No. 97112-9

COURT OF APPEALS NO. 77695-9-I

IN THE SUPREME COURT FOR THE STATE OF WASHINGTON

ETHEL FAY LONG and MELVIN LEROY LONG, husband and wife,

Appellants,

v.

RITE AID CORP.

Respondent.

PETITION FOR REVIEW

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A. INDENTITY OF PETITIONERS, CITATION TO A APPELLATE DECISION AND INTRODUCTION

Petititioners, Ethel and Melvin Long ("Petitioners") ask this court to accept review of the Court of Appeals' unpublished opinion in **Ethel Fay Long, et al, Appellants v. Rite Aid Corp, et al., Respondents,** No. 77695-9-I (March 25, 2019). This appeal addresses important issues, including whether *McKee v. American Home Products, Corp.*, 113 Wn.2d 706, 782 P.2d 1045 (1989) or the learned intermediary doctrine preclude Petitioners' medical malpractice claim against Respondent pursuant to RCW 7.70 for failing to warn a patient of the most common and severe side-effects of the antibiotic clindamycin, when the plaintiff has provided expert testimony establishing the standard of care was breached and the breach proximately caused the plaintiff injury.

Specifically, the decision erroneously applies *McKee* to preclude the Petitioners from pursuing a case they have a statutory right to pursue. Furthermore, if the decision applied *McKee* properly, then *McKee* violates the separation of powers doctrine by invading the legislature's province of regulating actions against healthcare providers. Moreover, allowing the Washington State Supreme Court to determine the level of duty owed by pharmacists under the standard of care contrary to RCW 7.70 is bad from a public policy standpoint.

B. ISSUES PRESENTED FOR REVIEW

1. Did the trial court err in denying the Petitioners' motion for reconsideration of the court's order in favor of Rite Aid's motion for summary judgement where the Petitioners brought a medical negligence claim against Respondent and timely disclosed qualified expert medical testimony to establish Respondent breached the standard of care and that the breach proximately caused injury?

C. FACTS RELEVANT TO PETITION FOR REVIEW

1. Testimony of Ethel Long and Melvin Long.

On December 31, 2012, Melvin Long took his wife Ethel Long to the Swedish Medical Center Emergency Department in Issaquah, WA. CP at 112, 139. She had been experiencing tooth and jaw pain. CP at 111. Mrs. Long was treated by David Karch, MD in the emergency room. CP at 112. Dr. Karch told Mrs. Long he was going to give her something to help with her tooth and left the room. *Id.*

Wendy Peterson, RN, provided Mrs. Long with a clindamycin prescription authored by Dr. Karch. *Id.* Discharge instructions were provided for vertigo and a tooth abscess. CP at 112, 166-167. No written warnings or instructions for clindamycin were provided. CP at 112.

After receiving the clindamycin prescription, Mr. Long drove Mrs. Long to the Rite Aid in Renton, WA where they usually went to fill their

prescriptions. CP at 150. Rite Aid filled the prescription and provided the pill bottle with clindamycin to Mr. Long inside a small bag. CP at 152. No counseling regarding the drug was offered and neither of the Longs' received any written material regarding the drug. CP at 120-22, 152. The prescription ran ten days and Mrs. Long took her medication as directed. CP at 36-37, 39, 122. No warning labels were attached to the prescription drug bottle. CP at 271.

On January 2, 2013, Mrs. Long saw her dentist Dr. Alecia Nowak and Dr. Nowak extracted the infected tooth. CP at 131. On January 16, 2013, Mr. Long learned that his brother in Atlanta, GA had passed. CP at 112, 142. The Long's flew to Atlanta on January 16, 2013 for the funeral. CP at 123. On January 19th, Mrs. Long developed diarrhea. *Id.* The diarrhea worsened, and Mrs. Long took some doses of Imodium AD, an over-the-counter anti-diarrheal medication. CP at 124. As the week progressed, she became ill. *Id.* Mrs. Long spent all of January 30th asleep in the bedroom. CP 125. On January 31st, Mr. Long told Mrs. Long she needed to see a doctor. *Id.* They visited a walk-in CVS clinic and Mrs. Long was told she needed to get to a hospital. CP at 114. An ambulance was called. *Id.* The last thing Mrs. Long remembered was starting an IV in the ambulance. CP at 114. She awoke from a coma one week later at Emory University Hospital. *Id.*

Upon her admission at Emory, Mrs. Long's large colon was removed, and an ileostomy performed. CP 170-177. Mrs. Long's small intestine was attached to her abdomen and a small hole was created so Mrs. Long could connect a colostomy bag to her stomach. *Id.* Mrs. Long now passes her fecal waste into the bag and will continue to do so the rest of her life unless the ileostomy is reversed. CP 115-116.

2. Testimony of Rite Aid Employees.

According to Rite Aid's regional manager, Ekaterni Kanevski and the pharmacist involved in preparing the clindamycin, Sumin Li, a pharmacist is supposed to counsel the patient regarding prescription medicine dispensed to them. CP at 217-219, 239. Ms. Kanevski, a licensed pharmacist herself, testified that as a Rite Aid pharmacist she provided counseling on diarrhea for clindamycin as the law requires the pharmacist "to provide the information on the most common and the most severe side effects." CP at 219. Also, when a drug is dispensed, Rite-Aid's policy is to print out the applicable information for the drug and provide it to the patient in addition to counseling. CP at 209. Auxiliary warning labels are also produced during the process and should be affixed to the prescription pill bottle. CP at 209, 216, 245. No warning labels were affixed to the prescription bottle in this case that would have warned Mrs. Long about what to do and what to avoid if persistent diarrhea

developed. CP at 271. Rite Aid had available information relating to clindamycin that could have been provided to Mrs. Long or her husband[1]. CP at 197-200. The information explicitly indicated that clindamycin could cause CDAD weeks or months after the treatment stopped and that if the patient developed persistent diarrhea at any point after taking the drug, they needed to contact their doctor immediately. *Id.* The warning also indicated that anti-diarrheal products should not be used. CP at 197-198.

3. Standard Of Care And Causation Expert Testimony.

Jeffery Tichenor, Pharm. D., is a pharmacist licensed to practice in Washington. CP at 268, ¶ 1. Mr. Tichenor testified that clindamycin carries a black box warning. CP 269 at ¶11. A black box warning is the strictest warning that the Food and Drug Administration can assign to a prescription drug. *Id.* If there is a black box warning for a drug, the pharmacist must be aware of it. *Id.* The warning is designed to call attention to a serious side effect of the drug. *Id.* While the pharmacist need not mention to the patient a black box warning exists for a drug if it is not applicable to that patient, the pharmacist must counsel the patient on the most common side effects and provide written warnings of the same.

[1] While Rite Aid indicated the information would have been given, the Long's testified they did not receive any written or oral warnings and there is no evidence to demonstrate they did in fact receive any written or oral warnings.

Id. The standard of care for a pharmacist in Washington is that when a patient receives a medication, that patient or his or her agent must receive counseling for the drug by the pharmacist. *Id.* at ¶9. This is designated by WAC 246-869-220 and applies to all pharmacists in Washington. *Id.* In a pharmacy setting, the pharmacist, when dispensing a drug, must attempt to counsel the patient or his or her agent based on the facts and circumstances of the individual situation. *Id.* at ¶10. When a drug that is new to the patient has been prescribed, the counseling at a minimum must include the most significant side effects of the drug. *Id.*

In the case of clindamycin, diarrhea is the most common side-effect. *Id.* at ¶12. Diarrhea that develops in a patient after they take clindamycin can be a sign of CDAD. *Id.* This is an intestinal condition that can be fatal. *Id.*

Mrs. Long had never taken clindamycin before so the drug was new to her. CP at 270, ¶13. Mr. Tichenor testified that the standard of care required that she or the person picking up the prescription on her behalf, in this case Mr. Long, be counseled on diarrhea and what to do if she developed it. *Id.* The standard of care required the pharmacist to counsel Mr. Long, that if persistent diarrhea occurred during or even after the clindamycin treatment, Mrs. Long needed to tell a doctor immediately and avoid taking anti-diarrheal medication. *Id.* While basic, this

counseling is intended to educate the patient on the drug and to make sure they know about the most common side effect of the drug, diarrhea, and what to do if diarrhea develops. *Id.* at ¶14. This basic information can be the difference between life and death and exists to educate the patient. *Id.* For example, had Mrs. Long been given the counseling and followed it, she would have been treated much sooner. *Id.*

Mr. Tichenor also testified that the standard of care in Washington requires a pharmacist dispensing clindamycin to provide the warnings regarding diarrhea in writing, and to attach auxiliary warning labels to the bottle that address diarrhea. *Id.* at 270, ¶'s 13-16. He opined that Rite Aid deviated from the standard of care for not: (1) providing a copy of the monogrammed receipt that includes the warnings for the drug clindamycin; (2) not counseling Mr. Long on the diarrhea and what to do if it developed; and (3) not labeling the pill bottle with the auxiliary warnings it had available. *Id.*

William Ehni, MD is board certified in Internal Medicine and Infectious Disease and is licensed to practice medicine in the State of Washington. CP at 258, ¶3. Dr. Ehni opined that Mrs. Long developed CDAD from the clindamycin that was prescribed to her. *Id.* Furthermore, he opined that Mrs. Long lost her colon due to the CDAD induced from clindamycin. *Id.* at ¶'s 14-17. Finally, he opined that if Mrs. Long had

contacted a doctor sooner after developing diarrhea, her CDAD could have been treated and her colon saved. *Id.*

The Long's theory of the case was that had Rite Aid followed the standard of care and provided written warnings and oral counseling for the drug clindamycin, Mrs. Long would have known to call a doctor in Atlanta when she developed diarrhea and to avoid taking anti-diarrheal products such as Imodium AD. Had she called sooner and received treatment, her CDAD could have been treated and her colon would have been saved.

4. Rite Aid's Motion for Summary Judgment and the Court's Ruling.

Rite Aid moved for summary judgment relying on the cases *McKee v. American Home Products, Corp.* ("*McKee*") and *Silves v. King* ("*Silves*"). CP 14-23. The trial court focused its analysis on the issue of "whether WAC 246-869-220 *sub silentio* overruled the holding" of *McKee* and *Silves*. RP 44:19-25. The court found the term counseling identified in WAC 246-869-220 ambiguous and orally ruled it was unclear whether the WAC was intended to overrule the holdings of *McKee* and *Silves*. RP 45:11-19. The court stated the plaintiff's expert did not create a question of fact because no duty to warn existed. RP 46:3-7. The court granted Rite Aid's motion. CP 644-646.

D. REASONS THIS COURT SHOULD ACCEPT REVIEW

1. This Court should accept review because the holding of *McKee v. American Home Products, Corp.* and its application conflicts with RCW 7.70 and violates the separation of powers doctrine.

In this case, the question is whether *McKee* or the learned intermediary doctrine preclude a medical malpractice claim from being brought against a pharmacist pursuant to RCW 7.70 for failing to warn, when the plaintiff provided expert testimony establishing the standard of care was breached and the breach proximately caused the plaintiff injury. While the *McKee* court held no judicially imposed duty to warn exists as a matter of law for a pharmacist dispensing prescription drugs, *McKee* is distinguishable because the plaintiff did not have an expert to support her medical negligence claim. Moreover, *McKee* did not implicitly or explicitly interpret, modify, or limit any claimant's rights under RCW 7.70.040, nor did it address the Washington Administrative Code ("WAC") provisions that are currently applicable to pharmacists and counseling. Thus, *McKee's* holding is limited to circumstances where the plaintiff is without the requisite expert support necessary to the meet the evidentiary burden of RCW 7.70.040. In the alternative, if *McKee* does preclude a duty to warn, the decision violates the separation of powers doctrine by preventing the Petitioners from pursuing their claim.

Washington's medical negligence statute is codified in chapter 7.70 RCW. The Legislature began with a declaration of intent that chapter 7.70 RCW would govern **all** actions for damages resulting from health care:

> The state of Washington, exercising its police and sovereign power, hereby modifies as set forth in this chapter and in RCW 4.16.350, as now or hereafter amended, certain substantive and procedural aspects of ***all civil actions and causes of action***, whether based on tort, contract, or otherwise, for damages for injury occurring as a result of health care which is provided after June 25, 1976.

RCW 7.70.010 (emphasis added). Whenever an injury occurs as a result of health care, the action for damages for that injury is governed exclusively by RCW 7.70. *Fast v. Kennewick Public Hospital District*, 187 Wash.2d 27, 34, 384 P.3d 232, 236 (2016). The specific question of whether the injury is actionable is governed by RCW 7.70.030. *Branom v. State*, 94 Wn. App. 964, 969, 974 P.2d 335, 338 (1999).

RCW 7.70.030 states in pertinent part:

> No award shall be made in any action or arbitration for damages for injury occurring as the result of health care which is provided after June 25, 1976, unless the plaintiff establishes one or more of the following propositions:
>
> (1) That injury resulted from the failure of a health care provider to follow the accepted standard of care...

To bring an action for injuries alleged to have been caused by a healthcare provider, the plaintiff must prove by a preponderance of the

evidence that the defendant or defendants failed to exercise that degree of skill, care, and learning possessed at that time by other persons in the same profession, and that as a proximate result of such failure the plaintiff suffered damages. *RCW 4.24.290*; *RCW 7.70.040*; *Bauer v. White*, 95 Wn. App. 663, 666–67, 976 P.2d 664, 666 (1999). In medical negligence cases, the issue of negligence will be taken from the jury only when no substantial evidence supports a claim that the defendant was negligent. *Keogan v. Holy Family Hospital*, 95 Wn.2d 306, 324, 622 P.2d 1246, 1258 (1980).

Pharmacists are defined as health care providers under RCW 7.70.020. *McKee*, 113 Wn.2d at 706. The applicable standard of care and proximate causation in a medical malpractice case generally must be established by expert testimony. *Grove v. Peace Health St. Joseph Hosp*, 182 Wn.2d 136, 144, 341 P.3d 261, 264 (2014). In turn, the trial judge must make a preliminary finding of fact under ER 104(a) as to whether an expert is qualified to express an opinion on the standard of care in Washington. *Winkler v. Giddings,* 146 Wn. App. 387, 392, 190 P.3d 117, 120 (2008). The policy behind the rule requiring expert testimony on standard of care, in medical malpractice actions, is to prevent laymen from speculating as to what is the standard of reasonable care in a highly

technical profession. *Housel v. James,* 141 Wn.App. 748, 759, 172 P.3d 712, 719 (2007).

Here, there is no dispute that the Petitioners met their burden under RCW 7.70.040 in presenting expert testimony to establish that Respondent deviated from the standard of care and that said deviation proximately caused Mrs. Long to lose her colon. Regardless, the Court of Appeals erroneously found *McKee* to hold that as a matter of law, pharmacists never have a duty under any circumstance, to warn patients about side effects regarding the drugs they dispense. (App. A at 7).

In *McKee v. American Home Products, Corp.*, 113 Wn.2d at 703, McKee received prescriptions for the appetite suppressant Plegine, a potentially addictive drug, to control a weight problem. Almost all her prescriptions for Plegene were filled at the same pharmacy over the course of 10 years by two different pharmacists. *Id.* at 703-704. The manufacturer's information warned the drug was for use as a "short-term adjunct" for exogenous obesity and that it had the potential for abuse. *Id.* at 703. Before giving McKee her Plegine, the pharmacists would remove the manufacturer's package insert from the bottle. *Id.* at 704. At no time did the pharmacists provide McKee with the possible side effects of extended use of the drug or give her the manufacturer's insert. *Id.* McKee sued alleging she developed injures from her addiction to Plegene as a

result of the pharmacists' joint failure to warn her of the possible side effects of long-term Plegene use. *Id.*

The pharmacists moved for summary judgement, alleging McKee could not meet her burden under RCW 7.70.040. *Id.* at 704-705. The only evidence provided by the McKee concerning the standard of care of a pharmacist practicing in Washington was an affidavit of an Arizona physician. *Id.* at 706. The physician did not reference the standard of care of a pharmacist in this state. *Id.* at 707. The trial court granted summary judgment on these grounds. *Id.*

The Washington Supreme Court affirmed the holding on direct review ruling that the affidavit did not meet the requirements of RCW 7.70.040 because it did not assert the standard of care for a pharmacist in Washington State. *Id.* at 705. With the issue decided, and while acknowledging it "need go no further," the court then went on to "discuss the merits of the primary issue because of the importance of the issue and the public interest therein." *Id.* at 707. Implicit in this acknowledgement is that if the requirements of RCW 7.70.040 had been met, no further discussion would be needed.

This "discussion" included the court's review of the laws in Florida and Michigan regarding the duty of a pharmacist to warn, and a review of the "closely-related" learned intermediary doctrine. *Id.* at 708-

709. The Court, in a 5-4 "narrow" decision held that a "pharmacist does not have a duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug, either orally or by way of the manufacturer's package insert." *Id.* at 720.

The *McKee* court refused to create a duty as a matter of law and used the learned intermediary doctrine as the rationale for not creating the duty. The Court of Appeals found that Respondent had no duty to warn pursuant to *McKee*. (App. A at p.9) Thus, the only way for this court to deny this petition is to accept that the Washington State Supreme Court can determine the standard of care duty owed by a medical professional, regardless of whether it's determination conflicts with the evidentiary standards set forth under RCW 7.70.40 for determining the same. This is an untenable position. While the Court can determine whether to impose a duty as matter of law, it cannot regulate medicine by intervening to deny valid medical malpractice claims brought under RCW 7.70. The Court of Appeals failed make this distinction, let account for it. Regardless, even if the decision was applied correctly, the decision itself must be reversed as it violates the separation of powers doctrine.

Furthermore, the *McKee* decision does not address WAC 246-869-220 which was promulgated after *McKee* was decided. WAC 246-869-220

specifically addresses patient counseling. WAC 246-869-220 states in pertinent part:

> Patient Counseling required....
>
> ...(3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.

WAC 246-869-220 is the product of the Legislature's delegation of the regulation of pharmacy. While "counseling" is not defined, the Petitioners' pharmacy expert testified that pursuant to WAC 246-869-220, Respondent needed to provide Mrs. Long written warnings for the clindamycin it dispensed and to counsel her on the most common and severe side effect, diarrhea. Respondent's regional manager, a licensed pharmacist herself, testified that as a Rite Aid pharmacist, she provided counseling on diarrhea for clindamycin as the law requires the pharmacist "to provide the information on the most common and the most severe side effects." CP at 219.

As contemplated by *McKee*, the governing body responsible for pharmacists has spoken on the issue of counseling by implementing the counseling WAC. *McKee* directly violates the rule promulgated by limiting the type of counseling the WAC was designed to provide.

The Washington State Constitution does not contain a formal separation of powers clause, but "the very division of our government into different branches has been presumed throughout our state's history to give rise to a vital separation of powers doctrine." *Brown v. Owen,* 165 Wash.2d 706, 718, 206 P.3d 310 (2009) (quoting *Carrick v. Locke,* 125 Wash.2d 129, 135, 882 P.2d 173 (1994). The doctrine of separation of powers divides power into three co-equal branches of government: executive, legislative, and judicial. *City of Fircrest v. Jensen,* 158 Wash.2d 384, 393–94, 143 P.3d 776 (2006), *cert. denied,* 549 U.S. 1254, 127 S.Ct. 1382, 167 L.Ed.2d 162 (2007). The doctrine "does not depend on the branches of government being hermetically sealed off from one another," but ensures "that the fundamental functions of each branch remain inviolate." *Hale v. Wellpinit Sch. Dist. No. 49,* 165 Wash.2d 494, 504, 198 P.3d 1021 (2009) (quoting *Carrick,* 125 Wash.2d at 135, 882 P.2d 173). If "the activity of one branch threatens the independence or integrity or invades the prerogatives of another," it violates the separation of powers. *Putman v. Wenatchee Valley Medical Center*, P.S., 216 P.3d 374, 377, 166 Wash.2d 974, 980 (2009). The judiciary should not invade the province of the legislative branch of government. *State v. Conifer Enterprises, Inc.*, 82 Wash.2d 94, 508 P.2d 149 (1973). The Legislature enjoys the power to

define and change tort law in our state. *Morgan v. Johnson*, 137 Wash.2d 887, 896, 976 P.2d 619, 624, (1999).

If *McKee* truly mandates that Petitioners cannot bring a medical negligence statute despite meeting all the statutory requirements of RCW 7.70, then the Washington State Supreme Court has violated the separation of powers doctrine by intruding upon the legislature's authority to regulate medical negligence claims. While the Court may have the authority to decide as a matter of law that certain duties exist, it does not have the authority to remove duties that are established under the mechanisms of the medical negligence statute. This is an irreconcilable conflict that violates the Washington State Constitution. Consequently, *McKee* must be reversed.

2. This Court should accept review because even if *McKee v. American Home Products, Corp.* explicitly limits the duty of a pharmacist to warn of potentially adverse side-effects, the decision impacts a substantial public interest.

McKee is a terribly flawed opinion because the scope of the holding is vague and uncertain. While the *McKee* Court ruled that the affidavit was not sufficient to establish that the standard of care had been breached, and thus decided the only issue before it, it continued on *sua sponte*, without briefing from the parties, to decide whether a duty to warn existed as a matter of law. In other words, the Court went on to address an

issue that had not been raised or briefed by either of the litigants. The end result is a confusing opinion.

For example, as pointed out in the dissenting opinion, it is impossible to tell whether the majority was trying to answer either of the following questions: (1) Is there a duty distinct from the duty of care which the pharmacists owed McKee; or (2) Was the pharmacists failure to warn McKee so extreme that it breached their duty of care as a matter of law? *McKee,* 113 Wn.2d at 725.

No scenario is imaginable where this Court would deprive a plaintiff the right to bring a medical negligence claim if the plaintiff had met all the elements of the statute. It does not stand to reason why *McKee* would create an exception to RCW 7.70.

Furthermore, the practice of medicine has changed over the last thirty years. It makes perfect senses that what constitutes medical negligence in legal terms should be decided by medical professionals who are trained, educated, and informed on the latest developments in medicine. The standard of care for any type of medical procedure or field inevitably will change as technologies improve. The same is true of the standard of care for pharmacists.

Pharmacists have computers at their disposal. They can print warning labels and access information regarding adverse side-effects of

drugs that are dispensed to patients. Pharmacists are highly trained medical professionals that counsel patients and are typically the last person to see the patient before they take their medications. The pharmacist is in the best position to advise patients on the most serious and common side effect of the drug being dispensed. If the pharmacist was never expected to counsel the patient, then prescription drugs could be dispensed by machines or teen-aged part-time workers following basic instructions. This does not make any sense, particularly when Respondent expects its pharmacists to provide the very same warnings that it failed to give Ms. Long.

In this day of prescription drug dependence, the issue of pharmacist liability under the medical negligence statute is a significant issue of public interest. Ms. Long presented evidence of what the standard of care required Respondent to do when she received clindamycin from its pharmacy. She met her statutory to establish breach of duty under the standard of care and burden to get to trial under RCW 7.70.040. Any judicial exception that would eliminate liability for a statutory right of action is bad policy to begin with; however, eliminating liability in all circumstances for one type of medical provider is non-nonsensical, particularly when it comes to pharmacists. Prescription drugs can be dangerous. Having a standard of care that requires pharmacists to counsel

patients, at least in some circumstances, makes practical sense from a patient safety perspective. Ultimately, pursuant to RCW 7.70, the pharmacy profession determines the standard of care for the practice of dispensing prescription medication. A poorly reasoned opinion from 30 years ago should not, especially when it deprives a litigant of bringing a claim that can otherwise be brought under RCW 7.70.

E. CONCLUSION

This court should accept review under RAP 13.4(b)(3) and (4) to examine whether the holding of *McKee* violates the separation of powers doctrine. If so, Mrs. Long was unconstitutionally deprived of her right to bring her medical negligence claim to trial. Also, judicial exclusion of a standard of care duty for pharmacists is an issue of substantial public interest. If the standard of care requires pharmacists to give warnings for the most common and serious side-effects of clindamycin, *McKee* should not negate the duty under any circumstances.

REPECTFULLY SUBMITTED this 23rd day of April 2019

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DECLARATION OF SERVICE

The undersigned declares under penalty of perjury under the laws of the State of Washington that the following is true and correct:

That on April 23, 2019 I served the foregoing Opening Brief of Appellant on the following parties:

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APPENDICES
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A. Ethel Fay Long and Melvin Leroy Long v. Rite Aid Corp., No. 77695-9-I

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The Court of Appeals
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CASE #: 77695-9-I
Ethel Fay Long, et al, Appellants v. Rite Aid Corp, et al., Respondents
King County, Cause No. 15-2-31353-3 SEA

Counsel:

Enclosed is a copy of the opinion filed in the above-referenced appeal which states in part:

"Therefore, we affirm."

Counsel may file a motion for reconsideration within 20 days of filing this opinion pursuant to RAP 12.4(b). If counsel does not wish to file a motion for reconsideration but does wish to seek review by the Supreme Court, RAP 13.4(a) provides that if no motion for reconsideration is made, a petition for review must be filed in this court within 30 days.

In accordance with RAP 14.4(a), a claim for costs by the prevailing party must be supported by a cost bill filed and served within ten days after the filing of this opinion, or claim for costs will be deemed waived.

Should counsel desire the opinion to be published by the Reporter of Decisions, a motion to publish should be served and filed within 20 days of the date of filing the opinion, as provided by RAP 12.3 (e).

Sincerely,

Richard D. Johnson
Court Administrator/Clerk

LAW

Enclosure

c: The Honorable John Erlick

A

FILED
3/25/2019
Court of Appeals
Division I
State of Washington

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION ONE

ETHEL FAY LONG and MELVIN LEROY LONG, husband and wife, Appellants, v. RITE AID HEADQUARTERS CORP. and RITE AID CORP., Respondents.	)	No. 77695-9-I UNPUBLISHED OPINION FILED: March 25, 2019

VERELLEN, J. — When a physician prescribes medication for their patient, it is the physician—a learned intermediary—and not the pharmacist who has the duty to advise the patient of potential adverse effects. Because Rite Aid had neither a general common law nor a statutory duty to warn Ethel Long about the potential adverse side effects of a prescribed medication, the trial court did not abuse its discretion in denying Long's motion for reconsideration of summary judgment.

Therefore, we affirm.

FACTS

On December 31, 2012, Long went to the emergency room at Swedish Medical Center for tooth pain. Dr. David Karch prescribed the antibiotic, clindamycin, to treat Long's tooth abscess. Long filled the prescription at her local Rite Aid. The United States Food and Drug Administration warns that (1) if a patient develops

diarrhea during or after taking clindamycin, they need to contact a doctor immediately and (2) if a patient develops diarrhea, they should not take antidiarrheal products.

On January 2, 2013, dentist Dr. Alecia Nowak extracted Long's infected tooth. On January 16, 2013, Long traveled to Atlanta. After arriving in Atlanta, Long developed diarrhea. Long took Imodium, an antidiarrheal product, when her diarrhea worsened. Over the next week, Long became progressively ill. On January 31, 2013, Long's husband took her to a walk-in clinic. The clinic called an ambulance to take Long to Emory University Hospital in Atlanta. At Emory, doctors removed Long's large colon and performed an ileostomy.

On December 24, 2015, Long sued Dr. Karch, Eastside Emergency Physicians, Swedish Medical Center, Dr. Nowak, and Rite Aid.[1] Long alleged Rite Aid had a duty to warn her about the potential adverse side effects of clindamycin. On September 22, 2017, the trial court granted Rite Aid's motion for summary judgment and dismissed Long's claim. On September 28, 2017, the court denied Long's motion for reconsideration.

Long appeals.

ANALYSIS

Long contends the trial court abused its discretion when it denied her motion for reconsideration of the court's summary judgment order.[2]

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[1] Long's claims against other parties have been resolved: Rite Aid is the sole remaining party on appeal.

[2] Long assigns error only to the trial court's denial of her motion for reconsideration.

We review summary judgment orders de novo.[3] Summary judgment is appropriate if "there is no genuine issue as to any material fact and [ ] the moving party is entitled to a judgment as a matter of law."[4] But we review a trial court's decision of a reconsideration motion for abuse of discretion.[5] A trial court abuses its discretion when its decision is manifestly unreasonable or based on untenable grounds or reasons.[6]

Long contends her claim against Rite Aid is exclusively governed by chapter 7.70 RCW. Under RCW 7.70.030(1), to prove damages for a health care injury, the plaintiff must show "[t]hat injury resulted from the failure of a health care provider to follow the accepted standard of care." RCW 7.70.040(1) further defines breach of the standard of care as the "fail[ure] to exercise that degree of care, skill, and learning expected of a reasonably prudent health care provider at that time in the profession or class to which he or she belongs, in the State of Washington, acting in the same of similar circumstances."

Long claims Rite Aid breached the accepted standard of care when its pharmacists failed to warn her of the adverse side effects of clindamycin. Long relies on the patient counseling requirement from WAC 246-869-220. WAC 246-869-220(1) requires the pharmacist to "directly counsel the patient or patient's agent on

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[3] Smith v. Safeco, Ins. Co., 150 Wn.2d 478, 483, 78 P.3d 1274 (2003) (quoting Jones v. Allstate Ins. Co., 146 Wn.2d 291, 300, 45 P.3d 1068 (2002)).

[4] CR 56(c).

[5] Federal Home Loan Bank of Seattle v. RBS Securities, Inc., 3 Wn. App. 2d 642, 648, 418 P.3d 168 (2018).

[6] Id.

the use of drugs or devices." And section (3) mandates the pharmacist to "determine the amount of counseling that is reasonable and necessary under the circumstance[s]."

In opposition to Rite Aid's motion for summary judgment, Long submitted a declaration from Jeffery Tichenor, a pharmacist licensed to practice in Washington. In his declaration, Tichenor stated, the counseling requirement from WAC 246-869-220 "at a minimum must include the most significant warnings of the drug."[7] Tichenor also stated, "The standard of care required the pharmacist to counsel Mr. Long that if persistent diarrhea occurred during or even after the clindamycin treatment, Mrs. Long needed to tell a doctor immediately and avoid taking anti-diarrheal medication."[8]

In granting Rite Aid's motion for summary judgment, the court relied on McKee v. American Home Products, Corp.[9] In McKee, the plaintiff alleged the pharmacists were negligent in selling her a drug without warning her of its adverse side effects or giving her the manufacturer's package insert.[10] Similar to the current case, the pharmacists in McKee moved for summary judgment dismissing the plaintiff's claims, arguing they had no duty to warn the plaintiff of the adverse side effects of a prescription drug.

As a preliminary matter, our Supreme Court determined an affidavit from an out-of-state physician was insufficient to establish the standard of care in Washington

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[7] Clerk's Papers (CP) at 269.

[8] CP at 270.

[9] 113 Wn.2d 701, 782 P.2d 1045 (1989).

[10] Id. at 704.

and defeat summary judgment.[11] Long attempts to distinguish McKee by arguing she presented sufficient expert testimony from Tichenor concerning the accepted standard of care. But in McKee, although our Supreme Court affirmed the summary judgment order because McKee failed to present sufficient expert testimony, the court decided "it [was] appropriate that we discuss the merits of the primary issue raised."[12]

Long interprets McKee as allowing a claim under RCW 7.70.040 for breach of the standard of care when a pharmacist fails to warn a patient of the potential adverse side effects of a prescription medication. Long contends our Supreme Court implicitly held that if the plaintiff provides sufficient expert testimony concerning the standard of care, there is a viable claim under RCW 7.70.040. But this argument ignores the explicit analysis in McKee under RCW 7.70.040.

> Although a pharmacist's duty to warn of potential hazards associated with a prescription drug is an issue of first impression in Washington, we choose to join the majority of those states with statutes similar to RCW 7.70.040 which have addressed this issue holding that a pharmacist has no duty to warn.[13]

This holding lines up with Washington's adherence to the learned intermediary doctrine. Under the learned intermediary doctrine, the duty to warn a patient of the adverse side effects of a medication rests solely on the physician. "'It 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.'"[14] Although

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[11] Id. at 706-07.

[12] Id. at 707.

[13] Id. at 707-08.

[14] Id. at 711 (quoting W. KEETON, R. KEETON & D. OWEN, PROSSER & KEETON ON TORTS § 96 at 988 (5th ed. 1984)).

pharmacists have "a duty to accurately fill a prescription, and to be alert for clear errors and mistakes," pharmacists do not "have a duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug."[15]

The duty to warn about potential adverse side effects must be the sole obligation of the prescribing physician because the physician "may often have valid reasons for deviating from the drug manufacturer's recommendations based on a patient's unique condition."[16] Additionally, excessive warnings by a pharmacist "could cause unfounded fear and mistrust of the physician's judgment, jeopardizing the physician-patient relationship and hindering treatment."[17]

> Requiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment. We believe that duty, and any liability arising therefrom, is best left with the physician.[18]

The pharmacist lacks the necessary knowledge concerning a patient's medical background "to question the physician's judgment regarding the appropriateness of each customer's prescription."[19] For example, physicians sometimes prescribe medication for an off label use. "Off-label prescription of drugs occurs when a doctor

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[15] Id. at 720.

[16] Id. at 716.

[17] Id. at 717.

[18] Id. at 712.

[19] Id. at 716.

prescribes a drug in any manner that varies from labeling specifications."[20] A pharmacist would rarely know whether the physician intends an off label use.

Whenever a physician prescribes a medication, it must be the physician who determines the appropriate warnings because 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.

Long contends that although our Supreme Court has previously added duties beyond those recognized under the current standard of care,[21] the court would never remove a duty recognized at common law. First, Long fails to provide any authority supporting this supposition.[22] Second, in making this argument, Long again ignores our Supreme Court's explicit determination in McKee that a pharmacist's failure to warn a patient about the potential adverse side effects of a medication does not give rise to a claim under RCW 7.70.040.

Long also attempts to sidestep McKee by arguing WAC 246-869-220 imposes a duty to warn on pharmacists. At the time the court decided McKee, former WAC 360-16-265 (1989) required pharmacists to "explain to the patient or the

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[20] Steven R. Salbu, *Off-Label Use, Prescription and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 189 (1999).

[21] See, e.g., Helling v. Carey, 83 Wn.2d 514, 518-19, 519 P.2d 981 (1974) (Under the undisputed standard of care, ophthalmologists were not required to give pressure tests for glaucoma to patients under the age of 40. But our Supreme Court held, as a matter of law, "reasonable prudence required the timely giving of the pressure test to this plaintiff.").

[22] RAP 10.3(a)(6); Cowiche Canyon Conservancy v. Bosley, 118 Wn.2d 801, 809, 828 P.2d 549 (1992).

patient's agent the directions for use and any additional information." The regulation also stated, "[W]here it is appropriate . . . when dispensing refill prescriptions, the pharmacist shall communicate with the patient or the patient's agent . . . *regarding adverse effects*."[23] Although McKee does not specifically mention WAC 360-16-265, our Supreme Court concluded, "Nothing in RCW 18.64 nor in WAC 360-16 requires pharmacists to disclose all contraindications or warnings."[24]

Our Supreme Court issued McKee in November 1989. In June 1992, the Department of Health, the state agency responsible for regulating pharmacists, repealed and replaced WAC 360-16-265 with WAC 246-869-220. In Silves v. King, which was decided in 1999, after WAC 246-869-220 went into effect, this court relied on McKee when it determined a pharmacist did not have a duty to warn a patient of potential drug interactions.[25]

More recently, in Luke v. Family Care & Urgent Medical Clinics, the Ninth Circuit determined the counseling requirement contained in WAC 246-869-220 does not include the duty to warn the patient of the potential adverse side effects associated with a prescription medication.[26] [27] The court stated, "The plain language

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[23] Former WAC 360-16-265 (1989) (emphasis added).

[24] McKee, 113 Wn.2d at 718.

[25] 93 Wn. App. 873, 880, 970 P.2d 790 (1999) (quoting id. at 720).

[26] 246 Fed. Appx. 421 (9th Cir., 2007).

[27] Both parties cite Luke, an unpublished opinion from the United States Court of Appeals, Ninth Circuit. Under GR 14.1, "A party may cite as an authority an opinion designated 'unpublished,' 'not for publication,' 'non-precedential,' 'not precedent,' or the like that has been issued by any court from a jurisdiction other than Washington state, only if citation to that opinion is permitted under the law of the jurisdiction of the issuing court." Under the Federal Rules of Appellate Procedure, Rule 32.1, "A court may not prohibit or restrict the citation of federal judicial opinions,

of the regulation restricts a pharmacist's role to counseling concerning the safe and effective administration of the medication, and does not impose any regulation to explain medical risks."[28]

As a matter of law, Rite Aid had neither a general common law nor a statutory duty to warn Long of the potential adverse side effects of clindamycin. We conclude the trial court did not abuse its discretion in denying Long's motion for reconsideration of the court's summary judgment order.

Therefore, we affirm.

WE CONCUR:

orders, judgments, or other written dispositions that have been: (i) designated as 'unpublished,' 'not for publication,' 'non-precedential,' 'not precedent,' or the like; and (ii) issued on or after January 1, 2007." The Ninth Circuit issued Luke on August 21, 2007.

[28] Luke, 246 Fed. Appx. at 425.

B

RCW 7.70.010

Declaration of modification of actions for damages based upon injuries resulting from health care.

The state of Washington, exercising its police and sovereign power, hereby modifies as set forth in this chapter and in RCW **4.16.350**, as now or hereafter amended, certain substantive and procedural aspects of all civil actions and causes of action, whether based on tort, contract, or otherwise, for damages for injury occurring as a result of health care which is provided after June 25, 1976.

[1975-'76 2nd ex.s. c 56 § 6.]

NOTES:

Severability—1975-'76 2nd ex.s. c 56: See note following RCW **4.16.350**.

C

RCW 7.70.030

Propositions required to be established—Burden of proof.

No award shall be made in any action or arbitration for damages for injury occurring as the result of health care which is provided after June 25, 1976, unless the plaintiff establishes one or more of the following propositions:

(1) That injury resulted from the failure of a health care provider to follow the accepted standard of care;

(2) That a health care provider promised the patient or his or her representative that the injury suffered would not occur;

(3) That injury resulted from health care to which the patient or his or her representative did not consent.

Unless otherwise provided in this chapter, the plaintiff shall have the burden of proving each fact essential to an award by a preponderance of the evidence.

[**2011 c 336 § 250;** 1975-'76 2nd ex.s. c 56 § 8.]

NOTES:

Severability—1975-'76 2nd ex.s. c 56: See note following RCW **4.16.350**.

D

RCW 7.70.040

Necessary elements of proof that injury resulted from failure to follow accepted standard of care.

The following shall be necessary elements of proof that injury resulted from the failure of the health care provider to follow the accepted standard of care:

(1) The health care provider failed to exercise that degree of care, skill, and learning expected of a reasonably prudent health care provider at that time in the profession or class to which he or she belongs, in the state of Washington, acting in the same or similar circumstances;

(2) Such failure was a proximate cause of the injury complained of.

[**2011 c 336 § 251; 1983 c 149 § 2;** 1975-'76 2nd ex.s. c 56 § 9.]

NOTES:

Severability—1975-'76 2nd ex.s. c 56: See note following RCW **4.16.350**.

THE LAW OFFICE OF DAN N. FIORITO III

April 23, 2019 - 2:05 PM

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