

IN THE FLORIDA SUPREME COURT

YOUR DRUGGIST,

Petitioner,

v.

ROBERT POWERS, as Personal
Representative of the Estate of
Gail Powers,

Respondent.

CASE NO: SC05-1191

LOWER COURTS

District Case No: 4D04-2061

Circuit Case No. 03-17380(12)

INITIAL BRIEF OF PETITIONER, YOUR DRUGGIST

On Appeal from an Opinion of the Fourth District Court Appeal Which Certifies
Direct Conflict with Opinions from the First and Fifth District Courts of Appeal

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***INTERESTED
PARTIES ARE TO
BE IN
ALPHABETICAL
ORDER

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INTRODUCTION

This case is before the Court based on certified conflict by the Fourth District Court of Appeal.

Petitioner, Your Druggist Inc., seeks review of the decision of the Fourth District Court of Appeal in Powers v. Thobani, 903 So. 2d 275 (Fla. 4th DCA 2005) holding, for the first time in Florida, that pharmacists have a duty to warn customers and their prescribing physicians of potential adverse drug interactions. The Medicine Shoppe also seeks review of the Fourth District Court of Appeal's ruling. That appeal is before this Court in the companion case of B.A.L Pharmacy, etc. v. Robert Powers, etc., et. al., Case No. SC05-1192.

Respondent, Robert Powers, as Personal Representative of the Estate of Gail Powers, was the named Plaintiff below. In this brief, the Respondent will be referred to as "Respondent." The decedent, Gail Powers, will be referred to by her full name, "Gail Powers."

Petitioner, Your Druggist, Inc., is one of the named Defendants below, and will be referred to as "Your Druggist." B.A.L. Pharmacy d/b/a The Medicine Shoppe, Petitioner in companion case SC05-1192 and a named Defendant below, will be referred to as "The Medicine Shoppe." Your Druggist and The Medicine Shoppe will be collectively referred to as the "Pharmacy Defendants." Shirin

Thobani, M.D., the final named Defendant below is not a party to this appeal. She will be referred to as “Dr. Thobani.”

References to the record on appeal will be designated as (R. ____) and references to the appendix will be referred to as (A. ____).

STATEMENT OF THE CASE AND FACTS

This is a negligence action against a treating physician and two pharmacies arising from the death of Gail Powers from a purported overdose of prescription painkillers. This matter is on appeal from a decision in the Fourth District Court of Appeal, *Powers v. Thobani*, 903 So. 2d 275 (Fla. 4th DCA 2005), reversing the trial court's order dismissing, with prejudice, the negligence counts against the pharmacy defendants in the amended complaint.¹ On April 5, 2002, Gail Powers began treating with Dr. Shirin H. Thobani (hereinafter "Dr. Thobani"), a duly licensed neurologist, for neck and back pain. (R. 42-56). During the next six months, Gail Powers consulted extensively with Dr. Thobani resulting in a total of 39 office visits. *Id.* On October 22, 2002, Gail Powers died in her home. *Id.* The Medical Examiner allegedly concluded Gail Powers died due to a "[c]ombined drug overdose (OxyCodone and [D]iazepam)." *Id.*

Over the course of treatment, Dr. Thobani prescribed lawful prescription medication for Gail Powers' neck and back pain. *Id.* These medications included

¹ The amended complaint alleged three negligence counts. (R. 42-56). Count I alleged negligence against Dr. Thobani. Counts II and III alleged negligence against The Medicine Shoppe and Your Druggist, respectively. *Id.* The action against Dr. Thobani remains presently in the trial court.

OxyContin and Percocet. Id. Your Druggist and The Medicine Shoppe purportedly filled these prescriptions. Id.

On October 27, 2003, Respondent filed a negligence action against Dr. Thobani, The Medicine Shoppe, and Your Druggist. (R. 1-14). Respondent did not allege that Your Druggist was improperly licensed; that it failed to compound the drugs prescribed; it failed to use due and proper care in filling the prescriptions; it failed to use proper methods in filling the prescriptions; or that it failed to ensure that the drugs were unadulterated. (R. 42-56). In response, the Pharmacy Defendants filed separate motions to dismiss² arguing that Florida law does not recognize a negligence cause of action against a pharmacy that properly fills a lawful prescription. (R. 15-19; 20-24; 33-39). The trial court agreed and entered an order dismissing the counts against the Pharmacy Defendants. (R. 40-41) & (A. 9-10). In its order of dismissal, the trial court stated that the motions to dismiss were “[g]ranted, as there is no cause of action as to liability of the [p]harmacist(s) and/or Pharmacy Defendants in this action pursuant to Florida law. The [d]ismissal [wa]s without prejudice ... allowing [Respondent] twenty (20) days from the date of th[e]

² Dr. Thobani answered the complaint on December 1, 2003. (R. 30-32). Respondent still has a viable claim against Dr. Thobani, the treating and prescribing physician.

[o]rder to amend concerning the pharmacies, if such amendment can under the facts be done in good faith.” Id. (emphasis in original).

Respondent filed his amended complaint on January 13, 2004. (R. 42-56). The allegations in the amended complaint were nearly identical to those in the original complaint. Id. The pharmacy defendants moved to dismiss Counts II and III of the amended complaint. (R. 61-65).³ Relying on Pysz v. Henry’s Drug Store, 457 So. 2d 561, 562 (Fla. 4th DCA 1984), the trial court granted the motions to dismiss, with prejudice, finding as follows:

The law in Florida is well settled that a pharmacist has no duty to warn the customer of the dangerous propensities of the prescription drug or warn the customer’s treating physician of the customer’s dependency and addiction to a treating drug. Pysz v. Henry’s Drug Store, 457 So. 2d 5621, 562 (Fla. 4th DCA 1984). The basis of these negligence claims against these Defendants is that they knew or should have known that Gail Powers’ prescriptions gave her access to too many pills within too short a period of time. Plaintiff’s allegations are strikingly similar to the facts in Pysz, supra. Plaintiff seeks to impose a duty of care upon these Defendants which does not exist under the law. Accordingly, Counts II and III of the [a]mended [c]omplaint fail to state legally cognizable claims.

³ Your Druggist also moved to dismiss the amended complaint because it failed to show that Your Druggist proximately caused Gail Powers’ death. Indeed, the amended complaint alleges the cause of death was due to OxyContin and Diazepam. There is no allegation Your Druggist filled any prescription for Diazepam or had personal knowledge through its employees, of Gail Powers’ medical condition or total number of prescriptions. Since proximate cause is not an issue on appeal, Your Druggist has not addressed same. However, Your Druggist reserves the right to assert a causation defense at a subsequent time, if necessary.

(R. 70) & (A. 11).

On July 27, 2004, the trial court entered final judgment of dismissal in favor of the Pharmacy Defendants. Respondent appealed. (R. 75-77).

On June 1, 2005, the Fourth District Court of Appeal reversed the trial court's order of dismissal holding that a pharmacist has a duty to warn customers and their physicians of potential adverse prescription drug reactions and interactions. (A. 1-8). The Fourth District Court certified conflict with Johnson v. Walgreen Co., 675 So. 2d 1036 (Fla. 1st DCA 1996) and Estate of Sharp v. Omnicare, Inc., 879 So. 2d 34 (Fla. 5th DCA 2004), both of which recognized there is no such duty to warn under McLeod. Powers, 903 So. 2d at 280.

On June 28, 2005, Your Druggist and The Medicine Shoppe filed separate notices to invoke the discretionary jurisdiction of the Florida Supreme Court. The Medicine Shoppe is before this Court in the companion case of B.A.L Pharmacy, etc. v. Robert Powers, etc., et. al., Case No. SC05-1192. The Court postponed its decision on jurisdiction in an Order dated July 12, 2005.

BASIS FOR JURISDICTION

This Court has discretionary jurisdiction to review a district court's decision which expressly and directly conflicts with the decision of another district court on the same issue of law. Art. V, § 3(b)(3), Fla. Const.; Fla. R. App. Proc. 9.030(a)(2)(A)(iv). This Court also has jurisdiction under Art. V, § 3(b)(3), Fla. Const. because the Powers decision misapplies decisional law in McLeod v. W.S. Merrell Co., 174 So. 2d 736, 739 (Fla. 1965).

1. Interdistrict Conflict

The Fourth District Court of Appeal has certified that the holding in Powers v. Thobani, 903 So. 2d 275, 279 (Fla. 4th DCA 2005) is in express and direct conflict with the decisions of two other district courts: Johnson v. Walgreen Co., 675 So. 2d 1036 (Fla. 1st DCA 1996) and Estate of Sharp v. Omnicare, Inc., 879 So. 2d 34 (Fla. 5th DCA 2004).

Powers holds that pharmacies could be held liable for failing to warn customers or their doctors even when they accurately fill lawful prescriptions. This holding is expressly and directly in conflict with the holding of Johnson. In Johnson, the plaintiff alleged negligence against a pharmacy for “fail[ing] to warn [the decedent] or his doctors of the potential adverse drug interactions ... a combination of prescriptions might cause.” The pharmacy moved to dismiss for

failure to state a cause of action. The trial court granted the motion to dismiss, with prejudice, holding that a pharmacist's duty is limited to accurately filling lawful prescriptions. See also Estate of Sharp, 879 So. 2d at 35 (limiting a pharmacist's duty to that imposed by the Florida Supreme Court in McLeod v. W.S. Merrell Co., 174 So. 2d 736, 739 (Fla. 1965)). Accordingly, this Court has jurisdiction to resolve this interdistrict conflict.

Powers' holding regarding a pharmacist's duties under Florida law creates uncertainty in the law and holds wide-ranging implications for both the practice of pharmacy and the practice of medicine in Florida. It is respectfully submitted that this is precisely the type of case that should be afforded further review by this Court.

2. Misapplication of McLeod

This Court also has jurisdiction because Powers misapplies this Court's holding in McLeod, 174 So. 2d at 739. See Aguilera v. Inservices, Inc., 905 So. 2d 84, 86 (Fla. 2005)(recognizing that the misapplication of a Florida Supreme Court decision creates conflict jurisdiction). Although McLeod was an implied warranty case, the pertinent facts of McLeod are indistinguishable from this case:

the salient facts... are: (1) an action against a retail [pharmacy]; (2) the drug was available only to a limited segment of the public who could present a medical doctor's prescription therefor; (3) the prescription was filled precisely in accordance with its directions, and even then,

in the manufacturer's original packet; (4) there was no adulteration; (5) both the patient-purchaser and the retail [pharmacy] relied upon the doctor's prescription, rather than upon the [pharmacy]'s judgment.

Id. at 738.

McLeod concluded that the duties of a pharmacist were the following:

(1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug has not been infected with some adulterating foreign substance.

Id. at 739. The Powers holding misapplies McLeod because it imposes additional duties not recognized by McLeod, any Florida statute, or the Florida Administrative Code.

Further, this Court should assume jurisdiction because this case is of great public importance and will have statewide ramifications for pharmacists, physicians, and their customers or patients. For the foregoing reasons, this Court is vested with conflict jurisdiction and should exercise its discretion in favor of assuming jurisdiction to eliminate these conflicts with and misapplications of Florida law.

SUMMARY OF THE ARGUMENT

Powers ignores over forty years of Florida case law consistently limiting pharmacists' duties to those listed in McLeod, and holds, for the first time in Florida, that pharmacists can be held liable for failing to warn customers or their prescribing physicians of adverse drug reactions even when they accurately fill lawful prescriptions. Under McLeod, pharmacists are required to (1) compound the drug prescribed; (2) use due and proper care in filling a prescription; (3) use proper methods in filling the prescription; and (4) ensure, where possible, that the drug dispensed is unadulterated. It is only when pharmacists deviate from these duties that a cause of action for negligence exists. Powers is not a case where a pharmacy filled prescriptions that were invalid on their face or outdated (as in Dee v. Wal-Mart Stores, Inc., 878 So. 2d 426 (Fla. 1st DCA 2004)), failed to compound the drugs prescribed, failed to provide the accurate dosage, failed to use due and proper care or proper methods in filling the prescriptions, failed to properly label the drugs, or failed to ensure that the drugs were unadulterated. Thus, the Fourth District erred in creating a new negligence cause of action against Your Druggist.

In determining that a duty to warn exists, the Fourth District mistakenly relied on Florida laws that regulate and license the practice of pharmacy. The district court failed to consider the legislative intent of these laws. These laws are

definitional and were not enacted by the Florida Legislature to impose additional duties on pharmacists to second-guess lawfully written prescriptions.

Imposing a duty to warn will adversely impact patients, physicians, and pharmacists. Because pharmacists do not have access to patient records and lack medical training, they will not be able to discern what warnings are appropriate for individual customers. Thus, in an effort to avoid liability under Powers, pharmacists will now have to warn customers of every possible risk or interaction and consult with prescribing physicians on all prescriptions. This new duty will harm the pharmacist-physician relationship and the patient-physician relationship. Imposing a duty to warn on pharmacists may compel some customers to discontinue prescription drug treatments because of heightened fears of adverse side effects or lead customers to mistrust their physicians. Further, the working relationship between pharmacists and prescribing physicians may deteriorate if pharmacists consult the physician about every prescription. The duty now imposed by Powers will cause more harm than good.

Lastly, Powers impermissibly weighs policy considerations in determining that a duty to warn exists. The determination of whether to impose additional duties should rest with the Florida Legislature because they are better equipped

than the courts to weigh the interests of everyone affected. See McKee v. American Home Products, Corp., 782 P. 2d 1045, 1055 (Wash. 1989).

For these reasons, Your Druggist requests that this Court quash Powers and approve Johnson and Estate of Sharp.

ARGUMENT

Standard Of Review

The duty element of negligence is a question of law. McCain v. Florida Power Corp., 593 So. 2d 500 (Fla. 1992). Questions of law are reviewed under the de novo standard of review. Fayad v. Clarendon Nat. Ins. Co., 899 So. 2d 1082 (Fla. 2005). See also Menendez v. The Palms West Condominium Association, Inc., 736 So. 2d 58 (Fla. 1st DCA 1999) (the duty element of negligence is a threshold legal question to be reviewed by the de novo standard of review).

I. THE FOURTH DISTRICT COURT OF APPEAL ERRED IN FINDING PHARMACISTS HAVE A GENERAL DUTY TO WARN OF POSSIBLE ADVERSE EFFECTS AND DID SO DESPITE FORTY YEARS OF UNWAVERING FLORIDA CASE LAW CONSISTENTLY LIMITING PHARMACISTS' DUTIES TO ACCURATELY FILLING LAWFUL PRESCRIPTIONS.

The duties of Florida pharmacists are clearly set forth by this Court in McLeod v. W.S. Merrell Company, 174 So. 2d 736 (Fla. 1965). Under McLeod, pharmacists are required to (1) compound the drug prescribed; (2) use due and proper care in filling a prescription; (3) use proper methods in filling the prescription; and (4) ensure, where possible, that the drug dispensed is unadulterated. *Id.* at 739.

For over forty years, Florida courts have uniformly adhered to McLeod. In Pysz, a case directly on point, a customer brought a claim against a physician, two drug manufacturers and a pharmacy for failing to warn the customer of the addictive propensities of Quaaludes. Pysz, 457 So. 2d at 561. The customer further alleged that in filling his prescriptions for more than nine years, the pharmacy should have known that his use of Quaaludes over that lengthy time period would subject him to physical and psychological dependence and addiction. Lastly, the customer alleged that the pharmacy was negligent because it knew he had become addicted to Quaaludes and failed to tell his physician. Id. at 561.

The trial court dismissed the customer's claims against the pharmacist, holding that "a supplier of drugs has no duty to fail or refuse to supply a customer with drugs for which the customer has a valid and lawful prescription from a licensed physician, nor any duty to warn said customer of the fact that one using the prescribed drug for any period of time could or would become addicted to the use thereof and would become physically and psychologically dependent thereon, even though the supplier of such drugs was aware of the fact that the customer had developed a physical and psychological dependence and addiction to the prescribed drugs." Id. at 561-562.

On appeal, the Fourth District Court of Appeal, following the rule in McLeod, affirmed the dismissal, with prejudice, finding that “[u]nder the circumstances, we do not view appellee’s failure to warn appellant, or to notify the physician, as a failure to exercise due care.” Id. The facts of Pysz are indistinguishable from this case. The Powers decision should be quashed because it is contrary to McLeod and implicates duties that are not recognized in Florida.

Similarly, the court in Johnson relied on McLeod in holding that pharmacists did not have a duty to advise customers or their doctors of adverse drug interactions. Johnson, 675 So. 2d at 1037. In Johnson, the decedent had been a regular customer of Walgreen’s pharmacy for two years. Id. His health problems were numerous, and he was seeing a number of different doctors for treatment, each of whom prescribed different medications. Id. The prescriptions were lawful and filled accurately, but in combination they potentially had lethal effects. The pharmacist did not advise the customer or his doctors about this fact. The customer subsequently died from multiple drug toxicity when the prescription drugs interacted fatally. Id. at 1037.

The customer’s spouse brought a claim against the pharmacy alleging the pharmacy breached its duty of care by failing to check the various prescriptions for interactions; failing to warn or counsel the customer; failing to consult the treating

physicians; giving inappropriate and inaccurate advice about the drugs prescribed; and recommending an inappropriate over-the-counter medication. Id.

The trial court dismissed the spouse's third amended complaint, with prejudice, "on the grounds that a Florida pharmacist's sole duty is to accurately and properly fill all lawful prescriptions presented." Id. at 1037. On appeal, the First District affirmed, citing to McLeod and Pysz. The First District ruled, among other things, that it was not able to distinguish the facts in McLeod and Pysz from Johnson. Id. at 1038. The facts of Johnson are also indistinguishable from Powers. It is well settled in Florida that pharmacists do not have a duty to warn customers or their physicians of the possible risks of using a prescribed drug or a combination of prescription drugs.

It is only when pharmacists deviate from the duties in McLeod, that they become liable in negligence. In Dee v. Wal-Mart Stores, Inc., 878 So. 2d 426 (Fla. 1st DCA 2004), a pharmacy was held liable because it filled a prescription that was flawed on its face. In Dee, the decedent was prescribed a 50 microgram Duragesic patch following a Cesarean section. The prescription was four-months old when the decedent sought to fill it. The prescription, as written by the physician, had no expiration date. Thus, from the face of the prescription, the pharmacist could have determined that the prescription was flawed. Dee is inapplicable to Powers. Here,

there are no allegations that any prescriptions filled by Your Druggist were outdated or otherwise invalid or defective. To the contrary, each prescription filled by Your Druggist was a lawful prescription, issued by a duly licensed physician, and valid on its face. Thus, the trial court correctly applied Florida law and properly dismissed the pharmacist defendants, with prejudice.

Despite unwavering adherence by Florida courts to the duties asserted in McLeod, the court in Powers now holds that a pharmacist may be held liable to a customer for failing to advise the customer or the customer's physician of possible adverse reactions of prescription drugs. Powers, 903 So. 2d at 279. This duty has never been recognized in Florida. This is not a case where a pharmacy filled prescriptions that were invalid on their face, failed to compound the drugs prescribed, failed to provide the accurate dosage, failed to use due and proper care or proper methods in filling the prescriptions, or failed to ensure that the drugs were unadulterated. Moreover, Respondent does not allege that Your Druggist had any personal knowledge of Gail Powers' medical condition. Rather, Respondent seeks to hold Your Druggist liable for negligence because it did not warn either Gail Powers or her duly licensed treating and prescribing physician, Dr. Thobani, of the risks of taking prescription painkillers. This duty does not exist in Florida.

Florida law does not impose a duty on a pharmacy to identify and immediately warn a customer of the dangerous propensities of prescription drugs or warn that customer's physician of the customer's dependency or addiction to prescription drugs. Pysz, 457 So. 2d at 562. Florida law is clear that the only duties required of a pharmacist are to (1) compound the drug prescribed; (2) use due and proper care in filling a prescription; (3) use proper methods in filling the prescription; and (4) ensure, where possible, that the drug dispensed is unadulterated. McLeod, 174 So. 2d at 739. Since Respondent did not allege that Your Druggist failed to compound the proper drugs; failed to use due and proper care in dispensing the prescribed drugs; failed to use proper methods in dispensing the drugs; or failed to ensure the drugs were unadulterated, the Fourth District Court of Appeal's opinion in Powers has no basis in Florida law and should be quashed.

II. THE FOURTH DISTRICT COURT OF APPEAL ERRED IN INFERRING ADDITIONAL DUTIES OF PHARMACISTS UNDER FLORIDA LAW DESPITE A COMPLETE LACK OF ANY LEGISLATIVE INTENT TO IMPOSE SUCH DUTIES.

Section 465.003(6), Florida Statutes, and Florida Administrative Code Rules 64B16-27.300 and 64B16-27.820 do not contain legally enforceable duties. When the Legislature creates statutory duties, its purpose is to protect a particular class of

persons from a specific societal harm. Here, there is no evidence that the Legislature was concerned with careless or overprescribing doctors when it enacted Fla. Stat. § 465.003, Fla. Admin. Code R. 64B16-27.300, or 64B16-27.820. Rather, the clear purpose of these laws is to license and regulate the practice of pharmacy.

Section 465.003(6), Florida Statutes, and Florida Administrative Code Regulations 64B16-27.300 and 64B16-27.820, simply do not support the duties advocated by Powers. Fla. Stat. § 400.003(6), Fla. Admin. Code R. 64B16-27.300, or Fla. Admin. Code R. 64B16-27.820 do not require that a pharmacist warn a customer or contact the prescribing physician about potential adverse reactions, interactions, or proper dosage regimens. Physicians are already charged with considering these factors prior to prescribing a particular drug or combination of drugs. As observed by Estate of Sharp, in McLeod “[this Court] chose not to make a pharmacist liable for duties that are ordinarily owed by a physician or care taker.” Estate of Sharp, 879 So. 2d at 35.

There should be no statutory duty without legislative intent. Johnson, 675 So. 2d at 1038. Section 465.003(6), Florida Statutes, and Florida Administrative Code Rules 64B16-27.300 and 64B16-27.820 do not provide for additional duties because they lack the requisite legislative intent. The Powers opinion fails to

address the legislative intent of these laws. Instead, it mistakenly concludes that a duty to warn is supported by Section 465.003(6), Florida Statutes, and Florida Administrative Code Rules 64B16-27.300 or 64B16-27.820 because “Florida pharmacists are already specifically charged with general knowledge of prescription medication and the risks presented by taking particular prescription drugs, such that they should be able to evaluate and explain the operative risks of taking a medication or series of medications.” Powers, 903 So.2d at 279. This rationale is flawed for two reasons. First, courts should not infer statutory duties absent clear legislative intent. Johnson, 675 So. 2d at 1038. Second, it ignores other important considerations in assessing appropriate drug treatments and identifying suitable warnings. See Eldridge, 485 N.E.2d at 553 (noting that “[t]he propriety of a prescription depends not only on the propensities of the drug but also on the patient’s condition. To fulfill the duty which the plaintiff urges us to impose would require that the pharmacist learn the customer’s condition and monitor his drug usage”).

The Florida Administrative Code does not create or support a general duty to warn. Regulation 64B16-27.300, Florida Administrative Codes, does not impose a legal duty on pharmacists to warn customers or physicians about the potential adverse effects of prescription drugs. This regulation establishes the Continuing

Quality Improvement Program. It is retrospective, not prospective, requiring that pharmacists prepare reports and implement procedures for peer review after the fact. It was not created to expand McLeod and impose additional, legally enforceable, duties on pharmacists. Notably, subsection (5) provides that records maintained pursuant to the Continuing Quality Improvement Program “are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.” Fla. Admin. Code R. 64B16-27.300(5). Accordingly, the Fourth District Court of Appeal erred in relying Regulation 64B16-27.300 to create a general duty to warn.

Similarly, a mandatory duty to warn is not supported by Fla. Admin. Code R. 64B16-27.820. Regulation 64B16-27.820, Florida Administrative Codes, addresses patient counseling by a pharmacist. Subsection (1) provides that a “pharmacist shall ensure that a verbal and printed offer to counsel is made to the [customer] or the [customer’s] agent.” Fla. Admin. Code R. 64B16-27.820(1). However, a pharmacist is not required to counsel a customer who refuses counseling. Fla. Admin. Code R. 64B16-27.820(3). Further, this regulation provides that patient counseling may include information about “the intended use of the drug and expected action (if indicated by the prescribing health care practitioner),” thus, it specifically defers to the medical judgment of the prescribing

doctor. Id. at 64B16-27.820(1)(c) (emphasis added). Thus, Fla. Admin. Code R. 64B16-27.820 does impose a general duty to warn.

No other court, besides Powers, has looked to Florida Administrative Code Regulations 64B16-27.300 or 64B16-27.820 to determine whether pharmacists have a general duty to warn. With respect to Section 465.003, Florida Statutes, two additional courts have scrutinized this statute: Johnson and Estate of Sharp. See Johnson, 675 So. 2d at 1038. See also Estate of Sharp, 879 So. 2d at 35 (citing Johnson). Both cases held that no cause of action or duty was created by this statute.

As here, the plaintiff in Johnson sued a pharmacy for failure to warn of potential adverse drug interactions from a combination of prescription drugs. The plaintiff argued that McLeod was no longer applicable because the Legislature's definition of the term "dispense" in Fla. Stat. § 465.003(5)⁴ created additional duties and a private cause of action against pharmacists. Id. at 1038. The court correctly looked to the legislative intent of this statute in determining that no such duty existed: "The legislative history in the instant case is devoid of any indication that the Legislature intended to create a private cause of action under these

⁴ In 1999, § 465.003 of the Florida Pharmacy Act was amended. Subsection (5), defining the term "dispense", was renumbered as section 465.003(6). The language of this subsection remained unchanged.

circumstances, and the language of section 465.003(5) was adopted within the regulatory scheme for pharmacists.” Id. at 1038.

Similarly, in Estate of Sharp, the court looked to the purpose of the Florida Pharmaceutical Act in determining that it did not impose duties outside the “narrow strictures of McLeod.” Estate of Sharp, 879 So. 2d at 35. “No connection has been pointed out by the [plaintiff] between the regulatory and licensing purpose of [the Florida Pharmaceutical Act] and the injuries suffered by [the plaintiff].” Id. (emphasis added). Indeed, the stated purpose of the Florida Pharmacy Act is very limited:

[t]he sole legislative purpose for enacting this chapter is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

Fla. Stat. § 465.002 (emphasis added). Thus, Fla. Stat. § 465.003 should not be relied on to impose duties that do not exist in Florida.

Section 465.003(6), Florida Statutes, and Florida Administrative Code Rules 64B16-27.300 and 64B16-27.820 are definitional. They define the practice of pharmacy and were not enacted to confer additional duties on pharmacists to supervise physicians and second-guess their judgment. Pharmacists are not doctors. They do not know, nor are they expected to know, a customer’s medical history.

Unlike physicians, pharmacists cannot, and lack training to, physically examine customers or order diagnostic tests. Moreover, a pharmacist may not even have the opportunity to interact with the customer. Oftentimes, customers send family members or friends to pick up their prescriptions. While the practice of pharmacy is a profession, it is not the practice of medicine. As in Johnson, courts in other jurisdictions, citing a lack of legislative intent, have declined to impose a duty on pharmacists based on nearly identical definitional laws governing the practice of pharmacy.

In McKee v. American Home Products, Corp., 782 P. 2d 1045, 1051 (Wash. 1989) the plaintiff claimed that Wash. Rev. Code § 18.64.011(11) created a duty to warn. Subsection 11 provided a detailed list of tasks performed by pharmacists including: “monitoring of drug therapy and use ... the initiating or modifying of drug therapy in accordance with written guidelines or protocols... the advising of therapeutic values, hazards, and the uses of drugs” Id. at 1051-1052. The Washington Supreme Court rejected this argument determining that “this statute is definitional and does not purport to set forth duties.” Id. at 1052 (emphasis added). The court further observed that “[i]f the [l]egislature intended pharmacists to be liable for failure to warn, the [l]egislature could have so provided.” Id. at 1054. See also Fakhouri v. Taylor, 618 N.E. 2d 518, 521 - 522 (Ill. App. Ct. 1993)(holding

that Illinois Pharmacy Act did not create duty to warn either the decedent or the decedent's doctor that the prescribed dosage of medication exceeded the manufacturer's recommended dosage because the Act was "silent as to any warnings which must be given to the customer"); Eldridge, 485 N.E.2d at 553 (refusing to recognize a duty to warn under the Illinois Controlled Substances Act noting that the Act was intended to curb unlawful drug use not prevent overdoses from lawful prescriptions).

The rationale in each of the foregoing cases is the same. As in Powers, the plaintiff in each of the foregoing cases attempted to use a definitional statute designed to regulate and license the practice of pharmacy to impose additional duties on pharmacists. In each instance, the court declined to impose a duty citing the lack of legislative intent to create additional duties for pharmacists and noted that the statute was enacted for a purpose other than imposing additional duties on pharmacists. Because there is a complete lack of legislative intent to impose a duty to warn on pharmacists in Fla. Stat. § 465.003, Fla. Admin. Code R. 64B16-27.300, or 64B16-27.820, the court in Powers erred in relying on these laws to find a general duty to warn.

In sum, there is no legislative intent or case law to support a pharmacist's general duty to warn of adverse interactions based on the provisions of Fla. Stat. § 465.003(6), Fla. Admin. Code R. 64B16-27.300, or Fla. Admin. Code R. 64B16-

27.820. These laws do not require that a pharmacist warn the customer and the prescribing physician when, in the pharmacist's opinion, the drug or combination of drugs prescribed is inappropriate for the customer or may have adverse effects. These laws are definitional and merely describe the functions of a pharmacist. They do not support a duty to warn. Pharmacists are expected to lawfully fill accurate, properly written, prescriptions. They are not qualified or expected to supplant their own judgment for that of the prescribing physician. For these reasons, the Powers decision should be quashed.

III. OTHER JURISDICTIONS HOLD THAT PHARMACISTS HAVE NO DUTY TO WARN

Other jurisdictions have come to the same conclusion as McLeod and held that pharmacists do not owe any duty to warn customers or their physicians of adverse side effects of prescription drugs, on facts nearly identical to Powers. In Eldridge v. Eli Lilly & Co., 485 N.E.2d 551 (Ill. App. Ct. 1985), the plaintiff brought a wrongful death action against a drug manufacturer, a physician, and a pharmacist, after his wife died from an overdose of prescription drugs. The trial court granted summary judgment in favor of the pharmacist. The issue on appeal was "whether a pharmacist is under a duty to warn a physician that drugs are being prescribed in excessive quantities." Id. at 552. The appellate court concluded that a pharmacist owed no such duty. Id. at 553. The court specifically rejected the plaintiff's argument that a duty to warn existed because "many pharmacists may

have greater knowledge of the propensities of drugs than physicians... [and] should, therefore, be under a duty to act as a safety supervisor and determine whether the physician has properly prescribed the drugs.” *Id.* (emphasis added).

Instead, the court observed that:

The propriety of a prescription depends not only on the propensities of the drug but also on the patient’s condition. A prescription which is excessive for one patient may be entirely reasonable for the treatment of another. To fulfill the duty which the plaintiff urges us to impose would require the pharmacist to learn the customer’s condition and monitor his drug usage. To accomplish this, the pharmacist would have to interject himself into the doctor-patient relationship and practice medicine without a license.

Id. (emphasis added).

Similarly, in *Adkins v. Mong*, 425 N.W.2d 151 (Mich. Ct. App. 1988), a customer and his wife brought a negligence action against various physicians and pharmacists claiming that the customer became addicted to narcotics. With respect to one pharmacy, the customer alleged that it filled 116 prescriptions for controlled substances over a period of six years. *Id.* at 152. The customer claimed the following statutory and common law duties were breached by that pharmacy:

(1) failing to maintain accurate customer profile cards, (2) failing to maintain accurate prescription records, (3) failing to identify over-prescribing physicians, (4) failing to independently determine that plaintiff was a drug abuser, (5) failing to communicate with area pharmacies regarding plaintiff’s status as a drug abuser, and (6) filling plaintiff’s prescription for highly abused substances.

Id. at 152.

The court surmised that the “plaintiff would argue that the pharmacist who identifies the addicted customer as a patient of an over-prescribing physician would then be obligated to act on the information and (1) refuse to fill prescriptions, (2) warn the customer or (3) notify the physician.” Id. In determining that no such duty existed under Michigan law, the court relied on its earlier decision in Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 383 (Mich. Ct. App. 1987) finding “that ‘a pharmacist ha[d] 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 warnings be given to the patient by the pharmacist.’” Id. at 152.

Similarly, Jones v. Irvin, 602 F.Supp. 399, 402 (S.D. Ill. 1985) applied Pysz finding that a pharmacist did not owe a duty to warn the customer or the prescribing physician of the risks of taking a combination of prescription narcotics. The facts of Jones are nearly identical to Powers. In Jones, the plaintiff brought a negligence action against a prescribing doctor and a pharmacy for injuries resulting from the purported over medication of his wife. The complaint alleged the following acts of negligence against the pharmacy:

- (a) That it knew or should have known that placidyl is a drug of abuse and that it was being prescribed in massive amounts; that it should have notified either the plaintiff or the physician prescribing the drug that something was amiss.

(b) That it knew that the plaintiff was being prescribed massive doses of placidyl, along with other drugs, and that it knew or should have known that the plaintiff was being over medicated and that it had a duty to notify either the plaintiff and/or her physician of this problem.

(c) That it knew or should have known that the various drugs being prescribed for the plaintiff in the quantities in which they were being prescribed could have adverse reactions and it failed to take any action whatsoever to notify the plaintiff or her physician.

Id. at 400.

The pharmacy defendants moved to dismiss the complaint arguing it owed no duty to warn the decedent or her doctor of the possible risks of the drugs being prescribed. Id. The issue before the court was the same issue in Powers: “whether a pharmacist, who correctly fills a prescription, is negligent for failing to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer.” Id. The court granted dismissal with prejudice in favor of the pharmacy. Citing to Pysz and case law from other jurisdictions, the court held that “a pharmacist ha[d] no duty to warn the customer or to notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer.” Id. at 402 (emphasis added). In determining that a pharmacy did not owe these duties, the court observed that:

It is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug.

Id. at 402 (emphasis added).

The same rationale applies to this case. Merely because pharmacists have a general knowledge of prescription medication and the risks presented by taking particular prescription drugs, does not mean pharmacists have a general duty to warn patients and physicians. With good reason, pharmacists are not required to review customers' medical records or question the medical judgment of the prescribing physician, in filling a prescription. Pharmacists are not physicians. They do not have access to their customers' medical records. They lack medical training to assess medical conditions and determine what warnings are appropriate for a particular customer in light of that customer's medical history. Unlike physicians, pharmacists cannot examine their customers or order diagnostic testing to determine what medication is most appropriate. This duty is squarely on the prescribing physician who is charged with examining the patient, discussing at length the patient's medical history, determining what prescription drug regimen, if any, is suitable for the patient, and closely monitoring that regimen. Accordingly, pharmacists need to rely on the medical judgment of the prescribing physician and

should not have a duty to warn the customer or the physician of possible adverse reactions.

IV. THE FOURTH DISTRICT COURT OF APPEAL ERRED WHEN IT FAILED TO DEFER TO THE FLORIDA LEGISLATURE AND IMPERMISSIBLY MADE POLICY DETERMINATIONS THAT WILL ADVERSELY IMPACT PHYSICIANS, PATIENTS, AND PHARMACISTS IN FLORIDA.

1. Courts Should Defer to the Legislature to Make Policy Determinations

The determination of whether policy considerations warrant imposing additional duties should rest on the Florida Legislature. It is the function of the Florida Legislature, not the courts, to consider policy. The Powers decision underscores the need to defer to the Legislature. In Powers the Fourth District opined that there is “a strong policy basis to support a pharmacy’s duty to warn” however, the court overlooked other important policy considerations that negate the imposition of this duty. These important considerations include: (1) preserving the sanctity of the physician-patient relationship; (2) protecting the working relationship between pharmacists and physicians; and (3) ensuring that patients continue to rely on and trust the advice of their physicians. See Eldridge, 485 N.E.2d at 553 (refusing to recognize a duty to warn citing concerns with interjecting a pharmacist into the physician-patient relationship); Jones v. Irvin, 602 F.Supp. at 402 (noting that a duty to warn would only serve to compel the

pharmacists to second-guess physicians); McKee v. American Home Products, Corp., 782 P. 2d 1045 (Wash. 1989)(noting that imposing a duty would “antagonize” relationship between doctor and pharmacist).

Unlike Powers, the court in Johnson prudently determined that “policy arguments are best made in the legislative context.” Johnson, 675 So. 2d at 1038. In McKee, the court left the determination of whether to impose a duty to warn on pharmacists to the legislature, noting that:

[t]he [l]egislature can better assess the relative costs and benefits involved, and determine what form any warnings should take. The legislative process can better reconcile the interests of all persons concerned with the imposition of such a duty: pharmaceutical manufacturers, medical societies, retail pharmacists, health care insurers, consumer groups and patient representative groups. We find before us a single injured plaintiff and two drug store owners. Holding that the drug store owners could be negligent for failing to warn her about the drug her doctor prescribed would muddy the waters as to where responsibility lies up and down the chain of health care. We decline to do so.

McKee, 782 P. 2d at 1055 (emphasis added).

For these reasons, the Legislature, not the courts, is in a much better position to carefully examine the pharmaceutical health care delivery system to determine which provider is best placed to warn the patients of problems with their prescription medications. The Legislature could take testimony from the various medical boards, health care providers, patients and insurers and debate how best to structure a system; rather than manufacture a judicial duty without considering the

ramifications to the entire health care system. The solution suggested by Fourth District ignores the impact on patients, doctors and pharmacists and will likely create more problems than it solves.

2. The Duties Advocated By Respondent Would Result In More Harm Than Good And Are Incompatible With The Current Practice Of Pharmacy And The Practice Of Medicine

To impose the duties advocated by Respondent, would reinvent the practice of pharmacy in Florida. Florida law does not require pharmacists to second-guess physicians or to exercise medical judgment. Additional duties would needlessly encroach on the function of a physician and unnecessary strain the working relationship between pharmacists and physicians. Pharmacists are simply unable to discern what drugs are better suited for individual customers. In order to satisfy the duties sought by Respondent, pharmacists would be compelled to practice medicine without a license.

The duties advocated by Respondent are not feasible, pose a safety risk to customers, and would have disastrous consequences on both the practice of pharmacy and the practice of medicine. As observed by one court:

To impose a duty to warn on the pharmacist ... would be to place the pharmacist between the physician who, having prescribed the drug, presumably knows the patient's present condition as well as his or her complete medical history, and the patient. Such interference in the patient-physician relationship can only do more harm than good.

Ramirez v. Richardson-Merrell, Inc., 628 F.Supp. 85, 88 (E.D. Pa. 1986). See also Fakhouri v. Taylor, 618 N.E. 2d 518, 521 (Ill. App. Ct. 1993)(noting that to impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship, without the physician's knowledge of the patient).

Unlike physicians, pharmacists do not have access to customers' medical records nor the training to identify what warnings are appropriate for each individual customer. "[P]harmacists are not doctors and are not licensed to prescribe medication because they lack the physician's rigorous training in diagnosis and treatment." McKee, 782 P. 2d at 1051 (Wash. 1989). "Determining which medication is to be utilized in any given case requires an individualized medical judgment which...only the patient's physician can provide." Fakhouri, 618 N.E.2d at 521. Thus, since pharmacists lack the training to discern what warnings are appropriate for individual customers, they would have to warn all customers of every conceivable risk and side effect of a prescription drug or combination of drugs. This task would be extremely taxing as most prescription drugs contain a laundry list of potential adverse side effects. See Frye v. Medicare-Glasser Corp., 605 N.E.2d 557 (Ill. 1992)(recognizing the difficulty in requiring pharmacists to warn customers of adverse reactions and noting that virtually all drugs contain an extensive list of possible side effects). Further, providing customers with an exhaustive list of warnings would likely confuse them, cause customers to mistrust

their physicians, or even frighten many into not taking prescribed drugs. McKee, 782 P. 2d at 1054 (observing that “unnecessary warnings to the patient could cause unfounded fear and mistrust of the physician’s judgment, jeopardizing the physician-patient relationship and hindering treatment”).

As observed by the court in McKee, imposing a duty to warn would adversely impact the working relationship between pharmacists and physicians:

A physician may often have valid reasons for deviating from the drug manufacturer’s recommendations based on a patient’s unique condition. The duty which [plaintiff] urges would result in a pharmacist second guessing numerous prescriptions to avoid liability. This would not only place an undue burden on pharmacists but would likely create antagonistic relations between pharmacists and physicians.

McKee, 782 P. 2d at 1053.

In order to avoid liability under Powers, Florida pharmacists would need to contact physicians before filling every prescription. See Jones, 602 F.Supp. at 402 (noting that “[p]lacing these duties to warn on the pharmacist would only serve to compel the pharmacist to second-guess every prescription a doctor orders in an attempt to escape liability”). Because of the unique relationship between physicians and patients, physicians are in the best position to: (1) diagnose and treat a patient’s condition; (2) weigh the benefits and risks of prescribing a drug or combination of drugs; (3) determine the appropriate course of treatment for that

patient; and (4) monitor the patient's drug usage. Thus, the duty to warn patients and monitor their drug treatments should fall solely on physicians.

Lastly, imposing a duty to warn on pharmacists would certainly delay a customer's access to prescription drugs. Conceivably, pharmacists would not fill prescriptions before conferring with the prescribing physician, interviewing the customer, and possibly reviewing medical records. Thus, prescriptions placed after regular business hours or on weekends and holidays would not be filled until at least the following business day when the pharmacist has had an opportunity to confer with the prescribing physician. As a result, many customers would not receive medically necessary, and often life-saving, drugs in a timely fashion. Thus, in addition to being unworkable, burdensome, and time consuming, these additional duties could increase medical risks to customers.

CONCLUSION

This Court should quash the decision of the Fourth District of Court of Appeal and decline to impose a duty on pharmacists to warn of adverse drug interactions and approve the decisions in Johnson and Estate of Sharp.

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing was served via Federal Express this 7th day of September, 2005 to all counsel listed on the attached service list.

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