]

In *Oakey v. May Maple Pharmacy*, the New Mexico Legislature imposed additional responsibilities on pharmacists, such as viewing patient profiles and identifying abuse or misuse of medications.[156] In its analysis, the *Oakey* court implicated several standard LID factors when considering the pharmacist's

150. *Id.*
151. Klasch v. Walgreen Co., 264 P.3d 1155, 1157-58 (Nev. 2011).
152. *Id.*
153. *Id.*
154. *Id.* at 1161.
155. Aldrich v. Ohm Spec. Pharmacy, 2018 WL 5276416, at *13 (Mich. Ct. App. 2018).
156. Oakey v. May Maple Pharmacy, 2017-NMCA-054, ¶35, 2017 N.M. Ct. App. LEXIS 21-27, 399 P.3d 939 (2017).

"corresponding responsibility" to that of the physician.[157] However, rather than apply LID, the court applied the more accessible negligence *per se* standard.

In *Carista v. Valuck*, an Oklahoma court, in its first occasion to apply the learned intermediary doctrine opined that there are few exceptions that would open pharmacists up to liability, while at the same time acknowledging that the Oklahoma Administrative Code imposes a duty on a pharmacist to attempt to address addictions, misuse, and abuse, but only as it pertains to the prescription being dispensed, and only if the pharmacist has a reasonable suspicion of such addiction or misuse.[158]

Even more recently, the Illinois Appellate Court applied the LID in *Urbaniak v. Am. Drug Stores, LLC* to relieve a pharmacist from liability where it was shown that the pharmacist did deliver the prescription warnings to the patient.[159]

Although legislatures are imposing additional obligations on pharmacists to maintain and monitor patient profiles regarding prescriptive histories and assigning "good faith" standards of care that carry with them a "corresponding responsibility" to that of the physician, courts are hesitant to delve into those uncertain considerations.

V. THE UNCERTAINTY BETWEEN THE LEGISLATURE AND THE COURTS LEAVES PHARMACISTS IN A PRECARIOUS POSITION

In *Muscogee (Creek) Nation v. Purdue Pharma,*[160] the United States District Court, citing *Carista v. Valuck,* noted that the learned intermediary doctrine applies with the exception that a plaintiff may prevail against a pharmacist by showing a prescription was "unreasonable on its face" or that the pharmacist knew a prescription was invalid.[161] The *Carista* court provided that the LID breaks the chain of causation in negligence theory as applied to pharmacists and insists that the prescribing physician is responsible to warn of prescription risks.[162] The *Muscogee* opinion found *Carista* controlling and reinforced the rule that "[w]hen a court concludes that the learned intermediary doctrine applies, *then* liability is cut off *unless* the pharmacy fills prescriptions that are facially unreasonable."[163] Thus, the LID is not an automatic shield from pharmacist liability, but absent a clear showing that a prescription was facially invalid, a pharmacist should be protected from liability. However, in *Muscogee,* the District Court refused to apply the LID to shield the pharmacy, stating that a pharmacist's knowledge of the illegitimacy of a prescription is still an issue of fact to be determined by a jury as it speaks to the nature of the validity of the prescription, despite such validity not being evident on its face.[164]

157. *Id.*
158. Carista v. Valuck, 394 P.3d 253 (Okla. Civ. App. 2016).
159. Urbaniak v. Am. Drug Stores, 126 N.E.3d 561, 570 (Ill. App. Ct. 2019).
160. *In re: National Prescription Opiate Litigation*, 2019 WL 3737023, at *4 (N.D. Ohio 2019).
161. *Id.* at *4 (citing *Carista*, 394 P.3d 253).
162. *Id.* at *4-5 (citing *Carista,* 394 P.3d 253).
163. *Id.* at *5 (citing *Carista*, 394 P.3d 253) (emphasis in original).
164. *Id.* at *7.

This case illustrates the uncertainty between the legislatively provided considerations for pharmacist negligence liability and the court's interpretation of those obligations. Despite the *Muscogee* court adopting the LID and its exception, it ultimately ruled that while the prescription may not be facially invalid, the court should still take a subjective look at the pharmacist's knowledge of any impropriety with the prescription, suggesting that even an LID application to relieve a pharmacist of liability should include an assessment of the pharmacist's knowledge beyond that of a facially valid prescription.

The healthcare industry, and more specifically the pharmaceutical community, is constantly changing in response to the needs of society. The prescribing and the availability of prescription medications, specifically controlled substances, unceasingly continue to grow.[165] The pharmacy industry, while not a new cultural subset, has certainly made its presence known in every home. While legislatures make a good faith effort to navigate the changing professional standards of the pharmacy industry in order to bring the law into compatibility with a pharmacist's expanded role in patient healthcare, it has instead imposed obligations on that role that are neither traditional nor easily considered in a courtroom. In Michigan, the imposition of a "good faith" standard and a "corresponding responsibility" to the physician's obligations to the patient has opened the door for the possibility of assigning negligence liability to pharmacists. But practically, it has provided little, if any, guidance as is illustrated through the court's reluctance to adhere to legislative considerations.

The conditions in front of the court are not easily cured. Certainly, courts will face a multitude of considerations as the law continues to navigate expanding pharmacist involvement in patient care. Suppose a pharmacist is presented with a facially valid prescription, but the pharmacist has personal knowledge concerning the patient's propensity to overuse painkillers. The court must assess whether or not the pharmacist is required to refuse to dispense the medication, or whether it is simply an authority the pharmacist can exercise if he chooses. If the pharmacist refuses to dispense the medication and a patient suffers injury, the court must decide whether the pharmacist's refusal crosses professional boundaries and places the pharmacist in the position of healthcare professional acting without the requisite license to make such decisions. Suppose the pharmacist instead uses his "professional judgment" and proceeds to dispense the medication and the patient is injured. In these instances, is the pharmacist liable for malpractice, negligence, or both? Judges will need to consider whether the pharmacist has adequate information, qualifications, and training to make skilled, independent decisions concerning patient care. Courts will need to interpret what legislatures mean with respect to the pharmacist's "good faith" duty, and what authority this duty grants to the pharmacist.

Beyond the uncertainty in the application of legislatively-imposed obligations, the heightened responsibilities assigned to filling prescriptions also creates public policy and efficiency concerns; requiring pharmacists to contact prescribing physicians regarding prescriptions leads to longer wait times at the

165. Gail K. Strickler et al., *Opioid Prescribing Behaviors — Prescription Behavior Surveillance System, 11 States, 2010–2016*, 69(1) MMWR SURVEILLANCE SUMMARIES 1 (2020).

pharmacy counter, and allowing pharmacists to make decisions with respect to a patient's medical care jeopardizes the sacrosanct relationship between physician and patient which could potentially open pharmacists up to additional malpractice liability.

VI. CONCLUSION

The disconnect between the view from the legislative seat and the view from the bench has led to a blurry illustration of the expectations of pharmacists in filling prescriptions. Where pharmacists could once rest comfortably under the blanket of the learned intermediary doctrine protection, provided that she filled and dispensed a facially valid prescription, the current trend in both legislative intent and judicial considerations displays a clear warning to the pharmacy community while lacking clear proactive methods to reduce impending negligence liability. While legislatures should be more diligent to provide express parameters for a pharmacist's "good faith" duty and should fully define what it means by a pharmacist's "corresponding responsibility" to that of the physician, judicial hesitancy to interpret the statutory obligations and considerations imposed upon pharmacists creates a dangerous uncertainty in tort law. Pharmacists are left with legislative prescriptions that courts have been historically derelict to interpret yet could be enforced at any time.