

IN THE FLORIDA SUPREME COURT

B.A.L. PHARMACY d/b/a
THE MEDICINE SHOPPE,

Petitioner,

v.

CASE NO: SC05-1192

LOWER COURTS

District Case No: 4D04-2061

Circuit Case No. 03-17380(12)

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

Respondent.

INITIAL BRIEF OF PETITIONER, THE MEDICINE SHOPPE

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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B.A.L. PHARMACY, INC., d/b/a THE MEDICINE SHOPPE v. ROBERT POWERS, as Personal Representative of the Estate of GAIL POWERS, ROBERT POWERS, Individually, PATRICK POWERS and REBECCA POWERS PALMER

Certificate of Interested Persons

Counsel for the Petitioner, THE MEDICINE SHOPPE, certifies that the following persons and entities have or may have an interest in the outcome of this case.

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2. B.A.L. Pharmacy, Inc. d/b/a The Medicine Shoppe
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3. Cole, Scott A.
(Attorney for Petitioner, Your Druggist, Inc. in companion case SC05-1191)
4. Damoorgian, The Honorable Dorian
(Trial Court Judge)
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6. Farber, David J.
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7. Florida Retail Federation
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8. Giddings, Katherine E.
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12. Herman, Peter G.
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14. Long Term Care Pharmacy Alliance
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15. Matzner, Jonathan M.
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16. National Association of Chain Drug Stores
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17. Polen, The Honorable Mark E.
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18. Pomerantz, Mark L.
(Attorney for Petitioner, Your Druggist, Inc. in companion case SC05-1191)
19. Powers, Patrick
(Respondent)

20. Powers-Palmer, Rebecca
(Respondent)
21. Powers, Robert
(Personal Representative of the Estate of Gail Powers, Respondent)
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23. Thobani, Shirin H., M.D.
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24. Silver, Harry R.
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25. Warner, The Honorable Martha C.
(Presiding Judge - Fourth District Court of Appeal)
26. Wites, Marc
(Attorney for Defendant in Trial Court case, Shirin H. Thobani, M.D.)
27. Your Druggist, Inc.
(Petitioner in companion case SC05-1191)

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INTRODUCTION

The Petitioner, B.A.L. Pharmacy d/b/a The Medicine Shoppe seeks review of an opinion from the Fourth District Court of Appeal in *Powers v. Thobani*, 903 So. 2d 275 (Fla. 4th DCA 2005) which certifies direct 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). In a companion case to this case (SC05-1191), Your Druggist has also sought review of the Fourth District Court of Appeal's opinion in *Powers*.

The Fourth District Court of Appeal's opinion in *Powers* reverses the trial court's final Order of dismissal with prejudice as to Powers' lawsuit against The Medicine Shoppe and Your Druggist.

The Petitioner, B.A.L. Pharmacy d/b/a The Medicine Shoppe, will be referred to as "The Medicine Shoppe." Your Druggist, will be referred to as "Your Druggist." Collectively, they will be referred to as "the pharmacies." Shirin Thobani, M.D., a Defendant in the trial court proceedings, but not a party to this appeal, will be referred to as "Dr. Thobani."

The Respondents, Robert Powers, as Personal Representative of the Estate of Gail Powers, Robert Powers, Patrick Powers and Rebecca Powers-Palmer will be referred to, collectively, as "Respondents." The decedent, Gail Powers, will be referred to as "Mrs. Powers."

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

On April 5, 2002, Gail Powers began treating with neurologist, Dr. Thobani, for neck and back pain. (R. 42-56). Over the next six months, Dr. Thobani saw Gail Powers on approximately 39 occasions, over which, she wrote approximately 118 prescriptions. (R. 45-46). The lawful prescriptions written by Dr. Thobani included OxyContin, Percocet, Soma and Xanax. (R. 45-46). On October 22, 2002, Mrs. Powers died. (R. 44). The medical examiner concluded that Mrs. Powers' death was caused by a combined drug overdose of OxyCodone and Diazepam. (R. 44).

The Respondents initially filed suit against The Medicine Shoppe, Your Druggist and Dr. Thobani on October 2, 2003. (R. 1-14). The initial complaint asserted negligence claims against both pharmacies for an alleged failure to warn of a number of risks, including the risks of addiction, potential for overdose, possibility of side effects and drug interactions. (R. 1-14). In response, both The Medicine Shoppe and Your Druggist filed motions to dismiss which asserted that Florida law does not recognize a claim for negligence where a pharmacy properly filled a valid and lawful prescription. (R. 15-19 & 20-24).

The trial court granted the motions to dismiss and entered an Order which stated:

Granted, as there is no cause of action as to liability of the Pharmacist(s) and/or Pharmacy Defendants in this action pursuant to Florida law. The Dismissal is without prejudice at this time, allowing Plaintiff twenty (20) days from the date of this Order to amend concerning the pharmacies, *if* such amendment can under the facts be done in good faith.

(R. 40-41) (emphasis in original).

On January 12, 2004, the Respondents filed an amended complaint with virtually the same allegations. (Compare R. 1-14 with R. 42 - 56). In the amended complaint, the Respondents alleged that The Medicine Shoppe owed the following duties to Mrs. Powers:

. . . to provide for the health, safety and welfare of its customers who had their prescriptions filled there commensurate with the prevailing professional standard of care. More specifically, the Defendant, The Medicine Shoppe, had a duty to review the decedent's patient record and each new and refill prescription presented by the decedent for dispensing in order to promote therapeutic appropriateness; by identifying whether the decedent was over-utilizing prescription drugs; identifying whether there was any therapeutic duplication being prescribed to the decedent; identifying any drug contraindications and/or interactions; identifying any incorrect duration of drug treatment being prescribed to the decedent; identifying any clinical abuse and/or misuse of prescribed drugs by the decedent. Further the defendant, The Medicine Shoppe, had a duty, upon recognizing any of the foregoing, to take appropriate

steps to avoid or resolve the potential problems which include consulting with the prescriber.

(R. 50).

Though raised on appeal, the Respondents did not allege, in either complaint, that the pharmacies owed any duty under Fla. Stat. chapter 465 or under the Florida Administrative Code.

Though it is alleged that The Medicine Shoppe and Your Druggist engaged in a pattern of filling prescriptions for Mrs. Powers, The Medicine Shoppe was only alleged to have filled the following seven prescriptions out of the total 118 prescriptions:

- 1) A prescription for 60 Percocet 10mg/325 mg on 8/2/02;
- 2) A prescription for 30 OxyContin 80 mg on 8/2/02;
- 3) A prescription for 60 Percocet 10mg/325 mg on 8/16/02;
- 4) A prescription for 30 OxyContin 80 mg on 8/16/02;
- 5) A prescription for 30 OxyContin 80 mg on 9/16/02;
- 6) A prescription for 30 OxyContin 80 mg on 9/20/02; and
- 7) A prescription for 60 Percocet 10mg/325 mg on 9/20/02.

(R. 47).

There is no allegation and no evidence in the record that The Medicine Shoppe failed to properly compound the prescribed drugs, failed to use due and proper care in filling the prescription, failed to use the proper methods in the compounding process, or that the drugs had been adulterated with some adulterating foreign substance. (R. 42-56).

Both pharmacies filed motions to dismiss the amended complaint based on the same grounds asserted in their previous motions. (R. 57-60 & 61-65). Following a hearing on those motions, the trial court, on April 27, 2004, entered an Order granting both motions and stated 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 562, 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 Amended Complaint fail to state legally cognizable claims.

(R. 70) & (A. 2).

On May 24, 2004, the Respondents filed a notice of appeal which sought appellate review, by the Fourth District Court of Appeal, of the final judgment of dismissal entered by the trial court. (R. 75). On July 27, 2004, the trial court entered a Final Judgment of Dismissal.¹ After the matter was fully briefed by the parties, the appellate court heard oral argument and subsequently issued an opinion reversing the trial court's final judgment of dismissal. (A. 1).

In its opinion, the appellate court held, for the first time in Florida, that:

A strong policy basis already exists supporting a pharmacist's duty to warn customers of the risks inherent in filling repeated and unreasonable prescriptions with potentially fatal consequences.

(A. 1).

In reversing the trial court, the appellate court further stated:

the trial court erred in dismissing the negligence claims against the pharmacies on a motion to dismiss. While we cannot say whether Powers' claims will necessarily survive a summary judgment motion or prevail at trial, we are unwilling to hold that under no set of alleged or discoverable facts could Powers sustain negligence claims against the pharmacies' motions to dismiss under Florida law.

(A. 1).

¹ The Final Judgment was obtained, upon Order of the District Court, after the filing of Respondents' notice of appeal.

The appellate court's opinion thus recognizes, for the first time in Florida, the numerous duties of a pharmacist alleged in the Respondents' amended complaint.

The appellate court opinion concluded with finding of direct conflict which stated as follows:

However, we recognize that our opinion in the instant case contradicts prior holdings by the first and fifth districts. *See Johnson v. Walgreen Co.*, 675 So. 2d 1036 (Fla. 1st DCA 1996); *Estate of Sharp v. Omnicare, Inc.*, 879 So. 2d 34, 35 (Fla. 5th DCA 2004). In *Johnson*, a case in which a prescription drug customer died from multiple-drug toxicity, the first district found no general duty to warn a customer or his physicians of potential adverse prescription drug reactions or potentially harmful drug interactions where the prescriptions were lawful and filled accurately, but in combination they had lethal effects. 675 So. 2d. at 1037. In *Estate of Sharp*, the fifth district held that a negligence action cannot be sustained against a pharmacy based upon alleged failure to review the customer's drug regimen on a monthly basis; or to account and reconcile the controlled drugs that were to be used by the customer; or to determine from her records that her drug regime was not effective in treating her conditions. 879 So. 2d at 36. We therefore certify conflict with *Johnson* and *Estate of Sharp*

(A. 1).

Both pharmacies then filed notices to invoke the discretionary jurisdiction of this Court. The case involving Your Druggist has been assigned case number SC05-1191.

BASIS FOR JURISDICTION

Pursuant to Article V, Section 3(b)(3) of the Florida Constitution, this Court has discretionary jurisdiction to “review any decision of a district court of appeal. . . that expressly and directly conflicts with a decision of another district court of appeal or of the supreme court on the same question of law.” The Fourth District certified conflict with the decision under review and the decisions in *Johnson* and *Estate of Sharp*. In addition to conflict with those cases, the Fourth District’s decision also misapplies and conflicts with this Court’s decision in *McLeod v. W.S. Merrell Company*, 174 So. 2d 736 (Fla. 1965). See *Ricks v. Rene Loyola, M.D.*, 822 So. 2d 502 (Fla. 2002) (A district court’s misapplication of an opinion from this Court provides this Court with jurisdiction, pursuant to Article V, Section 3(b)(3) of the Constitution, to review the lower court’s opinion); *Acensio v. State*, 497 So. 2d 640, 641 (Fla. 1986) (Same). In misapplying *McLeod*, the Fourth District has created new causes of action never intended by this Court. This Court should accept jurisdiction of this case and quash the Fourth District’s decision. If left intact, the Fourth District’s decision will cause significant harm. In *McLeod*, this Court set out four areas of implied warranties by a pharmacist presented with a

lawful prescription². *McLeod*, 174 So. 2d at 739. 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. This Court's opinion in *McLeod* stands for the proposition that a pharmacy must fill a lawful prescription in direct conformity with the prescription issued by the doctor. The four areas of duty set out by this Court in *McLeod* address the various actions which the pharmacist must accurately complete in **filling** a lawful and valid prescription. In other words, a pharmacist owes a duty to consumers to put the correct medication in the correct bottle with a correct label properly setting forth the physician's instructions.

The courts in the certified conflict cases, *Johnson* and *Estate of Sharp*, as well as the Fourth District's own decision in *Pysz*, all agree that a pharmacist's duty is to accurately and properly fill lawful prescriptions that are valid on their face. Those courts have concluded that this limited duty **does not include** a duty to check or warn for drug interactions or consult with the customer's prescribing physician on a lawful prescription.

² Florida courts have uniformly interpreted these areas of warranty as duties owed by the pharmacy when the Plaintiff has alleged a negligence claim against the pharmacy. *See Johnson, Pysz, and Estate of Sharp.*

In the opinion under review, the Fourth District erroneously relied on the second³ enumerated area of duty in *McLeod* in reaching its holding – concluding that the duty to properly fill a prescription includes a duty to warn consumers of the potential risks associated with the ingestion of drugs obtained pursuant to a valid and lawful prescription. The Fourth District’s decision is a clear misapplication of this Court’s holding in *McLeod* and thus vests this Court with jurisdiction. The Fourth District’s decision also conflicts with the decisions in *Johnson* and *Estate of Sharp*.

First, the Fourth District held that the Respondents stated a cause of action in alleging that The Medicine Shoppe had a duty to review Power’s patient record for therapeutic appropriateness of the medication prescribed by her doctor. This same duty was expressly rejected in both *Johnson* and *Estate of Sharp*. Second, the Fourth District held that Powers stated a claim in alleging that The Medicine Shoppe had a duty to identify, and presumably warn of, drug contraindications or interactions. This duty was also expressly rejected by the *Johnson* and *Estate of Sharpe* courts. Third, the Fourth District held that The Respondents stated a claim in alleging that the pharmacy had a duty to consult with Mrs. Powers’ prescribing physician concerning a lawful and valid drug prescription. Again, this duty also

³ The court below and the parties agree that the other three areas of duty set out in *McLeod* do not give rise to a duty on the part of the pharmacies in this case.

was expressly rejected by both *Johnson* and *Estate of Sharp*. Accordingly, this Court should exercise its jurisdiction to resolve these conflicts.

Moreover, this Court should accept jurisdiction to correct the Fourth District's erroneous and harmful expansion of *McLeod*. In *Hoffman v. Jones*, 280 So. 2d 431 (Fla. 1973), this Court made it abundantly clear that, while district courts are free to seek change by certifying to this Court questions of great public importance – and even to state their reasons for advocating change – the district courts are still bound to follow the common law as established by this Court. *Id.* at 434. “To allow a District Court of Appeal to overrule controlling precedent of this Court would be to create chaos and uncertainty in the judicial forum, particularly at the trial level.” *Id.* While the decision under review does not expressly overrule this Court's opinion in *McLeod*, it greatly expands the duties set forth therein, and thus has the same effect of creating great uncertainty as to a pharmacist's duty to his or her customer each time a lawful prescription is filled.

McLeod addressed this issue in the context of a products liability claim, and thus held that a pharmacist **does not warrant** the inherent fitness of a drug sold to a customer in conformity with a lawful and valid prescription. In the well-reasoned opinion in *Pysz v. Henry's Drug Store*, 457 So. 2d 561, 562 (Fla. 4th DCA 1984), the Fourth District itself expressly rejected the argument that this Court's holding in *McLeod* was distinguishable in a negligence action against a pharmacy

because *McLeod* was grounded in products liability rather than negligence. The *Pysz* Court found that this made no difference in determining that, based on *McLeod*, a pharmacist had **no duty to warn** a customer of such risks as the potential for addiction to a lawfully prescribed drug. In addition, neither the *Johnson* nor *Estate of Sharp* court found this to be a distinguishing factor. The decision under review erroneously expands *McLeod*, which, until now, has uniformly been interpreted to stand for the proposition that a pharmacy, in the context of a negligence claim, has no duty to warn a customer of the potential risks associated with a lawfully prescribed medication. Accordingly, this Court should accept jurisdiction to quash the decision under review.

Finally, this Court should exercise its jurisdiction and quash the opinion below because of the broad reaching consequences of that decision on the filling of each and every prescription in the State of Florida, a significance previously acknowledged by this Court in *McLeod*. Prior to the issuance of the opinion under review, there was uniformity and certainty among the courts in this State in that there was no duty for a pharmacy to warn a customer of any risks associated with drugs dispensed pursuant to a lawful prescription that is valid on its face. The opinion under review has created great uncertainty and conflict throughout the state as to what a pharmacies' duties now are when filling each and every

prescription. Thus, action by this Court is needed to resolve this important and far-reaching issue.

SUMMARY OF THE ARGUMENT

The Fourth District's creation of a duty requiring pharmacies and pharmacists to warn customers of the risks associated with a drug dispensed pursuant to a valid and lawful prescription conflicts with this Court's opinion in *McLeod*, the First District's opinion in *Johnson* and the Fifth District's opinion in *Estate of Sharp*. There is no basis in Florida law, either statutory, administrative or in common law for such a cause of action against pharmacies or pharmacists.

Moreover, the opinion below is contrary to the trend in American jurisprudence. An overwhelming majority of states have held that no such duty exists on the part of pharmacies and pharmacists, and many of those states have relied on this Court's opinion in *McLeod* and the Fourth District's opinion in *Pysz* in reaching that conclusion.

Prior to the Fourth District's opinion below, Florida courts uniformly placed the responsibility on a patient's prescribing physician to warn of the risks associated with ingesting a prescribed drug. The Fourth District's opinion below will do great harm to the physician-patient relationship, in that it will require pharmacies to second guess a customer's treating physician. Moreover, the pharmacy will be required to do this without the necessary training or education, without a physical exam of the customer or a review of the customer's medical records, without knowledge of whether the customer has purchased other

prescription drugs at other, non-affiliated, pharmacies, and most importantly, often without ever speaking with the customer who sends a friend or relative to pick up their prescription. As has been concluded by numerous other jurisdictions, insuring that patients are prescribed the appropriate medication and that they are aware of the risks in taking that medication is a job best left solely to the patient's treating physician.

Accordingly, The Medicine Shoppe respectfully requests that this Court quash the opinion of the Fourth District and approve the opinions of the First and Fifth Districts.

STANDARD OF REVIEW

The duty element of negligence is a question of law. *McCain v. Fla. 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 Ass'n, 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).

ARGUMENT

I.

THERE IS NO BASIS IN FLORIDA LAW FOR THE FOURTH DISTRICT'S HOLDING IN THE CASE BELOW THAT A PHARMACY CUSTOMER CAN STATE A CAUSE OF ACTION FOR NEGLIGENCE AGAINST THE PHARMACY WHERE THE PHARMACY HAS PROPERLY FILLED A LAWFUL AND VALID MEDICAL PRESCRIPTION.

- A. Chapter 465 of the Florida Statutes and Florida Administrative Code sections 64B16-27.300 and 64B16-27.820 do not provide a valid basis for the lower Court's holding.

The Fourth District based its creation of a new cause of action against **pharmacies** for failure to warn on the rationale that **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.” The Fourth District cites to Section 465.003(6), Florida Statutes, and Florida Administrative Code Rules 64B16-27.820 ("Patient Counseling") and 64B16-27.300 (Continuous Quality Improvement), in support of its conclusion. The Fourth District's reliance on this law is misplaced for two reasons. First, contrary to the Fourth District's conclusion, this law does not require a duty to

warn such as that which was imposed by the Fourth District. Second, as the Fourth District conceded, this law does not create any cause of action against pharmacies.

Section 465.003(6) is a definitional statute, which defines the term “dispense.” Although the definition of the term “dispense” includes a provision requiring a pharmacist to interpret and assess prescription orders and to provide counseling on proper drug usage, the definition specifically provides that such counseling is only triggered if the pharmacist believes it to be necessary in his or her professional judgment. Moreover, Section 465.003(6) must be read in context with the patient counseling rule, Rule 64B16-27.820, which provides that, even when a pharmacist believes such counseling is necessary, it is the patient’s decision to decide whether that counseling is to occur. In relevant part, the patient counseling rule provides:

(1) Upon receipt of a new or refill prescription, **the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present.** If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. **If the patient does not refuse such counseling, the pharmacist,** or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist; **shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient.** Such discussion shall be in person, whenever practicable, or by toll-free telephonic communication and shall include appropriate elements of patient counseling.

Fla. Admin. Code R. 64B16-27.820 (emphasis added).

Under this rule a pharmacist's obligation is to make a verbal and written **offer to counsel**. The patient counseling rule states that the pharmacist **only** has to review the patient's record and counsel the patient if the patient wants such counseling. Plaintiffs have not alleged that the defendant pharmacies failed to make the offer to counsel Mrs. Powers or her agent. Nor have they alleged that she or her agent accepted any such offer. **A pharmacist has no obligation to provide counseling where the patient or the patient's agent refuses the offer.**⁴

Under the rule, it is abundantly clear that the pharmacist has no obligation to undertake counseling if the patient refuses it. Intuitively, this makes perfect sense. Pharmacists, who dispense hundreds of prescriptions every day, should not have to undertake a review of a patient's record and provide counseling if the patient does not want the service. Thus, not only do regulatory statutes and rules not create any cause of action for failure to warn, even if they did, under the allegations in the complaint, there is no allegation sufficient to allow a fact-finder to conclude that the asserted duty was triggered in this case.

⁴ This applies equally to the drug utilization review required by Rule 64B16-27.810.

Moreover, like Section 465.003(6), Rule 64B16-27.820 leaves the decision of what medical issues to address to the professional judgment of the pharmacist.⁵ Assuming for the sake of argument that Mrs. Powers or her agent triggered the patient counseling statute by not refusing counseling, because Ms. Powers was under the care of a physician for on-going pain management, and because none of the factors that pharmacists must consider for dispensing controlled substances for pain under Rule 64B16-27.831 were present, it certainly would be reasonable for a pharmacist, in his or her professional judgment, to conclude that such counseling was unwarranted. Under such circumstances, the pharmacists reasonably could have determined there was no need to counsel the patient on these prescriptions, and thus a duty to warn would not have arisen.

Perhaps equally as important, this cause of action was filed against the pharmacies, not the individual pharmacists. Apparently, the Fourth District failed to recognize that the above cited statute and rules apply to pharmacists, not pharmacies, which are governed by wholly distinct rules. *See Fla. Admin. Code Ch. 64B16-28.* The Board of Pharmacy has acted carefully in crafting separate rules governing pharmacists and pharmacies and has made the rules governing patient counseling applicable only to pharmacists. Thus, even if such rules

⁵ In listing the elements to be discussed by the pharmacist during patient counseling, the Patient Counseling Rule states: "Such elements may include, in the professional judgment of the pharmacist, the following:" Rule 64B16-27.820(1).

imposed duties for pharmacists for the purpose of creating a cause of action, the pharmacies would be liable only if they somehow assumed that duty or actively interfered with the pharmacist's professional judgment. Plaintiffs have alleged no facts to support either situation.

In addition to erroneously interpreting the law governing pharmacies and pharmacists, the Fourth District erred in concluding this law supports imposing a new cause of action against pharmacies for failure to warn. It is uncontroverted that Chapter 465 of the Florida Statutes does not create a private cause of action against pharmacies. The Fourth District acknowledged this interpretation of Chapter 465 in its opinion below. Likewise, the *Johnson* court reached the same conclusion, finding that Section 465.003(5), Florida Statutes (Supp. 1986),⁶ is merely a regulatory statute and thus, under this Court's holding in *Murthy v. Sinha Corp.*, 644 So. 2d 983 (Fla. 1994), does not provide a basis for a private cause of action. *Johnson*, 675 So. 2d at 1038. The *Johnson* court further analyzed the statute's legislative history and concluded that it was devoid of any indication that the Legislature intended to create a private cause of action against pharmacists. *Id.*

⁶ Section 465.003 has since been amended. The only difference, for purposes of this argument, is that the statute was renumbered, so that the relevant subsection is now §465.003(6) and the last sentence of the subsection was later added. The additional sentence states "The administration shall not be considered dispensing." The amendment to the statute does not affect the validity of the holding in *Johnson*.

Notwithstanding the Fourth District's acknowledgement that Chapter 465 does not create a private cause of action, it proceeded with the creation of a new cause of action which has resulted in the creation of numerous new duties, which require pharmacies and pharmacists to warn customers of the risks associated with the ingestion of drugs dispensed pursuant to lawful and valid prescriptions.

Florida courts recognize a duty if the plaintiff suffered the type of injury that the statute was designed to protect. *Chevron U.S.A., Inc. v. Forbes*, 786 So.2d 1215, 1220 (Fla. 4th DCA 2001). No connection exists between the purpose of Chapter 465 and the damages incurred by Powers. Chapter 465 is nothing more than a licensing statute, meant to keep pharmacists who are not properly licensed from practicing. *McFarland & Son, Inc. v. Basel*, 727 So. 2d 266 (Fla. 5th DCA 1999) (the simple violation of a licensing statute, unless the violation can be shown to be directly related to the incident, is not proof of negligence). Chapter 465 does not impose any new standards of care upon pharmacists that exceed those imposed by the common law. There is no allegation in the instant case regarding the unlicensed practice by a pharmacist, and there is no allegation that the pharmacies in this case failed to comply with the law. Thus, Chapter 465 does not apply to this case.

Moreover, a licensing statute is typically enacted to protect the public in general. *Florida Industrial Com. v. Schoenberg*, 117 So.2d 538, 543 (Fla. 3d DCA

1960). Legislative enactments for the benefit of the general public do not create a duty of care owed to individuals who happen to benefit from the statutory provisions. *Holodak v. Lockwood*, 726 So. 2d 815, 816 (Fla. 4th DCA 1999); *Grand Union Co. v. Rucker*, 454 So. 2d 14, 16 (Fla. 3^d DCA 1984). Here, the statute does not protect any specific group of people, such as children. Rather, this statute licenses qualified pharmacists to ensure that *all* Florida citizens are served by licensed pharmacists. This analysis coincides with decisions from other states rejecting the argument that statutes regulating *pharmacists* impose a duty of care. See *Moore v. Memorial Hosp.*, 825 So. 2d 658, 665-666 (Miss. 2002); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W. 3d 455, 466-467 (Tex. Ct. App. 3d Dist. 2000); *Fakhouri v. Taylor*, 618 N.E. 2d 518, 521 (Ill. App. Ct. 1999); *Chamblin v. K-Mart Corp.*, 612 S.E. 2d 25 (Ga. Ct. App. 2005). Accordingly, Chapter 465 of the Florida Statutes and Florida Administrative Code sections 64B16-27.300 and 64B16-27.820 do not provide a basis for the new, private cause of action created by the lower court, and the lower court's decision must therefore be quashed.

B. The duty for managing pain such as that which Mrs. Powers was being treated for rests with the physician.

Respondents' case rests almost exclusively on the types of drugs prescribed in this case for pain management and the frequency with which those drugs were prescribed and filled. Florida law clearly places legal responsibility **solely on**

physicians, not pharmacies or pharmacists, for the management of care for patients receiving controlled substances for pain. Section 458.326(3), Florida Statutes, provides:

Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person for the treatment of intractable pain, **provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician** under similar conditions and circumstances.

(Emphasis added.) In furtherance of this statutory responsibility placed on physicians, the Florida Board of Medicine has directed physicians, in prescribing controlled substances for pain, to provide “effective pain management” as a part of “quality medical practice” for all patients (such as Ms. Powers) with acute or chronic pain. Fla. Admin. Code R. 64B8-9.013 (2002).

Physicians often must increase the frequency and amount of pain medications to attempt to control pain experienced by patients like Mrs. Powers. To address concerns that prescribing controlled substances for such pain management might subject physicians to discipline, the rule was drafted to provide that physicians “should not fear disciplinary action or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose.” Fla. Admin. Code R. 64B8-9.013(1)(b).

Physicians also are instructed to follow United States Agency for Health Care Policy and Research Clinical Practice Guidelines on acute and cancer-related pain. The findings in those Guidelines provide:

- Giving patients pain medicine only “as needed” can result in prolonged delays because patients may delay asking for help.
- Aggressive prevention of pain is better than treatment because, once established, pain is more difficult to suppress.
- Patients have a right to treatment that includes prevention of or adequate relief from pain.
- Physicians need to develop pain control plans before surgery and inform the patient what to expect in terms of pain during and after surgery.
- Fears of postsurgical addiction to opioids are generally groundless.⁷

Recognizing that patients such as Mrs. Powers often need more pain medications on a more frequent basis, the rule also states that the Board will evaluate the physician’s activities based on the “treatment outcome,” rather than the “quantity and chronicity of prescribing.” Fla. Admin. Code R. 64B8-9.013(g). Thus, even when physicians’ actions are reviewed, it is not the quantity and chronicity of prescribing that is the determinative issue – it is the treatment outcome.

⁷ Rule 64B8-9.013(1)(c) directs physicians to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines. At the time, these guidelines were summarized in the following document: Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. (March 5, 1992). Accessible at: <http://www.ahrq.gov/clinic/medtep/acute.htm> (last accessed September 6, 2005)

The Board's rule also employs "guidelines" requiring the physician to obtain the pain patient's "Informed Consent and Agreement for Treatment." Fla. Admin. Code R. 64B8-9.013(3)(c). The physician is responsible for discussing the risks of treatment with the patient and advising the patient to use only one pharmacy. These duties lie solely with the physician. If a patient is determined to be at "high risk for medication abuse or [has] a history of substance abuse, the physician may employ a written agreement between the physician and patient outlining [the] patient responsibilities" including those responsibilities for the "number and frequency of all prescription refills." Fla. Admin. Code R. 64B8-9.013(3)(c)3.

In managing the treatment for pain patients, the physician also is required to consider whether "extra care, monitoring, documentation, and consultation" with an expert on pain management is required. Fla. Admin. Code R. 64B8-9.013(3)(e). Additionally, physicians are required to undertake a periodic review of the patient's treatment, which includes a decision as to whether this treatment should be continued or modified. Physicians are required to monitor the patient's compliance to medication usage and related treatment plans.

The Board of Pharmacy also has adopted a rule addressing standards of practice for "dispensing controlled substances for the treatment of pain." Fla. Admin. Code R. 64B16-27.831. Unlike the Board of Medicine's rule, which is intended to guide physicians in their management of the treatment of patients in

pain, the clear gist of the Board of Pharmacy's rule is to guide pharmacists in the prevention of theft and diversion of controlled substances and to establish procedures for the reporting of controlled substance dispensing for law enforcement purposes.

- Frequent loss of controlled substance medications
- Only controlled substance medications are prescribed for a patient
- One person presents controlled substance prescriptions with different patient names
- Same or similar controlled substance medication is prescribed by two or more prescribers at the same time
- Patient always pays cash and always insists on brand name product

As these factors illustrate, the duties imposed on physicians and pharmacists in the realm of controlled substances are completely different: Physicians are charged with treating and monitoring the patient and warning the patient as to adverse effects, while the pharmacists' role is that of a drug diversion watchdog.

Importantly, the Board of Pharmacy's rule on pain medications, like the Board of Medicine's rule, also includes language indicating that **a pharmacist should not fear disciplinary or enforcement action for dispensing controlled substances for a legitimate medical purpose.** Thus, absent the factors listed in the rule showing that the prescription was not for a legitimate purpose, the pharmacist would have no reason to question the prescription. **None of the factors**

set forth in the rule were present in this case. Moreover, even if such factors were present, the pharmacist's duty is not one of warning the patient.

C. Public policy overwhelmingly supports reversal of the Fourth District's decision.

Important reasons exist for distinguishing between the duties of physicians and pharmacists. In the vast majority of cases, the pharmacist does not know the patient's medical condition or diagnosis. There is no requirement for prescriptions to reveal the diagnosis (and they rarely do). § 456.42, Fla. Stat. A pharmacist does not know why certain medications were prescribed and has no idea whether the patient is going to one pharmacy or many (as Mrs. Powers did in this case). The pharmacist has no knowledge as to whether an Informed Consent and Agreement for Treatment has been entered or what responsibilities the patient has assumed. Additionally, because the pharmacist is unaware of the patient's condition or treatment, the pharmacist has no way of monitoring a patient's compliance with the treatment. In fact, frequently, the patient is not the one picking up the prescription – it is the patient's spouse, parent, child, or other agent.

Even though physicians are specifically authorized, and indeed encouraged, to prescribe pain medications on a frequent basis when needed for a particular treatment, the Fourth District Court of Appeal would require pharmacists to second-guess those decisions and to warn patients **that following their doctors'**

instructions could adversely affect them. As the record in this case reflects, all of the prescriptions dispensed to Ms. Powers were **original written prescriptions**, each separately authorized by the same doctor, Dr. Thobani – they were not refills.⁸ Under such circumstances, the pharmacist should be able to presume the physician knows how to best treat the patient, and the pharmacist should not be required to interfere in that treatment – especially where the pharmacist has no information regarding why the drug was prescribed or for what the drug is being used to treat.

It is wholly inappropriate to use 20:20 hindsight to impose a duty on pharmacists to warn when (1) the entire regulatory scheme places the responsibility for management of patients and their pain drugs on the physician, and (2) that same physician is encouraged to provide large and frequent amounts of these pain medicines to these patients when needed to assist them to cope with their pain. It is untenable to require pharmacists to second-guess a physician when the pharmacist does not know the patient’s medical condition, the physician is totally responsible for managing the patient’s pain treatment, and the pharmacist has no knowledge of the scope of that treatment. This is especially true in a case such as this one where, because the patient was using at least two pharmacies, the

⁸ 21 CFR 1306.11 and 21 CFR 1306.22 respectively require that schedule II controlled substance prescriptions be in writing and prohibit refills of such prescriptions.

pharmacists could not possibly know all of the drugs the patient was taking or how many other pharmacies the patient was using.

In essence, because the pharmacist has such woefully inadequate knowledge of when and how to exercise the duty to warn imposed by the Fourth District Court of Appeal, the pharmacist's only alternative would be to call the patient's physician and ask: "Did you REALLY mean to prescribe this medication?" Given the hundreds of prescriptions dispensed each day by pharmacists, each prescription would be delayed while the pharmacist reviews each patient's history, contacts the patient's doctor, and waits to dispense the medication until the patient is properly advised. This, in turn, would delay all prescriptions for all patients. This would also be an incredible burden on physicians, who would be required to double-check medical records each time a pharmacist made an inquiry. This cannot be the intent of the Florida legislature and the Board of Medicine, which have clearly and completely placed the legal duty and responsibility on the physician for providing, supervising, managing, consulting and directing all facets of the care of the patient receiving pain medication.

This conclusion is bolstered by the fact that, under circumstances not present here, there are situations where a pharmacist can assume a greater responsibility in assisting with managing the therapy of a patient. In 1999, the Florida Legislature expanded the definition of the "Practice of the Profession of Pharmacy" to include

“other pharmaceutical services,” which were intended to allow pharmacists to provide professional health care services beyond mere dispensing. § 118, Ch. 99-397, Laws of Fla. The new language states that the practice of the profession of pharmacy includes:

other pharmaceutical services. For purposes of this subsection, “other pharmaceutical services” means the monitoring of the patient’s drug therapy and assisting the patient in the management of his or her drug therapy, and **includes review of the patient’s drug therapy and communication with the patient’s prescribing health care provider** as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider’s agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, **nothing in this subsection may be interpreted to permit an alteration of a prescriber’s directions**, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law.

Id. (Emphasis added.)

Under this provision, when a pharmacy chooses to undertake such drug therapy management activities, the pharmacy takes on the responsibility of reviewing the patient’s drug therapy and communicating with the physician regarding that therapy. While the legislature has authorized pharmacists to monitor and manage the patient’s drug therapy as part of this expanded practice of pharmacy, the Board of Pharmacy has recognized that a pharmacist will usually need much more patient health information and physician cooperation to be able to adequately and effectively manage the patient’s drug therapy. To that end, the Board of Pharmacy

has adopted a standard of practice as to when and under what conditions a pharmacist may engage in such drug therapy management activities. Fla. Admin. Code R. 64B16-27.830.

Specifically, the pharmacist must have in place a “prescriber care plan” **written by a physician**, which sets forth the pharmacist’s duties as to the monitoring and management of the patient’s drug therapy. The pharmacist also must establish a “pharmaceutical care area” separate from the rest of the pharmacy so the pharmacist may sit down with the patient and review the patient’s therapy. Finally, the pharmacy must adopt a continuous quality improvement program designed to evaluate and improve the drug therapy management services.

In this case, the pharmacists and pharmacies did not choose to take any of the regulatory steps required for them to be responsible for the management of Ms. Powers’ drug therapy. There is nothing in the record to suggest that her physician authorized the pharmacists to manage her drug therapy. At all times, her physician remained the professional responsible for her pharmaceutical care.

In imposing a duty to warn, the Fourth District cited to only one pharmacy statute in isolation – it did not consider the overall regulatory scheme for pain management. As the above discussion illustrates, where a pharmacy has not undertaken to manage a patient’s drug therapy and has properly filled a prescription that is valid on its face, it is inappropriate to expand this Court’s

decision in *McLeod*. This Court should therefore quash the lower court and find that this case has not distinguished precedent which holds that pharmacists do not have a duty to warn.

II.

THE CASE LAW RELIED ON BY THE LOWER COURT DOES NOT SUPPORT ITS HOLDING

A. The opinion of the lower court is contrary to this court's holding in *McLeod v. W.S. Merrell Company*, 174 So. 2d 736 (Fla. 1965) and thus the lower court's opinion must be quashed

In *Hoffman v. Jones*, 280 So. 2d 431 (Fla. 1973), this Court made it abundantly clear that, while district courts were free to seek change by certifying, to this Court, that questions at issue were of great public importance, and even to state their reasons for advocating change, the district court was still bound to follow the case law set forth by this Court. *Id.* at 434. "To allow a District Court of Appeal to overrule controlling precedent of this Court would be to create chaos and uncertainty in the judicial forum, particularly at the trial level." *Id.* While the opinion in the *Powers* case below does not expressly overrule this Court's opinion in *McLeod*, it does conflict with the holding in *McLeod*, and thus has the same effect in creating great uncertainty as to a pharmacist's duty to his or her customer each time a lawful prescription is filled.

The *McLeod* case involved a lawsuit against two pharmacies for injuries arising out of the adverse side effects from a prescription drug. It was alleged by the Plaintiff in *McLeod* that “[t]here was no warning by any of the respondents suggesting a possible inherent danger in the use of the drug.” *McLeod*, 174 So. 2d at 738. In rejecting the validity of this allegation, this Court focused on the fact that the drug was available only with a prescription, the pharmacist had filled the prescription with the prescribing doctor’s directions and in the manufacturer’s original packaging, the pharmacist had not adulterated the prescribed drug, and both the customer and the pharmacist relied on the doctor’s prescription and not the judgment of the pharmacist. *Id.*

With this factual background, this Court recognized four limited duties owed by a pharmacist to his or her customer, all based on insuring that the pharmacist put the correct drug in the correct bottle when filling a lawful and valid prescription. When these duties are read in context, it is clear that the Fourth District erred in relying on the second duty enumerated by this Court in *McLeod* and set out below:

The rights of the consumer can be preserved, and the responsibilities of the retail prescription druggist can be imposed, under the concept that a druggist who sells a prescription warrants that (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.

McLeod, 174 So. 2d at 739 [emphasis supplied by Fourth District in *Powers*, 903 So. 2d at 278] When the second duty, enumerated above, is read in context with the factual background of the case and the other three duties set out by the Court, it is clear that *McLeod* dealt solely with making sure that the pharmacy accurately followed the instruction of the prescribing physician. This is further made clear by the fact that this Court referred to “filling prescriptions” and not consulting with, or warning customers. The reference to “filling prescriptions” clearly limits the duty of the pharmacy to insuring that the medication prescribed by the doctor is correctly and accurately placed in a bottle for sale to the customer.

It is also clear from the context of the holding in *McLeod* that this Court’s reference to the fact that a pharmacy’s failure to use due and proper care in filling a prescription may also be the subject of a negligence action is merely a reference to the fact that the Plaintiff’s claim in *McLeod* was couched in terms of products liability and not negligence. In other words, under the second duty enumerated in *McLeod*, a pharmacy customer may bring a negligence action if the pharmacy fails to accurately fill the prescription in conformity with a valid and lawful prescription issued by the customer’s treating physician. Accordingly, the Fourth District’s interpretation of the second duty, enumerated by this Court in *McLeod*, to include a

duty to warn of various dangers associated with the ingestion of the valid and lawfully prescribed drugs was error and should be quashed.

B. The opinion in *Dee v. Wal-Mart Stores, Inc.*, 878 So. 2d 426 (Fla. 1st DCA 2004) does not apply to this case.

The decision in *Dee* does not support the creation of a duty for pharmacies or pharmacists to warn customers of the potential risks associated with the ingestion of drugs purchased pursuant to a lawful and valid prescription, and thus does not support the lower court's holding. The opinion in *Dee* is consistent with the holdings in *McLeod*, *Pysz* and *Johnson*, and thus, the lower court's reliance on *Dee* in support of its holding is misplaced.

In *Dee*, the First District Court of Appeal reversed the trial court's dismissal of a complaint against a pharmacy where the complaint asserted that the pharmacy was negligent for filling a prescription that did not have an expiration date. Under the circumstances in *Dee* the pharmacist could not determine from the face of the prescription, whether the prescription was valid, and thus, the Court held that the pharmacist had a duty to use due and proper care and inquire of the prescribing physician as to the validity of the prescription. *Dee*, 878 So. 2d at 427. Clearly, this made the prescription in *Dee* invalid on its face.

Unlike the new expansive duties created by the Fourth District in the *Powers* case, all of which would require the pharmacist to second guess the prescribing

physician, the holding in *Dee* did not expand the duties of a pharmacy, but rather affirmed that a pharmacy has a duty to insure that drugs are dispensed only when there is a valid prescription from the customer's physician. The Respondents in the instant case have not asserted, nor is there any indication in the record, that the prescriptions filled by The Medicine Shoppe were in any way invalid. Accordingly, the holding in *Dee* does not support the creation of new duties to warn on the part of a pharmacy and therefore does not support the holding of the lower court.

C. The case law from other jurisdictions cited by the lower court does not support the holding below and does not accurately portray the national trend on this issue.

The overwhelming majority of case law from around the country holds, like *McLeod*, that a pharmacy's only duty is to insure that prescription drugs are dispensed in conformity with the lawful and valid prescription issued by the customer's medical doctor. In fact, many of these cases from other jurisdictions rely on this Court's holding in *McLeod* and the Fourth District's holding in *Pysz* in holding that a pharmacy has no duty to warn its customers of the potential risks associated with ingesting a drug dispensed pursuant to a lawful and valid prescription. *Cottam v. CVS Pharmacy*, 764 N.E.2d 814 (Mass. 2002) (citing *Pysz*); *Jones v. Irvin*, 602 F. Supp. 399 S. D. Ill. 1985 (citing *Pysz*); *Eldridge v. Eli Lilly & Company*, 485 N.E.2d 551 (Ill. Ct. App. 1985) (citing *Pysz*); *Moore v.*

Memorial Hospital, 825 So. 2d 658 (Miss. 2002) (citing *Johnson*); *Adkins v. Mong*, 425 N.W. 2d 151 (Mich. Ct. App. 1988) (citing *Pysz*); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) (citing *Pysz*); *Nichols v. Central Merchandise, Inc.*, 817 P. 2d 1131 (Ka. Ct. App. 1991) (citing *Pysz*); *Batiste v. American Home Products Corp.*, 231 S.E.2d 269 (N.C. Ct. App. 1977) (citing *McLeod*); *Coyle v. Richardson-Merrell, Inc.*, 584 A. 2d 1383 (Pa. 1991) (citing *McLeod*); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455 (Tex. Ct. App. 2000) (citing *Pysz*); *McKee v. American Home Products Corp.*, 782 P.2d 1045 (Wash 1989) (citing *Pysz*); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P. 3d 922 (Utah 2003); *Raynor v. Richardson-Merrell, Inc.*, 643 F.Supp 238 (D. Dist. Columbia 1986); *Bichler v. Willing*, 397 N.Y.S.2d 57 (N.Y. App. Div. 1977). Like *McLeod* and *Pysz*, the overwhelming majority of states, in the cases cited above, limit the Pharmacies' duty to insuring that the lawful and valid prescription is filled in compliance with the instructions of the prescribing physician.

Instead of selecting out-of-state cases which reflect the national trend on this issue, the foreign case law cited in the opinion below represents those cases with unique circumstances where very narrow exceptions to the general rule have been applied and thus the cases have no application to the instant case. Moreover, in some instances, the out-of-state cases cited by the court below are of questionable precedential value.

In *Riff v. Morgan Pharmacy*, 508 A. 2d 1247 (Pa. Super. Ct. 1986), a pharmacy was held to have had a duty to consult with the customer's prescribing physician where the prescription presented to the pharmacy by the customer's husband did not authorize refills and, instead of indicating the maximum dosage in a 24 hour period, simply authorized a dosage every four hours. Much like the facts in *Dee* where the prescription was missing a necessary expiration date, the information missing from the prescription in *Riff* rendered the prescription defective on its face, as the prescribed drug could not be accurately dispensed without the missing information. Subsequently, the pharmacy in *Riff*, at the request of the customer's husband, refilled the prescription on four separate occasions with the doctor's authorization and the patient was injured from the long-term, improper use of the drug. The *Riff* opinion is entirely inapplicable to the instant case, as there is no allegation that the prescriptions filed for Mrs. Powers by The Medicine Shoppe were, in any way, defective.

Moreover, cases in Pennsylvania decided after *Riff*, including the Pennsylvania Supreme Court's opinion in *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383 (Pa. 1989), which relied on *McLeod*, have narrowed the applicability of *Riff* to its facts, and found that pharmacies do not have a general duty to warn. See *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374 (Pa. Super Ct. 1987) (citing the *McLeod* standards as support; finding that a retail pharmacist does not

have an independent duty to warn the patient-consumer of all possible adverse consequences associated with a drug); *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986) (specifically adopting the standard set forth in *McLeod*). In fact, in *Coyle* the Pennsylvania Supreme Court refused to find that pharmacists have an independent duty to warn of the dangerous characteristics of the prescription drugs they dispense. *Coyle*, 584 A.2d at 214-15. In addition, the Pennsylvania Supreme Court acknowledged that “such a rule would have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing.” *Id.* at 215. Clearly, the opinion in *Riff* does not represent a national trend on this issue, but rather addressed an unusual and completely different set of circumstances from that found in the instant case and thus *Riff* does not provide a valid basis for the holding below.

The Fourth District’s reliance below on *Lasley v. Shrake’s Country Club Pharmacy, Inc.*, 880 P. 2d 1129 (Ariz. Ct. App. 1994) is particularly curious given that the facts in *Lasley* are indistinguishable from the facts in the Fourth District’s opinion in *Pysz*. Both *Lasley* and *Pysz* involved customers who, over the course of nine or ten years, had repeatedly presented to the defendant pharmacy, lawful and valid prescriptions for drugs that had the propensity to be highly addictive. *Pysz*, 457 So. 2d at 561 and *Lasley*, 880 P. 2d at 585. The Plaintiff in each case sued the

pharmacy where they had their prescriptions filled and alleged that the pharmacy was negligent in failing to warn of the danger of addiction to the prescribed drug.

In *Pysz*, the Fourth District held that the pharmacist had no duty to warn because “. . . it is the physician who has the duty to know the drug that he is prescribing and to properly monitor the patient.” *Id.* at 562. While, in *Lasley*, the Arizona intermediate appellate court held that it was an issue of fact as to whether the pharmacist owed a duty. Inexplicably, the Fourth District, in its opinion below, found that it was not bound by its own holding in *Pysz* because the facts in the instant case are different, yet relied on *Lasley* in holding that Powers had stated a cause action against The Medicine Shoppe for failure to warn. One would expect that, if *Pysz* is inapplicable to the instant case based on its facts, then *Lasley* would also be inapplicable to the instant case, because its facts are the same as those found in *Pysz*. Accordingly, *Lasley* does not support the creation of a new duty and thus is not a sound basis for the holding below. If *Pysz* is analogous to the instant case, its holding should have binding on the Fourth District in the instant case

The next case relied on by the Fourth District in its opinion below, *Horner v. Spalitto*, 1 S.W.3d 519 (Mo. Ct. App. 1999) is also clearly distinguishable. *Horner* was decided under Missouri law, which unlike Florida law, provides a statutorily based private cause of action against a pharmacist for failure to warn of the risks

associated with the ingestion of a prescription drug taken pursuant to a lawful and valid prescription. As set out in the *Horner* opinion, Mo. Rev. Stat. § 538.205(4) (1994), contains a definition of health care provider which includes pharmacists and Mo. Rev. Stat. § 538.210.1 (1994) creates a private cause of action against health care providers for “. . . damages for personal injury or death arising out of the rendering or the failure to render health care services. *Horner*, 1 S.W.3d at 523. Missouri statutes also set out the pharmacists’ duty as a health care provider. *See Horner*, 1 S.W.3d at 523 *citing* Mo. Rev. Stat. § 538.225.1. This statutory framework clearly places the State of Missouri in the minority on the issue of a pharmacy and/or pharmacists’ duties to their customers and also renders *Horner* and Missouri law entirely inapplicable to the instant case, as there is no analogous statutory framework in Florida. Accordingly, the lower court’s reliance on *Horner* was misplaced and does not support the lower court’s holding.

The decisions in *Pittman v. The Upjohn Company*, 890 S.W.2d 425 (Tenn. 1994) and *Dooley v. Everett*, 805 S.W.2d 380 (Tenn. Ct. App. 1990), which both interpret Tennessee law, are also distinguishable from the instant case and thus do provide valid support for the opinion below. Both *Pittman* and *Dooley*, utilized the Tennessee statutes⁹ which regulate the practice of pharmacy in creating a cause of

⁹ *Pittman* and *Dooley* relied on Tenn. Code Ann. § 63-10-102 (1990) and § 63-10-101 (1990) respectively. Since the decision in each case, the Tennessee Legislature has renumbered and revised the code regulating pharmacists, beginning at Tenn. Code Ann. § 63-10-201 et. seq.

action against pharmacies and/or pharmacists which included a duty to warn of the risks associated with ingesting medication obtained pursuant to a lawful and valid prescription. Clearly, Florida law does not permit reliance on regulatory statutes for the creation of a private cause of action, and thus both *Pittman* and *Dooley* are distinguishable from the instant case. See *Murthy v. Sinha Corp.*, 644 So. 2d 983 (Fla. 1994) and *Johnson*, 675 So. 2d at 1038. Accordingly, the lower court's reliance on *Pittman* and *Dooley* was misplaced and does not support the lower court's holding.

The final case cited by the court below, *Heredia v. Johnson*, 827 F.Supp. 1522 (D. Nev. 1993), aside from being in a very small minority of cases which find a duty to warn on the part of the pharmacy, utilizes extremely suspect logic in arriving at that conclusion. *Heredia* was decided by the Federal District Court of Nevada. At the time of the opinion, the issue of whether a pharmacy has a duty to warn a customer of the risks associated with taking medication obtained pursuant to a lawful and valid prescription was a question of first impression, and a question that remains unanswered by the Nevada state courts. Consequently, the *Heredia* Court turned to the Washington Supreme Court's opinion in *McKee* for guidance on the issue of the extent of a pharmacies' duty to its customers. In doing so, the *Heredia* court set out what it perceived to be the holding in *McKee* as follows:

While a generalized duty to warn has been held to be inappropriate in some jurisdictions, generally a pharmacist has a duty to exercise due care in filling prescriptions. At a minimum, a pharmacist must be held to a duty to fill prescriptions as prescribed and properly label them (**include proper warnings**) and be alert for plain error. See *McKee v. American Home Products Corp.*, 782 P. 2d 1045 (Wash. 1989)

Heredia, 827 F. Supp at 1525. [emphasis added]

The inclusion of the phrase “include proper warnings” by the court in *Heredia* blatantly misstates the holding in *McKee*. Based on this misstated holding, the *Heredia* court found that there was an issue of fact as to whether the defendant pharmacy had a duty to include the manufacturer’s written warning which the defendant sold to the plaintiff.

The actual holding in *McKee* was as follows:

In summary, our holding is narrow. The pharmacist still has a duty to accurately **fill** a prescription [internal citation omitted] and to be alert for clear errors or mistakes in the prescription. The pharmacist does not, however, 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.**

McKee, 782 P. 2d at 1055. [emphasis added]

Because the actual holding in *McKee* found that a pharmacy **does not have a duty** to include the manufacturer’s package insert with each prescription dispensed

to a customer, the opinion in *Heredia* is of little, if any precedential value. The holding in *Heredia* is entirely without precedential support and flies in the face of overwhelming national precedent and this Court's holding in *McLeod* and the Florida District Court holdings in *Pysz*, *Johnson* and *Estate of Sharpe*.

III.

THIS COURT SHOULD EXTEND THE LEARNED INTERMEDIARY DOCTRINE TO HOLD THAT ANY DUTY ON THE PART OF THE PHARMACY TO WARN CUSTOMERS OF THE DANGERS ASSOCIATED WITH PRESCRIBED DRUGS IS DIRECTED TO THE PRESCRIBING PHYSICIAN.

The application of the learned intermediary doctrine to manufacturers of prescription drugs is well-settled in the State of Florida. In *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989), this Court stated that:

[a]t the outset, it is clear that the manufacturer's duty to warn of [the prescription drug's] dangerous side effects was directed to the physician rather than the patient. [internal citations omitted] This is so because the prescribing physician, acting as a "learned intermediary" between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs. [internal citations omitted]

Id.

Although no Florida court has expressly applied the learned intermediary doctrine in a case such as the instant case¹⁰, where a pharmacy is alleged to have a duty to warn its customer of the dangers associated with the ingestion of a lawful and validly prescribed drug, this Court laid the groundwork for the application of the learned intermediary doctrine in *McLeod*. Specifically, in *McLeod*, this Court stated “[o]bviously, the patient-purchaser did not rely upon the judgment of the retail druggist in assuming that the drug would be fit for its intended purpose. This confidence had been placed in the physician who prescribed the remedy.” *McLeod*, 174 So. 2d at 739. Similarly, the Fourth District, in *Pysz*, and the Fifth District in *Estate of Sharp*, both stated “. . . it is the physician who has the duty to know the drug that he is prescribing and to properly monitor the patient.” *Pysz*, 457 So. 2d at 562 and *Estate of Sharp*, 879 So. 2d at 36.

In addition, numerous courts from other states have applied the learned intermediary doctrine under the same circumstances found in the instant case, in holding that the duty to warn the patient of the dangers associated with the ingestion of the prescribed drug rest with the prescribing physician, and not the pharmacy where the prescription is filled, or with the pharmacist who filled the

¹⁰ It is arguable that heretofore, it was unnecessary to apply the learned intermediary doctrine to the circumstances in this case, as there has never been a duty on the part of a pharmacy to warn a customer of the dangers associated with the ingestion of a lawful and validly prescribed drug.

prescription. *Walls v. AlPharma USPD, Inc.*, 887 So. 2d 881, 886 (Ala. 2004); *Moore v. Memorial Hospital*, 825 So. 2d 658 (Miss. 2002); *Cottam v. CVS Pharmacy*, 764 N.E.2d 814 (Mass. 2002); *Fakhouri v. Taylor*, 618 Ne. 2d 518 (Ill. App. Ct. 1993); *Deed v. Walgreen Company*, 2004 Conn.Super.Lexis 3412 (Conn. Super. Ct. 2004); *Chamblin v. K-Mart Corp.*, 612 S.E.2d 25 (Ga. Ct. App. 2005); *Leesley v. West*, 518 N.E.2d 758 (Ill. Ct. App. 1988); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455 (Tex. Ct. App. 2000); *McKee v. American Home Products Corp.*, 782 P.2d 1045 (Wash 1989); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P. 3d 922 (Utah 2003).

Moreover, it makes little sense to apply the learned intermediary doctrine to manufacturers, but fail to apply the doctrine to pharmacies and pharmacists. See *Farkhouri*, 618 N.E. 2d at 330-331. Such a framework results in pharmacies and pharmacists being held to a higher standard of care than the prescription drug's manufacturer. The pharmacist often does nothing more than act as the retail agent for the manufacturer; simply retailing the drugs in the same packaged condition that they are received in from the manufacturer. In many other cases, the pharmacy simply repackages the prescribed drug from the bulk container that it is received in to an individual pill bottle that is sold to the customer. In many circumstances, the pharmacy, like the manufacturer, does not even have contact with the end user of the drug, such as in the case where a family member or

someone other than the end user, picks up the prescription from the pharmacy. The only uniform element through the entire process is the prescribing physician. Accordingly, it is the patient's prescribing physician that should be charged with the duty to warn the patient of the dangers associated with ingestion of the prescribed drug, and this Court should therefore formally adopt the learned intermediary doctrine with reference to pharmacies and pharmacists.

Clearly, the prescribing physician is in a far more advantageous position to address the risks associated with the ingestion of a particular drug than the pharmacist who simply packages and sells the medication in conformity with a doctor's prescription. The patient's treating physician is in the unique position of having access to the patient's medical history, the opportunity to physically examine and consult with the patient, and the knowledge of what other prescription drugs the patient is already taking. Accordingly, this Court should expand the learned intermediary doctrine to apply to pharmacies and pharmacists.

CONCLUSION

For the foregoing reasons, The Medicine Shoppe respectfully requests that this Court quash the decision of the Fourth District in *Powers* and approve the decisions in *Johnson* and *Estate of Sharpe*, holding that pharmacies and pharmacists do not have a duty to warn their customers of the risks involved with the ingestion of medication dispensed pursuant to a valid and lawful prescription.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of The Medicine Shoppe's Initial Brief was provided by mail to all counsel listed on the attached mailing list on this 7th day of September, 2005.

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**ROBERT POWERS, etc. v. B.A.L. PHARMACY d/b/a THE MEDICINE
SHOPPE, et al.**

IN THE FLORIDA SUPREME COURT
CASE NO: SC05-1192

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the font of this brief is Times New Roman-14 point, in compliance with Florida Rule of Appellate Procedure 9.210(a)(2).

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