NO. 97112-9

SUPREME COURT OF THE STATE OF WASHINGTON

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

Appellants,

v.

RITE AID CORP.,

Respondent.

RESPONDENT'S ANSWER TO PETITION FOR REVIEW

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I. INTRODUCTION

This case concerns a lawsuit for malpractice against a pharmacist for allegedly failing to warn of potential side effects of a medication prescribed by a treating physician. Plaintiff Ethel Long and her husband ("the Longs") petition this Court for review of the Court of Appeals' unpublished opinion, which followed the precedential case *McKee v. American Home Products, Corp.*, 113 Wn.2d 701, 782 P.2d 1045 (1989). In that opinion, the Supreme Court held there is no duty for pharmacists to warn patients of potential side effects of the medications they fill.

In the present case, Long's doctor prescribed an antibiotic for a tooth abscess. She filled the prescription at a Rite Aid pharmacy. After taking the medication she developed diarrhea and suffered injuries as a result. The Longs then sued multiple defendants including the hospital, the prescribing doctor, and Rite Aid. With respect to Rite Aid, they claim that the pharmacist breached the standard of care in Washington by not warning her of the potential side effects of the medicine when it filled the prescription, either orally or by way of a package insert. Under the learned intermediary doctrine and Supreme Court precedent, however, it is the prescribing doctor and not the pharmacist who has a duty to warn the patient of potential side effects. The Court of Appeals accurately applied this precedent to the case

at hand and did not create any new law warranting review by the Supreme Court. Therefore, the petition for review should be denied.

II. ISSUES PRESENTED FOR REVIEW

Should the Supreme Court deny the Longs' petition for review of the Court of Appeals' unpublished decision upholding the trial court's denial of the Longs' motion for reconsideration of its order granting summary judgment to Rite Aid?

III. COUNTER-STATEMENT OF CASE

This medical malpractice action arises out of a prescription for Clindamycin filled by Rite Aid. On December 31, 2012, Appellant Ethel Long ("Long") went to the Emergency Room at the Swedish Medical Center complaining of tooth pain. A doctor examined Long and discovered she had an extremely abscessed tooth. He prescribed a ten-day course of Clindamycin antibiotics and instructed her to have the tooth removed as soon as possible. The doctor and nurse who treated her testified that they would have given their usual warnings and instructions for Clindamycin. This included to return if the patient developed any new symptoms, and to seek medical attention if she developed diarrhea. The Longs deny that they received warnings from the medical providers.

The Longs filled the prescription at Rite Aid. There is no dispute that Rite Aid filled the prescription accurately, but the Longs contend that Rite Aid failed to warn them of the potential side effect of diarrhea.

Long took the mediation as directed. On January 18, 2013, more than one week after her last dose of Clindamycin, she experienced diarrhea. She took Imodium, but the diarrhea continued for thirteen days before she finally sought medical attention. Long was transported to the hospital and diagnosed with clostridium difficile colitis ("C. Diff.") and underwent an ileostomy. She then brought suit against a number of defendants, including her treating doctor who prescribed the antibiotic, the hospital, and Rite Aid.

Rite Aid moved for summary judgment, and the trial court granted the motion relying on *McKee v. American Home Products, Corp.* and the learned intermediary doctrine. The Longs moved for reconsideration of this ruling, which was denied. The Longs then appealed the denial of their motion for reconsideration, and the Court of Appeals affirmed. The Longs now ask this Court to grant their petition for review of the Court of Appeals' unpublished opinion.

IV. REASONS WHY THE REVIEW SHOULD BE DENIED

A petition for review will be accepted by the Supreme Court only if the decision of the Court of Appeals (1) is in conflict with a decision of the Supreme Court, (2) if the decision is conflict with another decision of the

Court of Appeals, (3) if a significant question of law under the United States or Washington Constitution is involved, or (4) if the petition involves issues of substantial public interest. RAP 13.4(b).

It is not readily apparently from the Long's petition which of these criteria they believe provide basis for review. While they claim this case involves an issue of substantial public interest and that the *McKee* opinion violated the separation of powers doctrine, they also argue that the Court of Appeals erred in its ruling because *McKee* is distinguishable, and/or that *McKee* is simply a terrible opinion that must be overruled.

Review should be denied because the petition fails to satisfy any of the criteria for acceptance of review. The unpublished decision of the Court of Appeals simply followed existing precedent and made no new law. Also, and perhaps most importantly, *McKee* is a well-reasoned decision and should not be disturbed. Therefore, the petition should be denied.

1. The decision of the Court of Appeals is not in conflict with a decision of the Supreme Court and the Court correctly applied *McKee*.

Although less than clear, the Longs seem to argue that the Court of Appeals decision conflicts with *McKee* (or that *McKee* is distinguishable) because the expert opinion in *McKee* was deemed inadmissible where—as here—the Longs successfully proffered the opinion of an expert. In other words, they assert that *McKee* allows a claim under RCW 7.70.040 for

breach of the standard of care if a plaintiff offers sufficient expert testimony. This is an inaccurate reading of *McKee*.

Although the Supreme Court in *McKee* affirmed summary judgment because the plaintiff failed to present sufficient expert testimony, the Court decided it was appropriate to "discuss the merits of the primary issue raised." *Id.* at 707. The Supreme Court then went on to explicitly hold that it chose 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." *Id.* at 707-08.

While an expert's opinion is needed to sustain a medical negligence case under RCW 7.70, the opposite is not true. That is, a medical expert's opinion cannot override the court's determination that there is no duty as a matter of law. *Silves v. King, MD*, 93 Wn. App. 873, 879-80, 970 P.2d 790 (1999) (upholding *McKee* and the learned intermediary doctrine and extending its application to nurses, even where an expert's opinion has been offered).

Therefore, *McKee* is directly on point and the Court of Appeals' opinion is not in conflict. Even if the plaintiff in *McKee* had presented sufficient expert testimony, the Supreme Court would have reached this same conclusion: pharmacists have no duty to warn as a matter of law. *Id.*; *id.* at 720. Review should not be granted on this basis.

2. The decision of the Court of Appeals is not in conflict with another decision of the Court of Appeals.

The Longs do not argue how the unpublished decision of the Court of Appeals is in conflict with another decision of the Court of Appeals. Therefore, review should not be granted on this basis.

3. The decision of the Court of Appeals does not involve a significant question of law under the United States Constitution or the Constitution of the State of Washington.

The Longs contend that *McKee* (and by extension, the unpublished opinion of the Court of Appeals) violate the separation of powers doctrine. Their argument is that *McKee* conflicts with RCW 7.70, the medical malpractice statute, by denying valid medical malpractice claims against pharmacists for failure to warn of side effects as a matter of law, even where the claimant has expert testimony to support that the standard of care was breached. Petition at 16-17. By doing so, they argue, the judiciary invaded the providence of the legislative branch. Petition at p. 14.

The Longs are mistaken. The existence of a legal duty is a question of law for the courts. *Folsom v. Burger King*, 135 Wash.2d 658, 671, 958 P.2d 301 (1998); *McKown v. Simon Prop. Grp., Inc.*, 182 Wn.2d 752, 762, 344 P.3d 661 (2015). Therefore, making a determination of legal duty cannot violate the separation of powers doctrine. *See Silves*, 93 Wash. App. at 882 (citing *McCluskey v. Handorff–Sherman*, 125 Wash.2d 1, 6,

882 P.2d 157 (1994) (an action for negligence does not lie unless the defendant owes a duty of care to the plaintiff)).

Because of this, Washington courts have long made determinations of legal duties within the medical malpractice context. *See, e.g.*, *Helling v. Carey*, 83 Wn.2d 514, 518-19, 519 P.2d 981 (1974) (as a matter of law ophthalmologist required to give eye pressure test to plaintiff.); *see also Mohr v. Grantham*, 172 Wn.2d 844, 850-51, 859 (2011) (extending cause of action for lost chance doctrine within medical malpractice actions). The Court's determination of a legal duty is fully within its province. The Longs provide no authority or argument for why this case is any different.

4. The decision of the Court of Appeals does not involve an issue of substantial public interest that should be determined by the Supreme Court.

The Longs request review of the opinion of the Court of Appeals because the underlying issue of medical malpractice is an issue of public importance. They assert that the practice of medicine has changed since *McKee* was issued, warranting review. Petition at p. 18. They also seek review on the basis that *McKee* did not address Washington's current administrative rule regarding pharmacy counseling, which did not go into effect until 1992.

While the subject matter is certainly an issue of substantial public interest, *McKee* definitively answered the question posed here. It was

appropriately decided and the rationale behind that opinion is of equal force today as it was 30 years ago.

A. Whether a pharmacist has a duty to warn of potential side effects has already been determined by the Supreme Court.

As is described above, *McKee* extended the learned intermediary doctrine to pharmacists and held that it is the doctor, not the pharmacist, who has a duty to warn of potential side effects. *McKee*, 113 Wn.2d at 707. The Longs ask the Court to accept their petition for review on the basis that *McKee* was wrongly decided.

Where this court has been urged to abandon a long-established Washington doctrine and to adopt a new rule, stare decisis "'requires a clear showing that an established rule is incorrect and harmful before it is abandoned.'" *1000 Virginia Ltd. P'ship v. Vertecs Corp.*, 158 Wash. 2d 566, 596–97, 146 P.3d 423, 439 (2006), as corrected (Nov. 15, 2006) (citing *Riehl v. Foodmaker, Inc.*, 152 Wash.2d 138, 147, 94 P.3d 930 (2004) (quoting *In re Rights to Waters of Stranger Creek*, 77 Wash.2d at 653, 466 P.2d 508). The Longs have not established that threshold has been met here.

The Washington Supreme Court in *McKee* held that the learned intermediary doctrine bars the liability of pharmacists for alleged failures to warn a customer about the dangers of a medication. 113 Wn.2d at 707. The learned intermediary doctrine provides that physicians (the learned

intermediaries) decide "which available drug fits the patient's needs, and choosing which facts from the various warnings should be conveyed to the patient. The extent of the disclosure is a matter of medical judgment." *McKee* at 710 (citing *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill.2d 507, 513 N.E.2d 387, 395 (1987)). The physician is not required to disclose all risks associated with a drug, only those that are material. *Smith v. Shannon*, 100 Wash.2d 26, 31, 666 P.2d 351 (1983). In other words, a doctor's decision as to whether or not warn of a potential side effect as material is part of a doctor's diagnosis. *Terhune v. A.H. Robins., Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978).

The Court's opinion in *McKee* was sound and should not be overturned. Although Doctors and pharmacists are both healthcare providers, they play very different roles. 113 Wn.2d at 707-11. A pharmacist is not trained nor licensed to diagnose medical conditions. *Id.* Therefore, a pharmacist should not interfere with the relationship between a doctor and patient by issuing warnings to customers that a doctor already deemed unnecessary. *Id.* at 719-20. As stated in *McKee*, "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." *Id*. at 712. Nothing about this basic principle has changed that would warrant review of *McKee*.

B. Neither WAC 246-869-220 nor its Predecessor, WAC 360-16-265, Limit Application of the Learned Intermediary Doctrine or Create a Duty to Warn of Side Effects.

The Longs alternatively argue that their petition for review should be granted because *McKee* did not address the counseling requirements for pharmacists delineated by the Washington Administrative Code ("WAC"). Further, the WAC provision in place at the time of *McKee* has since been repealed and replaced with another provision. Their position is that the "only reasonable" interpretation of current WAC 246-869-220, based on the wording of its predecessor, WAC 360-16-265 (1989), is a pharmacist sometimes has a duty to warn of attendant side effects of prescribed medication, and review must be allowed since *McKee* is at odds with this regulation.

First, although the *McKee* opinion does not specifically mention WAC 360-16-265, the Supreme Court concluded, "Nothing in RCW 18.64 (governing pharmacists) nor WAC 360-16 requires a pharmacist to disclose all contractions or warnings." 113 Wn.2d at 718. Thus, the argument *McKee* was wrongly decided because it did not consider the WAC is unavailing.

Second, the current WAC does not impose a duty to warn of side effects, and did not disrupt the holding of *McKee*. Prior to its repeal, WAC 360-16-265 required pharmacists, for each new prescription, to "explain to the patient […] the directions for use and any additional information." WAC 360-16-265(1). Subsection (2) stated that for refill prescriptions, "[w]here appropriate, when dispensing refill prescriptions, the pharmacist shall communicate with the patient […] regarding adverse effects […] with respect to the use of medication." WAC 360-16-265(2).

In 1992 the Washington Department of Health WAC 360-16-265 and replaced it with WAC 246-869-220. WAC 246-869-220 no longer contains the words "adverse effects" and does not reference communication with customers regarding side effects of dispensed medication for new or refill prescriptions. Instead, WAC 246-869-220(1) states that a pharmacist shall "counsel" customers on "the use of drugs." *Id*. This is not at odds with the *McKee* opinion.

The precise argument the Longs advance has been reviewed and answered by the Ninth Circuit Court of Appeals. In *Luke v. Family Care and Urgent Medical Clinics*, 246 Fed.Appx. 421 (2007), a decision handed down after the introduction of the current Washington Administrative Code provision, the Ninth Circuit noted that express purpose of WAC 246-869-220 is to "educate the public in the use of drugs and devices." *Id.* at 425

(citing WAC 246-869-220). The court concluded that "the plain language of the regulation restricts a pharmacist's role to counseling concerning the safe and effective administration of the medication, and does not impose any requirement to explain medical risks." *Id*.

Therefore, even though *McKee* does not address WAC 246-869-220, nothing in that provision requires a pharmacist to counsel a patient on potential adverse side effects. The rationale behind *McKee* is still valid—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. 246 Fed.Appx. at 425. The Court should decline the Longs' petition to review the Court of Appeals unpublished opinion on this basis.

V. CONCLUSION

For the foregoing reasons, review should not be granted in this case.

Dated this 3rd day of June, 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 June 3, 2019, I served the foregoing Respondent's Answer to Petition for Review on the following parties:

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