IN THE SUPREME COURT OF FLORIDA
CASE NOS. SC05-1191, SC05-1192

YOUR DRUGGIST, INC.,

***Petitioner*,**

vs.

ROBERT POWERS, etc. et al.,

Respondent.

B.A.L. PHARMACY, etc.,

Petitioner,

vs.

ROBERT POWERS, etc. et al.,

Respondent.

RESPONDENT'S CONSOLIDATED ANSWER BRIEF

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STATEMENT OF THE CASE AND THE FACTS

I. Course Of Proceedings And Dispositions In The Lower Courts

This is an appeal from the Fourth District Court of Appeal's decision to reverse the trial court's dismissal of negligence claims against two pharmacies, Petitioner Your Druggist and Petitioner The Medicine Shoppe (collectively, "the Pharmacies"), for the wrongful death of Gail Powers. The facts, for purposes of this discretionary appeal, are straightforward (and have been taken largely from the Amended Complaint).

II. Statement Of Facts Relevant To The Appeal

On October 21, 2002, Gail Powers (hereinafter, "Mrs. Powers") collapsed at home. (R. 42-56). She was taken to Coral Springs Medical Center but never regained consciousness, and died on October 22, 2002. (R. 47). The blood tests performed in connection with her autopsy were positive for Atropine, Diazepam, Nordiazepam, OxyCodone, Benzodiazepines and Opiates. Id. The Medical Examiner determined Mrs. Powers' cause of death to be "Combined drug overdose (OxyCodone and diazepam)." Id.

Dr. Thobhani was Mrs. Powers' primary neurologist and she had been treating Mrs. Powers regularly since April 5, 2002. During the six months preceding Mrs. Powers' death, Dr. Thobhani rendered neurological medical care and treatment to Mrs. Powers for ongoing complaints of neck and back pain. Said

medical care was in the form of steroid injections and prescription drug treatment. During the six-month period in which Dr. Thobhani was treating Mrs. Powers, she prescribed a minimum of six varieties of drugs and narcotics to treat Mrs. Powers' neck and back pain. (R.44). At no time during the six-month period of their doctor/patient relationship did Dr. Thobhani recommend or render alternative treatment. Id. At one point, Dr. Thobhani did refer Mrs. Powers to another neurologist for a second opinion. However, despite the second neurologist's recommendations to wean Mrs. Powers off of the addictive narcotics she was taking, Dr. Thobhani continued to prescribe large doses of dangerous narcotic combinations that included OxyContin/OxyCodone and Percocet along with Soma, Xanax, Diazepam and injections of steroids at almost every office visit. On October 22, 2002, Mrs. Powers died of a combined drug overdose with toxic levels of OxyCodone and therapeutic levels of Diazepam. Id.

Dr. Thobhani began prescribing OxyContin, along with other narcotics in April, 2002. OxyContin/OxyCodone is an opioid agonist and a Schedule II controlled substance with an abuse level similar to Morphine. (R.45). The U. S. Food and Drug Administration issued warnings to Health Care Professionals on July 18, 2001, which set out indications and usage for OxyContin. Id. The FDA specifically warned doctors and pharmacists that OxyContin was not intended for use as a prn (as needed) analgesic and that, like Morphine, it has a high potential

for abuse.[1] Moreover, OxyContin is a controlled-release narcotic and a single dose should not be taken more than once every 12 hours for moderate or severe pain. 80mg and 160mg are the highest doses prescribed. It is not to be taken with other narcotics and treatment with OxyContin should be closely monitored. Id. Percocet is also a narcotic prescribed for moderate to severe pain and should not be taken with other narcotics. Diazepam, in turn, belongs to a class of drugs called benzodiazepines, which are generally prescribed for the treatment of anxiety disorders. Diazepam is more commonly known as Valium or Zoloft and should not be prescribed with other narcotics such as Percocet or OxyContin. OxyContin, Percocet and Diazepam all are habit forming and have known addictive qualities. Id.

From April 5, 2002 through October 22, 2002, Dr. Thobhani prescribed the following drugs to Mrs. Powers (and also often injected her with steroids):

4/5/02	Percocet, Soma	(Steroid injection in office)
4/17/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
4/24/02	Percocet	
5/2/02	Percocet, Soma, Xanax	(Steroid Injection in office)
5/6/02	OxyContin, Soma, Xanax	(Steroid injection in office)
5/10/02	Percocet, Soma	(Steroid injection in office)
5/15/02	OxyContin, Soma, Xanax	(Steroid injection in office)
5/20/02	Percocet, Neurontin, Xanax	
5/24/02	Percocet, Soma, OxyContin, Xanax	(Steroid injection if office)

[1] Additional reference to the FDA's 2001 OxyContin warnings to doctors and pharmacists can be found at http://www.fda.gov/bbs/topics/ANWERS/2001/ANS01091.html and http://www.fda.gov/medwatch/safety/2001/oxycontin.htm.

5/29/02	Percocet, Soma, Xanax	(Steroid injection in office)
5/31/02	OxyContin	(Steroid injection in office)
6/3/02	Percocet, OxyContin, Soma	(Steroid injection in office)
6/7/02	Percocet	(Steroid injection in office)
6/10/02	OxyContin, Soma, Xanax	(Steroid injection in office)
6/12/02	Injection in office and prescription for antibiotic for sore throat	
6/17/02	Percocet, OxyContin, Soma, Xanax	
6/22/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
6/26/02	Percocet, Soma, Xanax Toradol(anti-inflammatory)	
7/1/02	Percocet, OxyContin, Soma, Xanax	
7/8/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
7/15/02	OxyContin, Soma, Elavil, Neurontin	(Steroid injection in office)
7/20/02	Toradol, OxyContin, Percocet, Soma, Xanax	
7/24/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
8/2/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
8/11/02	Morphine	
8/14/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
8/21/02	Percocet, OxyContin, Soma, Xanax	
8/28/02	Steroid Injection	
9/5/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
9/11/02	Morphine, Percocet	
9/16/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
9/20/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
9/25/02	Morphine, Percocet, Xanax, Baclofen	
9/27/02	OxyContin	(Steroid injection in office)
9/30/02	Percocet, OxyContin, Soma, Xanax	(Steroid injection in office)
10/2/02	OxyContin, Percocet, Morphine(Steroid injection in office)	
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10/18/02	Percocet	(Steroid injection)

(R. 45-46). In addition, Dr. Thobhani's records note an office visit of November 14, 2003, three weeks after Mrs. Power's death. Id.

During the six-month period in which Dr. Thobhani was treating Mrs. Powers, she repeatedly prescribed the foregoing narcotics and other medications to

Mrs. Powers days before Mrs. Powers should have depleted the preceding prescription. It is undisputed in the record that Dr. Thobhani was prescribing two or more narcotics at the same time along with other drugs that were contraindicated. (R. 46) More specifically, Dr. Thobhani would prescribe the foregoing drugs and the Pharmacies, Your Druggist and The Medicine Shoppe, would dispense, without question, every one of these prescriptions. Id.

For example, The Medicine Shoppe filled a prescription for 60 Percocet 10mg/325mg on 8/2/02 along with a prescription for 30 OxyContin 80mg. (R.47). Then, on 8/16/02, The Medicine Shoppe filled the same exact prescriptions again. As another example, on 9/16/02, The Medicine Shoppe, filled a prescription for 30 OxyContin 80mg and, a mere 4 days later, filled another prescription for 30 OxyContin 80mg *and* for 60 Percocet 10mg/325mg, all without questioning Mrs. Powers or her doctor. Id.

Moreover, Petitioner Your Druggist also filled numerous prescriptions for these narcotics during the same periods. For example, on 5/29/02, Your Druggist filled a prescription for 60 Percocet 10/325mg. On 5/31/02, it also filled a prescription for 45 OxyContin 80mg. Then, on 6/3/02, a mere 3 days later, Your Druggist filled yet another prescription for 30 OxyContin 80mg. This prescription filling pattern for both Pharmacies continued until the day of Mrs. Powers' death.

On October 21, 2002, Mrs. Powers died from a drug overdose. Her autopsy revealed that she had Atropine, Diazepam, Nordiazepam, OxyCodone, Benzodiazepines and Opiates in her system at the time of her death. All of Mrs. Powers' narcotic prescriptions had been filled by the Pharmacies. (R. 47). The Medical Examiner determined the cause of Mrs. Powers' death to be "Combined drug overdose (OxyCodone and diazepam)." Mrs. Powers was only 46 years old when she died. (R. 48).

Suit was brought against Dr. Thobhani and the Pharmacies by Robert Powers ("Powers"), as Personal Representative of Gail Power's Estate. Powers' Amended Complaint asserted negligence claims against the Pharmacies that were premised on the general duty of Florida pharmacists to meet the applicable standard of care and to use due and proper care in filling prescriptions. The Amended Complaint alleged that the Pharmacies breached their duty to meet the applicable standard of professional care in their failure to warn or advise Mrs. Powers about the dangerous drugs they were dispensing to her or to use appropriate professional judgment in filling repeated --and overly frequent-- prescriptions for high-dose opioid narcotics, which were both addictive and dangerous. (R. 49-56).

The Circuit Court dismissed Powers' negligence claims against the Pharmacies with prejudice, holding that:

> The basis of the negligence claims against the [Pharmacies] 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. . . . [Powers] seeks to impose a duty of care upon these [The Pharmacies] which does not exist under the law. Accordingly, Counts II and III of the Amended Complaint fail to state legally cognizable claims.

(R. 70). In sum, the Circuit Court held that Powers' negligence claims against the Pharmacies were legally insufficient because the Pharmacies owed no legal duty to Mrs. Powers. The Fourth District Court of Appeal reversed in a very narrow holding:

> We hold that 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.

Powers v. Thobhani, 903 So.2d 275, 278 (Fla. 4th DCA 2005). From the questions asked at oral argument below, it was apparent that the Fourth District Court of Appeal was very concerned about the Pharmacies' arguments that they had absolutely no legal duty to their patients even when they knew with certainty that filling a prescription would lead to death or serious bodily injury. Thereafter, the Pharmacies filed notices of discretionary jurisdiction with this Court, and this appeal followed.

SUMMARY OF ARGUMENT

This is an appeal involving a pharmacist's duty of care towards his or her patients. This Court should exercise its discretion to decline review of this appeal. The Fourth District's decision below holds only that

> 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.

Powers, 903 So.2d at 278. The Fourth District's decision is a very narrow one and does not directly conflict with any decision of this Court or of the lower appellate courts.

Counts II and III of Powers' Amended Complaint allege that the Pharmacies breached their duty to meet the applicable standard of care owed to Mrs. Powers with respect to their dispensing of repeated and unreasonable narcotic and opioid prescriptions to her. Until recently, the law with respect to a pharmacist's duties to his or her patients had been developing only sporadically in Florida. However, in Dee v. Wal-Mart Stores, Inc., 878 So.2d 426 (Fla. 1st DCA 2004), a case with facts very similar to those of the instant appeal, the First District Court of Appeal recently reversed a trial court's decision to dismiss the plaintiff's negligence claim against her pharmacist, holding:

> A pharmacy must use due and proper care in filling a prescription. McCleod v. W.S. Merrell Co. Div. Of Richardson-Merrill, Inc., 174 So.2d 736 (Fla. 1965). When a pharmacy fills a prescription which is unreasonable on its face, even though it is lawful as written, it may breach this duty of care. It is alleged that the prescription for this Duragesic patch, without a time limit for filling or using the prescription, renders the prescription unreasonable on its face. It is alleged that this Duragesic patch, if used by one not on a fentanyl regimen, will likely cause hypoventilation resulting in death. It is alleged that a pharmacist viewing this prescription which is more than four months old would reasonably conclude that the patient is opioid-naive. The pharmacist should warn of this danger and/or inquire of the physician whether the prescription should be filled for this patient. It is alleged that the pharmacist did neither. These allegations of the amended complaint state a cause of action for negligence.

Dee, 878 So.2d at 427-428.

In this case, the Pharmacies repeatedly filled narcotic and other opioid prescriptions within, for example, just days of each other in a manner which clearly suggested that these drugs were being dangerously over-prescribed and were clearly contraindicated in the first place. Both state and federal law confirm that, under the facts presented by this appeal, the Pharmacies owed a duty of care to Mrs. Powers, especially in the context of excessive prescriptions for controlled substances. The standards of the pharmacy profession also support the holding that the Pharmacies owed a duty of reasonable care to Mrs. Powers. It matters little whether the statutory duties of pharmacists in Florida (as codified in the Florida Pharmacy Act) actually creates the applicable standard of care or whether they serve as evidence of the professional standard of care since both lead to the same

result (namely, that pharmacists owe a duty of reasonable care to their patients and that the breach of professional pharmacy standards are actionable).

The application of the "learned intermediary" doctrine to insulate pharmacists from liability to their patients should be rejected by this Court. The professional pharmacy standards codified in both federal and state law requiring pharmacists to screen every prescription and to take appropriate corrective measures (i.e., counseling the patient and/or contacting the prescriber) effectively preclude or preempt application of the "learned intermediary" doctrine to the pharmacist-patient relationship. Moreover, the "learned intermediary" doctrine has never yet been applied to the pharmacist-patient relationship in Florida. Surely, Florida common law and the standards of professional practice set out in the Florida Pharmacy Act must mean the same thing; that pharmacists owe a duty of reasonable care to their patients in evaluating prescriptions and dispensing prescription drugs that cannot be abrogated by the "learned intermediary" doctrine.

ARGUMENT

I. THE FOURTH DISTRICT OPINION DOES NOT DIRECTLY CONFLICT WITH A DECISION OF THIS COURT OR WITH THE DECISION OF ANY DISTRICT COURT OF APPEAL.

The Florida Constitution, Article V, § (3)(b)(4), provides that this Court may review the decision of a district court of appeal "that is certified by it to be in direct conflict with a decision of another district court of appeal." In its decision, the Fourth District Court of Appeal recognized that its opinion contradicted prior holdings of the First and Fifth Districts in the cases of Johnson v. Walgreen Co., 675 So.2d 1036 (Fla. 1st DCA 1996) and Estate of Sharp v. Omnicare, Inc., 879 So.2d 34, 35 (Fla. 5th DCA 2004). Closer analysis of those opinions reveals, however, that the cited cases do not directly conflict with the Fourth District's decision here.

In this case, the Fourth District simply allowed negligence claims against the Pharmacies to survive a motion to dismiss because it was 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." Powers, 903 So.2d at 278. Neither the Johnson case nor the Estate of Sharp case conflicts with this narrow holding.

In Johnson, the First District Court of Appeal held in 1996 that a pharmacy had no duty to warn a customer of the potentially adverse drug reactions of the

customer's several prescriptions, and also had no liability for recommending an over the counter allergy medication that was inappropriate for someone taking the drugs that the customer had been prescribed. 675 So.2d at 1037-38. It is important for this Court to note that the Johnson case—unlike this appeal—did not even involve a claim of negligence, but held that the definition of "dispense" in the Florida Pharmacy Act did not create a private right of action. Hence, the Johnson case is wholly distinguishable, on a legal basis, from this negligence case. Moreover, the Johnson court left open the possibility that more egregious factual allegations than those described there could create pharmacy liability for negligently failing to warn or counsel a patient before filling prescription(s) that lead to serious injury or death. Id.

It is also significant to explain that the 1996 Johnson decision was likely overruled by the First District's recent decision in Dee v. Wal-Mart Stores, Inc, 878 So.2d 426 (Fla. 1st DCA 2004). In the Dee case, the First District Court held last year that:

> A pharmacy must use due and proper care in filling a prescription. McCleod v. W.S. Merrell Co. Div. Of Richardson-Merrill, Inc., 174 So.2d 736 (Fla. 1965). When a pharmacy fills a prescription which is unreasonable on its face, even though it is lawful as written, it may breach this duty of care. It is alleged that the prescription for this Duragesic patch, without a time limit for filling or using the prescription, renders the prescription unreasonable on its face. It is alleged that this Duragesic patch, if used by one not on a fentanyl regimen, will likely cause hypoventilation resulting in death. It is

> alleged that a pharmacist viewing this prescription which is more than four months old would reasonably conclude that the patient is opioid-naive. The pharmacist should warn of this danger and/or inquire of the physician whether the prescription should be filled for this patient. It is alleged that the pharmacist did neither. These allegations of the amended complaint state a cause of action for negligence.

878 So.2d at 427-428. Hence, the only—and recent—pronouncement by the First District Court of Appeal as to whether negligence claims can be asserted against pharmacists for their failure to warn or contact the prescribing physician before dispensing dangerous prescriptions actually supports the holding of the Fourth District in this case. Since the Johnson case is legally distinguishable and, in any event, was likely overruled by the First District's later decision in Dee, there really is no conflict with the Johnson case that would support this Court's exercise of jurisdiction.

The Estate of Sharp case is similarly distinguishable. In Estate of Sharp, the Fifth District recognized that pharmacists could be liable in negligence under limited circumstances, but noted that, in looking at the claims asserted against the nursing home's pharmacists, it could "detect no breaches of duty owed by the pharmacist to Mrs. Sharp." 879 So.2d at 36. The Fifth District went on to allow Mrs. Sharp's estate an opportunity to amend under negligence or voluntary undertaking theories since it believed that cases should be decided on their merits. Id. The Fifth District did "not know whether the Estate [would] be able to state a

viable claim using this theory, or perhaps some other theory not disposed of by [its] decision, but [] concluded that [the Estate] ought to at least have the chance." Id. Thus, to the extent that the Fifth District's decision in Estate of Sharp actually acknowledges that pharmacists can be liable to their customers in negligence under certain circumstances and actually gives the Estate leave to amend to pursue its claims, that decision does not conflict with the Fourth District's very narrow decision here either. It is, thus, respectfully asserted that the Fourth District's acknowledgement of a conflict with the Johnson and the Estate of Sharp cases is not, upon closer examination, totally accurate.

Even if the Johnson and Estate of Sharp cases did, however, conflict with the Fourth District's decision, this Court should still decline to exercise its discretionary jurisdiction over this appeal. The Fourth District's decision is an extremely narrow one, and holds only that the

> 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.

Powers, 903 So.2d at 278. This was an extremely logical holding in the context of a motion to dismiss (in which the dismissal of a claim can only be affirmed where no set of facts could be asserted to support the claim). The narrowness of this

holding (coupled with the motion to dismiss posture of the appeal) makes it a bad candidate for exercise of this Court's discretionary jurisdiction. Thus, for all the foregoing reasons, this Court should find that there is no conflict supporting the exercise of discretionary jurisdiction over this appeal or decline to exercise its discretionary jurisdiction on the grounds that the Fourth District's holding is a narrow one that might better be reviewed in a more substantive context (rather than in the context of an appeal from a motion to dismiss).

II. THE FOURTH DISTRICT COURT OF APPEAL CORRECTLY CONCLUDED THAT PHARMACIES CAN BE SUED IN NEGLIGENCE.

The Fourth District Court of Appeal's decision was eminently correct. The Pharmacies clearly had a duty toward their repeated and ongoing patient, Mrs. Powers, and this duty, according to Powers, was breached when the Pharmacies repeatedly filled narcotic prescriptions too quickly and when Mrs. Powers ultimately died as a direct result of those prescriptions. But, the ultimate legal issue of whether the Pharmacies breached the standard of care should be left up to the finder of fact after all the facts have been discovered.

This Court has already held that a pharmacy's failure to use "due and proper care" when filling a prescription may give rise to a cause of action in negligence against the pharmacy. See McLeod v. W.S. Merrell Co. Div. Of Richardson-Merrill, Inc., 174 So.2d 736 (Fla. 1965). Simply put, pharmacists are professionals

who "cannot escape liability [by] compounding and dispensing deadly poisons in deadly and unusual doses, even though the physician's prescriptions called for such [a] dosage." Gassen v. East Jefferson Gen. Hosp., 628 So.2d 256, 258 (La.App. 5th Cir. 1993), quoting People's Serv. Drug Stores v. Somerville, 158 A. 12 (Md. 1932).

A. *Both Federal And State Law Impose A Duty of Care Upon Pharmacists.*

The existence of a legal duty is a question of law. This Court has held that "[w]here a defendant's conduct creates a foreseeable zone of risk, the law generally will recognize a duty placed upon defendant either to lessen the risk or see that sufficient precautions are taken to protect others from the harm the risk poses." Kaisner v. Kolb, 543 So.2d 732, 735 (Fla. 1989). In this case, the Pharmacies clearly had a duty to Mrs. Powers both in common law and by statute. According to Prosser's hornbook on Torts, the existence of a legal duty depends upon the character of the relationship between the two parties, rather than the nature of the actions those parties undertake:

> It is better to reserve "duty" for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal standard of what is required to meet the obligation. In other words, "duty" is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases the

> duty is always the same—to conform the legal standard of reasonable conduct in light of the apparent risk.

W. Prosser & W. Keeton, The Law Of Torts § 53 (5th Ed. 1994). In the pharmacy context, both state and federal statutes regulate the standards of the profession and these statutes either determine the applicable standard of pharmacy care or serve as evidence of it. Either way, the Pharmacies can be sued in negligence for breaching the duty of care owed Mrs. Powers as the law clearly obligates pharmacists to act with due care and adhere to professional standards for the benefit of their patients.

According to one legal scholar, pharmacists can be sued in negligence under the common law apart from any statutory obligation regardless since

> a pharmacist's duty is determined by the relationship between the pharmacist and the plaintiff. There is no need to refer to a statute or regulation to establish this duty, and there is no need to create a private right of action through a statute or a regulation. Pharmacists have a duty as a matter of common law to prevent foreseeable adverse consequences of their actions or failure to act. There is no duty for a pharmacist to protect an unforeseeable medication user, who is not a patient, from harm caused by a drug dispensed by the pharmacist. There is no duty for a pharmacist to protect a patient from an adverse effect that was unknown and unknowable at the time a medication was dispensed. However, if a pharmacist-patient relationship exists, then the pharmacist owes to the patient a duty to act with reasonable care, and reasonableness is measured by the standard of care applicable to the pharmacy profession.

Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. Leg. Med. 475, 497 (1997)(citations omitted). Thus, the legal issue presented by this appeal is not really whether the standards regulating the pharmacy profession in Florida

create a private right of action. Rather, the legal issue here is how the standards imposed upon the pharmacy profession – by statute or otherwise-- define the parameters of the applicable pharmacy standard of care or serve as evidence of it.

In DeJesus v. Seaboard Coast Liner Co., 281 So.2d 198 (Fla. 1973), this Court divided statutory violations into three categories: 1) violation of a strict liability statute designed to protect a particular class of persons who are unable to protect themselves, constituting negligence *per se*; 2) violation of a statute establishing a duty to take precautions to protect a particular class of persons from a particular injury or type of injury, also constituting negligence *per se*, and; 3) violation of any other kind of statute, constituting mere *prima facie* evidence of negligence. See Jackson By & Through Whitaker v. Hertz Corp., 590 So.2d 929 (Fla. 3d DCA 1990), quashed on other grounds by 617 So.2d 1051 (Fla. 1993). Accordingly, there is a distinction between claiming that a statute creates a statutory cause of action and using the violation of a statute as evidence of common law negligence. Applying the triumvirate of statutory violations discussed in DeJesus, violations of the applicable Florida and federal pharmacy statutes is, at the very least, evidence of negligence (if not a *per se* breach of the standard of professional care). Pharmacy disciplinary statutes or license revocation/suspension statutes are clearly enacted to protect the public at large (or, at least, patients who take prescription drugs) and, therefore, their violation must

be at least evidence of negligence (if not negligence *per se*). See Lingle v. Dion, 776 So.2d 1073 (Fla. 4th DCA 2001); Borrego v. Agency for Health Care Administration, 675 So.2d 666 (Fla. 1st DCA 1996). The violation of statutes regulating prescriptions for controlled substances constitutes similar evidence of negligence.

As noted above, the duty element of a negligence claim focuses on whether a defendant's conduct foreseeably creates a broader "zone of risk" that poses a general threat of harm to others. See McCain v. Florida Power Corp., 593 So.2d 500 (Fla. 1992). A duty exists where there is a relationship between individuals which imposes upon one the legal obligation to conform to a standard of reasonable conduct to protect the other from foreseeable and unreasonable risk of harm. See Florida Power & Light Co. v. Lively, 465 So.2d 1270, 1273 (Fla. 1985). The relationship of pharmacist and patient, under the law, clearly imposed a duty upon the Pharmacies not to dispense excessive controlled substances to Mrs. Powers without advising her or consulting with her prescribing physician, particularly since both Florida and federal statutes create a legal presumption that doing so was harmful to Mrs. Powers.[2]

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[2] The issue in this case may ultimately be one of proximate cause, not duty. The "proximate cause" element of a negligence claim measures whether—and to what extent—a defendant's conduct foreseeably and substantially caused the plaintiff's injury. See Florida Power & Light Co. v. Periera, 705 So.2d 1359 (Fla. 1998).

This case involves the repeated filling and dispensing of prescriptions for OxyContin and other controlled substances that were contraindicated and prescribed in excessive doses. Both state and federal law heavily regulate prescriptions for these kinds of controlled substances. Virtually all of the prescriptions filled by the Pharmacies in this case involved subscriptions for heavily-regulated narcotics such as OxyContin, Diazepam, and Soma (a strong muscle relaxant). ***Both state and federal law require pharmacists to screen and counsel patients before dispensing drugs that are contraindicated or may be subject to abuse.*** Under the circumstances, the Pharmacies each had a duty, imposed upon them by state and federal law (either by statute or by common law), to take action when these narcotics were obviously being prescribed together and in excessive quantities in clear violation of multiple laws. In their briefs before this Court, the Pharmacies argue that they should be able to defer to physicians completely and that they should have no liability for filling a lawful prescription. The Pharmacies are essentially seeking a form of immunity that is belied by the controlling Florida and federal law.

However, proximate cause is generally a question of fact for the jury and cannot be resolved in this appeal taken at the very beginning of a case in response to the Pharmacies' motions to dismiss. Hence, the Fourth District was correct in letting Powers' negligence claims survive the Pharmacies' multiple attempts at dismissing them.

Pursuant to 21 CFR § 1306.04, for example:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, ***but a corresponding responsibility rests with the pharmacist who fills the prescription***. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) ***and the person knowingly filling such a prescription***, as well as the person issuing it, ***shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.*** (emphasis supplied).

Thus, federal law clearly imposes a "responsibility" with "the pharmacist who fills the prescription" for every controlled substance. In addition, the Omnibus Budget Reconciliation Act of 1990 ("OBRA") was passed by Congress, in part, to mandate that states, as a condition to participation in the Medicaid program, expand pharmacy practice standards to include requirements that pharmacists participate in the screening of all prescriptions, offer to discuss medications with patients, and maintain extensive records. <u>See</u> 42 U.S.C. § 1396r-8(g)(1996). In the OBRA-mandated screening function that has now been codified in all states (and broadened to apply to all prescriptions), pharmacists must participate in a program designed to detect potential problems with drug therapy. Specifically, OBRA states that the

> state plan shall provide for a review [by pharmacists] of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point-of-distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of treatment, drug-allergy interactions and clinical abuse/misuse.

42 U.S.C. § 1396r-8(g)(2)(A)(1996).

Hence, under federal law, all states (as a condition precedent to participating in the Medicaid program) were required to adopt legislation requiring pharmacists to screen all prescriptions and to counsel their customers where prescriptions are contraindicated or where there is clinical abuse/misuse of drugs. These are the very same duties (along with the laws regulating prescriptions for controlled substances in excessive quantities) that Powers asserts that the Pharmacies have—and breached—in this case.

It is clear from the discussion above that federal law imposes multiple duties upon the Pharmacies that are implicated in this appeal. Powers alleges that the Pharmacies dispensed repeated, excessive, and deadly prescriptions for controlled substances to Mrs. Powers and that they should be liable in negligence for failing to warn her or her doctor. Federal law imposes a specific responsibility upon pharmacists who dispense controlled substances and also requires pharmacists to screen every prescription to avoid potential harm to customers. Powers claims that

the Pharmacies violated both of these professional duties. Florida law is in accord with federal law.

The Florida Pharmacy Act is set out in Chapter 45 of the Florida Statutes. Pursuant to Florida Statute § 465.002, the Florida legislature specifically found that "the practice of pharmacy is a learned profession. The 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." Moreover, pursuant to Florida Statute § 465.0155, the Florida Board of Pharmacy was empowered to define the standards of the profession:

> Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.

In addition, the Florida Pharmacy Act, Florida Statute § 465.003(6), also defines "dispens[ing]" of a drug to

> mean[] the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. ***As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer***. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. (emphasis supplied).

Pharmacists who do not comply with the Florida standards of practice are subject to discipline by the Florida Board of Pharmacy. Moreover, according to Florida Statute § 465.016(1)(i), the following act constitutes grounds for denial of a pharmacist's license or subjects a pharmacist to disciplinary action:

> Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of professional practice of pharmacy. ***For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy***. (emphasis supplied).

Under Florida law, then, the dispensing of "legend" (or prescription)[3] drugs in excessive quantities is, *per se*, outside of the "course of the professional practice of pharmacy." See also Florida Statute § 893.04 (requiring pharmacists to dispense controlled substances only in good faith). But, a fine or suspension does little to correct the harm caused to an innocent patient by a pharmacist who failed to comply with the professional standard and failed to correct a preventable problem. The Florida legislature has very clearly established that pharmacy is a "profession" and mandated that the Florida Board of Pharmacy define the applicable standards thereof. The intent of the Florida Pharmacy Act to hold pharmacists to high professional standards of care is obvious from this legislation and the Act's

specific requirements that every prescription be screened and that appropriate corrective counseling be taken. Hence, for purposes of a negligence claim, these mandated standards of care must either define the applicable standard of care or serve as evidence of it.

Florida pharmacists are also specifically charged with general knowledge of prescription medication such that they should be able to explain the operative risks of taking a medication to an inquiring customer. See Fla. Admin. Code R. 64B16-27.300; Fla. Admin. Code R. 64Bl6-27.820; Fla. Stat. § 465.003(6) (2000). It is Powers' contention that this Court should recognize the duties of pharmacists set out in Florida law (also federal law) in determining the "duty of care" issue before this Court. In addition, the standards of the Pharmacies' own profession impose duties upon them to intervene to avoid poor patient outcomes and to promote the therapeutic appropriateness of prescriptions by identifying:

1) Over-utilization or under-utilization;
2) Therapeutic duplication;
3) Drug-disease contraindications;
4) Drug-drug interactions;
5) Incorrect Drug dosage or duration of Drug treatment;
6) Drug-allergy interactions; and
7) Clinical abuse/misuse.

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[3] Florida Statute § 465.003(8) defines "legend" drugs to mean prescription drugs (or "drugs which are required by state or federal law to be dispensed only on prescription").

See the National Association of Boards of Pharmacy Model Rules for Pharmaceutical Care, Section 3G (available at http://www.nabp.net). Moreover, the dictates of this rule require that

> [u]pon recognizing any of the above***, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner***.

Id. (emphasis supplied).

Section 3H of the Model Rules for Pharmaceutical Care, in turn, also requires that a pharmacist personally counsel every patient or their caregiver about the applicable drug therapy, its intended use, precautions, common side effects, contraindications, and techniques for self-monitoring and that the pharmacist actually consult the physician, if necessary. See also the American Pharmaceutical Association's Principles of Practice of Pharmaceutical Care and other standards.[4] Hence, it must be apparent from federal law, state law, and the Pharmacies' own professional standards, that they definitely had a legal duty to Mrs. Powers when filling her prescriptions, especially prescriptions for controlled substances such as OxyContin and Diazepam (both of which undisputedly contributed to Mrs. Powers' death).

[4] The American Pharmaceutical Association is the national association of the pharmacy profession, comparable to what the American Bar Association is for lawyers. See http://www.aphanet.org.

More specifically, Powers contends that the Pharmacies each filled prescriptions for controlled substances such as OxyContin, Diazepam and Soma in excessive and inappropriate quantities. Powers also contends that these drugs should not have been taken together as they were specifically contraindicated for use together. Powers has, thus, alleged that the Pharmacies were guilty of repeated conduct that should subject them to disciplinary action for breach of the "professional practice of pharmacy" under express Florida law. As such, Powers contends that they each breached their duty to Mrs. Powers in filling the prescriptions that eventually lead to her death without warning her of the danger or contacting Dr. Thobhani. Liability will ultimately be decided by the trier of fact, but, for purposes of this appeal, this Court should confirm that pharmacists owe a duty of reasonable care to their patients and they can be liable for breaching the applicable standard of professional care.

With respect to controlled substances, in particular, both Florida law and federal law are clear that pharmacists have an equal duty with physicians to make sure that such drugs are prescribed and dispensed appropriately. This means that pharmacies who breach that established duty of care should be liable in negligence, and Powers should be allowed to pursue her negligence claims against the Pharmacies, and ultimately have her case heard by a jury. In this case, the Fourth District held only that Powers' negligence claims against the Pharmacies should

survive a motion to dismiss. Based upon the duties imposed upon by pharmacists under federal and state law (as well as the professional standards of the Pharmacies' own profession), the Fourth District's decision was legally correct.

It is important to point out that, in this case, the prescriptions filled by the Pharmacies ultimately lead to Mrs. Powers death and that, it should have been obvious from all the warnings surrounding the dangers of OxyContin, that the repeated filling of those prescriptions would cause serious harm—if not death—to Mrs. Powers. The Pharmacies did not have to know anything about Mrs. Powers or her health to know that OxyContin was dangerous (and that it should not have been prescribed in such excessive quantifies or with other narcotics) since the FDA had issued repeated warnings—directed at health care professionals such as pharmacists—that OxyContin was an extremely dangerous drug that was being prescribed inappropriately and was subject to abuse. As one legal scholar has explained, pharmacist liability should follow easily under such circumstances:

> Perhaps the easiest argument for expanded pharmacy practice standards can be made for cases in which a medication has been prescribed in such a way that it would cause harm to virtually anyone who used it. Suggestions that pharmacists should not be expected to detect and resolve such problems, because pharmacists cannot examine patients and cannot diagnose disease, fall on deaf ears in this situation. Physical examination and diagnosis are unnecessary when the drug, not the patient's physiology, is the problem. Pharmacist's knowledge about patients is increasing, but it is still far from complete. Pharmacists' knowledge of drugs surpasses that of any other health professional. There is no excuse for a pharmacist not

> knowing the red flags that would indicate a drug has been prescribed so as to create a potentially unnecessary risk of harm for any patient. The pharmacist's job is not to make independent decisions about a patient's drug therapy. As gatekeeper, the pharmacist's job is to detect indicators of potential problems and contact the prescriber to request clarification.
>
> It is the pharmacist's drug specific knowledge, as opposed to patient-specific knowledge, that is addressed by the OBRA-90 requirement for screening of prescriptions prior to their being dispensed. Such resolution usually involves pharmacist contact with the prescriber, not with the patient, although sometimes the patient may be able to provide clarification that removes the problem. For example, when two interacting drugs have been prescribed for the same patient, at two different times, the patient may explain that he or she has discontinued taking the first one, and therefore will not be taking it with the second one. However, if no satisfactory explanation is forthcoming, then the OBRA-90 prescription screening standard requires contact with the prescriber. This standard is fully consistent with the standard of care for pharmacists recognized in recent case law.

Brushwood, 18 J. Leg. Med. at 503.

B. Case Law Confirms That Pharmacists Do Have A Duty Of Care Towards Their Patients.

Despite the fact that this very Court has specifically held that a pharmacy's failure to use due and proper care in the filling of a prescription "may give rise to an action in negligence," there have been few appellate cases affirming a negligence cause of action against a pharmacy until recently. In Section I of this brief, Powers explains how the Fourth District's narrow holding below is not in conflict with any prior decision of this Court or lower appellate courts. The case

law is, however, evolving to confirm the breadth of a pharmacist's duties to his or her customers in the wake of OBRA's and the Florida Pharmacy Act's screening and counseling requirements and in light of the concomitant evolution of pharmacy law and practice. See also Fla. Admin. Code R. 64B16-27.820 ("Patient Counseling").

In Dee v. Wal-Mart Stores, Inc., 878 So.2d 426 (Fla. 1st DCA 2004), a case very similar to the case at bar, the First District Court of Appeal recently reversed a trial court's decision to dismiss the plaintiff's negligence claim against her pharmacy, holding:

> A pharmacy must use due and proper care in filling a prescription. McCleod v. W.S. Merrell Co. Div. Of Richardson-Merrill, Inc., 174 So.2d 736 (Fla. 1965). When a pharmacy fills a prescription which is unreasonable on its face, even though it is lawful as written, it may breach this duty of care. It is alleged that the prescription for this Duragesic patch, without a time limit for filling or using the prescription, renders the prescription unreasonable on its face. It is alleged that this Duragesic patch, if used by one not on a fentanyl regimen, will likely cause hypoventilation resulting in death. It is alleged that a pharmacist viewing this prescription which is more than four months old would reasonably conclude that the patient is opioid-naive. The pharmacist should warn of this danger and/or inquire of the physician whether the prescription should be filled for this patient. It is alleged that the pharmacist did neither. These allegations of the amended complaint state a cause of action for negligence.

878 So.2d at 427- 428; see also Sanderson v. Eckerd Corp., 780 So.2d 930 (Fla. 5th DCA 2001)(pharmacist may be liable in negligence pursuant to the voluntary undertaking doctrine).

If this Court exercises its discretion to hear this appeal, it should affirm the evolution of pharmacy law to recognize the obvious rule that pharmacists have a duty of reasonable care towards their patients under the common law (and that the Florida Pharmacy Act either defines the applicable standard of care or is plainly evidence of it). Just as in the Dee case, the prescriptions here involved narcotics which could easily lead to overdose and the prescriptions in both cases eventually led to death. Indeed, Powers contends that the facts alleged in this case are even more troubling since the deadly prescriptions were repeatedly filled, were dangerous in combinations and legally contraindicated (and obviously filled too frequently), and the Pharmacies had many chances to warn Mrs. Powers or contact Dr. Thobhani in a manner consistent with their professional standards-- and federal and state requirements--, but did not.

More specifically, Powers alleges in the Amended Complaint that the Medicine Shoppe filled a prescription for 60 Percocet at the very same time it filled a prescription for 30 OxyContin only to refill the exact prescriptions again in short order. (R. 51). Indeed, it is undisputed that the Medicine Shoppe filled yet another prescription for 30 OxyContin only to fill yet another prescription for another 30 OxyContin and for 60 Percocet just 4 days later. Id. The same allegations of negligence have been made against Your Druggist. In the Amended Complaint, Powers alleges that Your Druggist filled multiple prescriptions for

OxyContin only 3 days apart. (R. 55). Indeed, the applicable prescription records prove that Your Druggist routinely filled OxyContin prescriptions for Mrs. Powers every 3-4 days until just days before her death. Id. Such egregious facts should be more than enough to assert claims for negligence against the Pharmacies in negligence.

According to the published guidance, OxyContin/OxyCodone is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to Morphine. (R.45). The U. S. Food and Drug Administration issued warnings to Health Care Professionals on July 18, 2001, which included indications and usage for OxyContin. Id. The FDA specifically warned doctors ***and pharmacists*** that OxyContin was not intended for use as a prn (as needed) analgesic and that, like Morphine, has a high potential for abuse.[5] Moreover, OxyContin is a controlled-release narcotic and a single dose should not exceed every 12 hours for moderate or severe pain. 80mg and 160mg are the highest doses prescribed. It is not to be taken with other narcotics and treatment should be closely monitored by the prescribing physician. Id. Percocet is also a narcotic prescribed for moderate to severe pain and should not be taken with other narcotics. Diazepam, in turn, belongs to a class of drugs called benzodiazepines for the treatment of anxiety

disorders. Diazepam is more commonly known as Valium or Zoloft and should not be prescribed with narcotics such as Percocet or OxyContin. OxyContin, Percocet and Diazepam all are habit forming and have addictive qualities. Id. Hence, it should have been immediately obvious to the Pharmacies' that there problems with these prescriptions.

The McCleod and Dee cases confirm that factual circumstances do exist under which negligence liability can be imposed upon a pharmacy for failing to use due and proper care in filling prescriptions (even when the pharmacy fills the prescription in accordance with the physician's instructions). The factual allegations of pharmacy negligence in the present action amount to more serious breaches of duty than those of the pharmacies involved in the Johnson and Pysz v. Henry's Drug Store, 457 So.2d 561 (Fla. 4th DCA 1984). Powers respectfully asserts that the instant appeal easily presents those facts "which would support an action for negligence against a druggist who has lawfully filled a prescription issued by a licensed physician," Pysz, 457 So.2d at 562, just as in the Dee case recently decided by the First District Court of Appeal. In fact, older cases like Pysz are not likely good law given the changes in the Florida Pharmacy Act wrought by

[5] Reference to the FDA's 2001 OxyContin warnings to doctors and pharmacists can be found at http://www.fda.gov/bbs/topics/ANWERS/2001/ANS01091.html and http://www.fda.gov/medwatch/safety/2001/oxycontin.htm.

the OBRA-mandated screening and warning duties imposed upon pharmacists in the interim.

In Johnson, the First District Court of Appeal held in 1996 that a pharmacy had no duty to warn a customer of the potentially adverse drug reactions of the customer's several prescriptions, and also had no liability for recommending an over the counter allergy medication that was inappropriate for someone taking the drugs that the customer had been prescribed. 678 So.2d at 1037-38. In so holding, however, the Johnson court specifically left open the possibility that more egregious factual allegations than those described there could create liability in a pharmacy for negligently—though accurately—filling a customer's prescription. Id. This is exactly what happened in the Dee case (and Powers would also respectfully assert that the Johnson case has been overruled by the very recent Dee decision by the same Court).

Indeed, close examination reveals that many of the cases cited in support of the Pharmacies' position are, like the Johnson case, no longer good law. In Pysz, for example, the Fourth District held that a pharmacy had no duty to warn a customer of the potentially addictive qualities of prescribed Quaaludes, even where the pharmacy was on constructive notice that the plaintiff was at risk of addiction because the plaintiff was re-filling a Quaalude prescription consistently over a nine-year period. See Pysz, 457 So.2d at 561-562. It must be noted that the Pysz

case was decided in 1984. This was before OBRA greatly expanded pharmacists' duties and before much of the current Florida Pharmacy Act was even codified or amended to conform to the changing standards.

Regardless, in its holding, the Pysz decision acknowledges that "we limit our [decision] to the facts of this case since we recognize that a factual situation could exist which would support an action for negligence against a druggist who has lawfully filled a prescription issued by a licensed physician." Id. Powers asserts that just such a sufficient "factual situation" is plainly present here. The factual allegations of the instant case are distinguishable from those alleged in the Johnson and Pysz cases (and are clearly more egregious). The plaintiff in Johnson attempted to impose a duty to warn on a pharmacy based on the pharmacy's review of multiple prescriptions written by multiple physicians. 678 So.2d at 1037. The individual prescriptions, by themselves, were reasonable, and only in combination did they pose a health risk to the customer. See id. In this case, however, the repeated filling of the same excessive narcotic prescriptions from the very same doctor just days apart should clearly support a claim for negligence. (Powers also believes that both the Johnson and Pysz cases would be decided differently if they were decided today since pharmacy law and statutes have evolved so much during the interim).

In Pysz, the plaintiff there had argued that a pharmacy had a duty to warn a customer of a drug's addictive properties at the customer's initial visit to the pharmacy. 457 So.2d at 561. Alternatively, even if the pharmacy had no duty to warn a customer of the drug's propensity to cause addiction at the customer's initial visit, argued the plaintiff, the pharmacy later incurred a duty to warn the plaintiff of the possibility of addiction or to inform the customer's physician of the addiction risk with respect to the plaintiff, based on the pharmacy's observations of the plaintiffs repeatedly filling prescriptions for the drug over a nine year period. Id. ***Both Florida law and federal law now, however, specifically provide that the dispensing of narcotic prescriptions in too-frequent quantities or intervals is outside of a pharmacist's standard of care.*** This means that Pysz should no longer be considered good law.

When compared to the Pysz case, the instant case seeks to impose a duty upon pharmacists that is already recognized by the Florida Pharmacy Act, federal law, and the pharmacy profession's own standards- simply to use "due and proper care" in reviewing each individual prescription as it is filled, and, in the event that any single prescription is being renewed too frequently (as, for example, being renewed only three or four days after receiving a thirty-day supply) and/or where the customer is filling multiple (and contraindicated) narcotic prescriptions in excessive numbers and constitutes a threat to the customer, to counsel the

customer, call her doctor, or refuse to fill the prescription in accordance with the threat.

In sum, Powers respectfully asserts that the allegations of the instant case—the failure of a pharmacy to recognize and appropriately warn a customer (or her physician) of unreasonable, potentially life-threatening, and repeated prescriptions over very short periods—present sufficient facts "which would support an action for negligence against a druggist who has lawfully filled a prescription issued by a licensed physician." Pysz, 457 So.2d at 562; see also Johnson, 678 So.2d at 1038.

In support of the argument that pharmacies owe a duty to warn a customer of the risks inherent in filling dangerous and controlled prescriptions that are repeated too frequently (with lethal consequences), Powers respectfully cites several recent cases from other states that have imposed a similar duty upon pharmacies. The cases confirm the established legal trend of recognizing, and expanding, pharmacy liability in negligence. See Riff v. Morgan Pharmacy, 508 A. 2d 1247, 1252 (Pa. Super. Ct. 1986), rev. den., 524 A. 2d 494 (Pa. 1987)(holding that pharmacist has a duty of due care and diligence which goes beyond accurately filling the prescription and includes notifying a physician or warning a patient of obvious inadequacies on the face of the prescription); see also Morgan v. Wal-Mart Stores, Inc, 30 S.W. 3d 455, 466, 467 (Tex. App. Austin 2000)(observing that "courts holding that pharmacists owe their customers a duty beyond accurately filling

prescriptions do so based on the presence of additional factors, such as known contraindications, that would alert a reasonably prudent pharmacist to a potential problem. We do not dispute that a pharmacist may be held liable for negligently filling a prescription in such situations," and holding that "any liability of Wal-Mart's for negligently filling Cameron's prescription for Desipramine must be based on neglect in the face of information on which a reasonably prudent pharmacist would have acted"); Pittman v. Upjohn Company, 890 S.W. 2d 425, 435 (Tenn. 1994)(holding that a pharmacy has a duty to warn a customer of a reasonably foreseeable risk of injury resulting from administration of the prescribed medication); Heredia v. Johnson, 827 F. Supp. 1522, 1525 (D. Nev. 1993)(opining that, while a generalized duty to warn is inappropriate, a pharmacist's duty of due care necessarily includes a duty to fill prescriptions as prescribed, properly label them, and be alert for "plain error"); Gassen v. East Jefferson Gen. Hosp., 628 So. 2d 256, 258 (La. Ct. App. 1993) (holding that a pharmacist has no duty under Louisiana law to warn a patient of adverse reactions but does have limited duty to "inquire or verify from [the] prescribing physician clear errors or mistakes in the prescription"); Horner v. Spallitto, 1 S.W. 3d 519, 522 (Mo. Ct. App. 1999)(holding that the range of duty of care owed by pharmacist to a customer was not limited to accurately filling the prescription, and was a jury issue based on the specific facts of the case and the trial testimony

regarding the applicable standard of care); Lasley v. Shrake's Country Club Pharmacy. Inc, 880 P. 2d 1129, 1134 (Ariz. App. Div. 1994)(holding that the range of duty of care owed by pharmacist to the customer was a jury issue based on the specific facts of the case and the trial testimony regarding the applicable standard of care); Dooley v. Everett, 805 S.W. 2d 380, 386 (Tenn Ct. App. 1990)("whether the duty to warn of a potential drug interaction is included within the pharmacist's duty to his customer is a disputed issue of fact preventing… summary judgment"). The growing number of cases on this issue demonstrates that pharmacy negligence is an evolving doctrine and these recent cases from other states are consistent with the growing evolution of the case law in Florida as evidenced by the Dee case recently decided by the First District Court of Appeal and the Powers decision decided by the Fourth District here below. See also Gorod, *The Evolving Duty of Pharmacists to Warn or Not to Warn*, 16-JUL S.C. Law. 15 (2004); Green, *Pharmacist Liability: The Doors of Litigation Are Opening*, 40 Santa Clara L. Rev. 907, 919-22, 931 (2000); Neiner, *A New Cure for Contraindication: Illinois Supreme Court Prescribes a New Duty to Warn On Pharmacists: Happel v. Wal-Mart Stores, Inc., 766 N.E.2D 1118 (Ill. 2002)*, 28 S. Ill. U. L.J. 483 (2004)

In Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1125 (Ill. 2002), the Illinois Supreme Court held that a patient's pharmacy owed a duty to warn either the patient or her physician that a prescribed anti-inflammatory was contraindicated. The holding of the Illinois Supreme Court is consistent with state and federal pharmacy law imposing a duty upon pharmacists to screen every prescription and warn either the prescribing physician or the patient about potential problems. This is especially true where, as here, it was reasonably foreseeable that a failure to convey the potential danger might result in injury to the patient. Id. at 1124. The Illinois Supreme Court further noted, in part, that

> [t]he burden on the defendant [pharmacy] of imposing this duty is minimal. All that is required is that the pharmacist telephone the physician and inform her or him of the contraindication. Alternatively, the pharmacist could provide the same information to the patient. Since this burden of warning about the contraindication is extremely small, this factor also favors the imposition of a duty here.

Id. The Happel decision holds explicitly that, under the circumstances, the pharmacist "had a duty to warn and this duty is encompassed within the pharmacist's duty of ordinary care." Id. at 1125. Pharmacy law and practice has expanded to the degree that pharmacists, in many circumstances, possess knowledge of prescription medication which is equal to or greater than that of the physicians prescribing the medication. Pysz, 457 So.2d at 562; see also Smith, *Between a Rock and a Hard Place: The Propriety and Consequence of*

Pharmacists' Expanding Liability and Duty to Warn, 1 Houston J. Health L. & Poly 187, FN 8, 101-109, 245-251 (2002). In this appeal, Powers is asking only that this Court confirm that the Pharmacies had a duty to Mrs. Powers to use reasonable care and diligence (in the very manner required by the controlling pharmacy statutes and the accepted standards of the pharmacy profession).

III. The Learned Intermediary Doctrine Is Inapposite.

The Pharmacies and their *amici* argue that they did not have a duty to warn Mrs. Powers about any potential danger or to contact her physician because the "learned intermediary" doctrine entitles them to blindly defer to her doctor's prescriptions even though the drugs the Pharmacies dispensed in excessive quantities unequivocally killed her. As set forth below, the learned intermediary doctrine plainly has no applicability to a pharmacist's duty to warn or counsel a patient/physician involving prescriptions that are abusive, lethal, known contraindications, or otherwise violate the law.

The lynchpin of the Pharmacies' arguments to this Court is that the "learned intermediary" doctrine precludes them from being liable, in any and all respects, for the death of Mrs. Powers. Nothing could be more legally incorrect. As noted above, the Florida Pharmacy Act is set forth at Chapter 45 of the Florida Statutes. Many of the standards of professional pharmacy practice adopted therein were

originally mandated, at least in part, by federal law. See OBRA; see also 42 U.S.C. § 1396r-8(g)(2).

The Florida Pharmacy Act clearly sets forth the duties that a pharmacist must undertake in rendering pharmaceutical care, thus establishing a "checks and balances" system with respect to drugs—especially controlled substances—prescribed by a physician for the purpose of protecting public health. Thus, to the extent that the Florida Pharmacy Act (and controlling federal law) clearly set out the screening and consultation duties of pharmacists, they must necessarily have voided or prohibited the application of the "learned intermediary" doctrine to pharmacists and their patients. Regardless, the "learned intermediary" doctrine should never have been applied to the pharmacist-patient relationship in the first place (and it has never been so applied or ratified by this Court).

In Dooley v. Everett, 805 S.W. 2d 380 (Tenn Ct. App. 1990), a physician prescribed the drug Theophylline on a recurring basis to a 3-year old for the treatment of asthma. The physician also later prescribed an antibiotic that was contraindicated with Theophylline. The child eventually suffered cerebral seizures caused by the toxic levels of the drug in his blood. The plaintiff thereafter filed a complaint against the physician and the pharmacist for injuries to the child caused by the failure to warn of the dangerous drug interactions. The pharmacy moved for summary judgment on the grounds that it did not have a legal duty to warn of the

potential drug interaction. In rejecting the applicability of the "learned intermediary" doctrine to the pharmacy-patient relationship, the Dooley court stated:

> Conceived as an exception to the manufacturer's duty, the doctrine has recently taken a quantum leap and attached to a pharmacist's duty to warn his or her customers under a negligence theory.

Id at 386.

But, in a case where the focus was specifically on the duty of a pharmacy to its patient, the Dooley court found the learned intermediary doctrine inapposite under a pharmacy act very similar to Florida's. The Dooley Court also relied on an affidavit of the plaintiff's expert, which opined that:

> "Pharmacy is a profession that requires considerable knowledge about drugs and how they affect the human body;" that "pharmacists recognize that there exists a standard of care applicable to the practice of pharmacy…;" that "there are certain duties and responsibilities generally accepted by members of the pharmacy community;" that the "accepted standard of care of professional practice for the profession of pharmacy as they existed in… [the community] and similar communities" included that "the patient profile should be reviewed by the pharmacist prior to filling a new prescription for several purposes" including a determination of whether the new drug prescribed for the patient and presented for filling to the pharmacist interacts with any other drug currently ordered for the patient.
>
> [The expert] further testified:
>
> [T]he standard of care also required the pharmacist alerted to the interaction to call the [antibiotic] prescriber, alert him or her to the potential interaction, and/or advise the patient or patient's representative of the potential interaction and encourage him or her to

> (1) have his or her serum Theophylline levels monitored and/or (2) to be alert for side effects of Theophylline toxicity. It is difficult to articulate what the standard of care requires of a pharmacist without knowing the exact circumstances under which the [antibiotic] prescription was presented, but, regardless of the circumstances, the pharmacist is required to alert the patient or patient's representative to the potential interaction.

Id. at 382-283; see also Ferguson v. Williams, 92 N.C.App. 336 (N.C.App.Ct. 1988)(rejecting the learned intermediary doctrine as applied to pharmacists).

The Pharmacies cannot contend in good faith that the "learned intermediary" doctrine shields them from liability for breaching their professional standard of care. There is no reason to grant the Pharmacies the immunity they seek. Pharmacists are more than just pill counters. In Riff v. Morgan Pharmacy, 508 A.2d 1247, a pharmacy was sued for refilling a prescription for the drug Cafergot on several occasions without advising the patient of the side effects of overmedication. In rejecting the argument that the sole function of the pharmacy was to correctly fill the prescription, the Riff Court stated:

> The statement by the appellant [pharmacy] that "its function and duty was to supply the medication" is incorrect, and yet it is quite illustrative of the appellant's disregard for the professional duty owed the plaintiff by the defendant pharmacy. The appellant would seem to argue that a pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians. Such is not the case.
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> * * *
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> A pharmacist is a professional. In the performance of his professional duties he will be held to the standard of care, skill, intelligence which

> ordinarily characterizes the profession. Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it.

Riff, 508 A.2d at 1251. The Pharmacies are making the very same argument in this case, and it should be similarly rejected.

The "learned intermediary" doctrine should be limited to its original use. Under that doctrine, drug manufacturers are required to advise physicians of the adverse propensities of prescriptions drugs and physicians, in turn, acting as learned intermediaries and using their sound medical judgment, are required to advise patients of the propensities of these drugs. Despite the fact that the "learned intermediary" doctrine clearly applies only to manufacturers and physicians, some courts have expanded the doctrine to protect pharmacists on the grounds that, if physicians have the duty to advise patients of the possible adverse effect of drugs, pharmacists cannot also have that duty. With all due respect, this makes no sense. Clearly, neither Congress nor the Florida legislature thought that the "learned intermediary" doctrine should be applied to negate pharmacists' duties to screen prescriptions and counsel their patients since both have clearly passed laws that specifically charge pharmacists with the very duties they are trying, via this appeal,

to escape.[6] See also Happel v. Wal-Mart Stores, Inc., 766 N.E. 2d 1118 (Ill. 2002)(holding that, under the facts presented, the "learned intermediary" doctrine did not relieve the pharmacy of a duty to warn). In sum, the application of the "learned intermediary" doctrine to the pharmacist-patient context should be rejected by this Court.

IV. The Fourth District Opinion Is In Accord With The Public Policy Of Florida.

The Fourth District's opinion is in accord with this Court's previous decision in McCleod, simply allows a plaintiff to plead a claim of negligence against a pharmacy, and is in conformity with the public policy of Florida. The Florida Pharmacy Act (as well as the controlled substances statute at Fla. Stat. § 893.04) clearly evidence the public policy that pharmacists have an explicit duty to use due and reasonable care in the performance of their profession. Moreover, the abuse of Oxycontin and other narcotics is a problem that the State of Florida is actively trying reduce. See John Kennedy, *Panel to Fight Rise In Abuse of Pills*, Orlando Sentinel (December 13, 2003)(announcing a multi-agency task force to

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[6] From a purely logical perspective, application of the "learned intermediary" doctrine would seem inapposite regardless since pharmacists, in the context of the dispensing of drugs, are not any kind of intermediary but actually function as the last clear chance in catching prescription problems. This is precisely why both federal and Florida law impose a duty upon pharmacists to screen every

fight the rise in abuse of OxyContin); see also the Florida Office of Drug Control, *Why Florida Needs a Prescription Validation Program* (dated June 13, 2003 and noting that Florida had a serious problem with prescription drug abuse).

The public policy arguments made by the Pharmacies and their *amici* are not compelling. The duty of a pharmacist to warn either a patient or physician is minimal and pharmacists regularly contact physicians' offices to verify prescriptions and regularly counsel and respond to patient questions, as they are required to do. Hence, any duty of care announced by this Court would not impose any duty beyond that which already exists and would not require a pharmacist to make any kind of medical judgment, but merely to pass on the knowledge that, for that particular patient, the prescription(s) might lead to harm and that the patient's prescribing physician should be consulted. The policy arguments made by the Pharmacies and their *amici* virtually ignore the fact that no reasonable pharmacist would fill repeated narcotic prescriptions for drugs that were contraindicated without some consultation with the patient and/or her physician. That is the professional standard of care imposed upon pharmacists of this State, and it is the established public policy of Florida.

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prescription and to counsel patients and consult directly with prescriber-physicians, as necessary.

The decision of the Fourth District Court of Appeal below does not require a pharmacist to "second guess" the prescribing physician in any way, but merely to advise the physician if he or she has prescribed drugs together that are contraindicated or has authored a prescription that might lead to serious physical harm. There is, thus, little—if any—risk to the physician-patient relationship by requiring a pharmacist, under the facts of this case, to consult with the patient or her physician prior to dispensing what is potentially a deadly cocktail.

The Pharmacies' policy arguments that a pharmacist never has a duty to warn a patient or her physician of the consequences of a prescription or prescriptions that—if filled—could foreseeably result in serious injury or death is antithetical to common sense and Florida public policy. As cited above, both Florida and federal law impose a heightened duty upon pharmacists in the context of the dispensing of controlled substances such as OxyContin and Diazepam. Those laws exist for a reason, and the violation of those express legal duties should be sufficient to establish both a duty and a breach of duty for purposes of a negligence claim in the context of this case. The decision of the Fourth District Court of Appeal should be affirmed in all respects as it is in complete accord with the public policy of Florida.

V. The *Amici's* Arguments Are Not Persuasive.

In their support of Florida pharmacists, the Florida Retail Federation and the Florida Association of Retail Pharmacists argue essentially that pharmacists owe no actionable duty of care to their patients. As set forth above, this position cannot be reconciled with the Florida Pharmacy Act or federal law. Both require pharmacists to review every prescription and to counsel the patient (and/or call the prescribing physician) if a problem with a prescription is suspected. Hence, to the extent that the *amici curiae* who have filed briefs in support of the Pharmacies fail to specifically address Florida pharmacy law, the established standards of the pharmacy profession, or the evolving case law recognizing that pharmacists owe a duty of reasonable care to their patients (including the Fourth District's decision below and the First District's recent decision in Dee v. Wal-Mart Stores, Inc.), their positions cannot ultimately be persuasive.

CONCLUSION

In this appeal, the Pharmacies are essentially seeking blanket immunity from negligence liability. Under controlling Florida common and statutory, however, the Pharmacies clearly owed Mrs. Powers a duty of reasonable care. It makes little sense for failure to meet the professional standard to result in loss of a pharmacist's license, but not to entail any corresponding liability for damages caused to a patient injured by that very failure. Moreover, application of the "learned

intermediary" doctrine to the pharmacist-patient relationship has been precluded by the duties set out in the Florida Pharmacy Act (and applicable provisions of federal law). In addition, the public policy arguments asserted by the Pharmacies and their *amici* in opposition are extremely deleterious to Florida citizens who rely on the training and expertise of their pharmacists when having their prescriptions filled. The Fourth District's decision is very limited in scope, and is not in direct conflict with any decision of this Court or lower appellate court. Thus, the exercise of this Court's jurisdiction in not truly warranted.

WHEREFORE, for all the foregoing reasons, if this Court decides to exercise its discretion and take jurisdiction over this appeal, Respondent respectfully requests that this Court: 1) acknowledge the professional standards of pharmacy practice required by the Florida Pharmacy Act (and federal law) and how those standards inform the duty of care; 2) refuse to expand the "learned intermediary doctrine" beyond its application to drug manufacturers and recognize its inapplicability to pharmacists and pharmacies; 3) affirm the decision of the Fourth District Court of Appeal in all respects, and remand this case for trial; and, 4) order any further relief it deems just and proper. By so holding, this Court will be carrying out the intent of the Florida legislature to better protect the health and welfare of the citizens of Florida.

CERTIFICATE OF SERVICE

We hereby certify that a true and correct copy of the foregoing was furnished via U.S. Mail to the persons on the attached service list, this 8th day of December, 2005.

CERTIFICATE OF COMPLIANCE

We hereby certify that this brief complies with the font requirements set forth in Florida Rule of Appellate Procedure 9.210(a)(2).

Respectfully submitted,

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