

IN THE SUPREME COURT OF FLORIDA

**YOUR DRUGGIST, INC.**

**Petitioner,**

**CASE NO. SC05-1191**

v.

**ROBERT POWERS, etc., et al.,**

**Respondent.**

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**B.A.L. PHARMACY, ETC.,**

**Petitioner,**

**CASE NO. SC05-1192**

v.

**ROBERT POWERS, etc., et al.,**

**Respondent.**

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**CORRECTED BRIEF OF *AMICUS CURIAE*  
LONG TERM CARE PHARMACY ALLIANCE  
IN SUPPORT OF PETITIONERS**

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## STATEMENT OF INTEREST

This *amicus* brief is filed on behalf of the Long Term Care Pharmacy Alliance (“LTCPA”) in support of the Petitioners, Your Druggist, Inc. and B.A.L. Pharmacy. LTCPA is a voluntary association of long term care pharmacies, incorporated in Delaware as a Limited Liability Corporation. LTCPA’s member companies serve approximately two of every three long term care residents in the nation, including over 80 percent of the nursing home beds in the State of Florida.

Long term care pharmacies (known in Florida as “institutional pharmacies”) contract with nursing homes to provide prescription drug services to facility residents, so that the nursing homes can meet their federal and state law obligations and provide routine and emergency drugs to their residents. *See* 42 C.F.R. § 483 and Fla. Admin. Code R. 58A-4. Because nursing homes are typically too small to support an in-house pharmacy, long term care pharmacies deliver the drugs to the nursing home to be distributed by a facility nurse to each resident. Long term care pharmacies, using centralized facilities, package the drugs in special “unit dose” or bingo card systems, offer 24/7 delivery services, and provide emergency boxes to the nursing homes. Long term care pharmacies, however, are not open to the public, and one cannot walk into one of these facilities to have a prescription filled.

The court below, in *Powers v. Thobani*, 903 So. 2d 275, 280 (Fla. 4<sup>th</sup> DCA 2005), certified its decision to be in conflict with *Estate of Sharp v. Omnicare, Inc.*, 879 So. 2d 34 (Fla. 5<sup>th</sup> DCA 2004), in which the Fifth District correctly held that a long term care pharmacy had no duty that would support a nursing home resident's negligence claims. Although *Powers* imputed a duty from retail pharmacists to their customers by certifying the conflict with *Sharp*, the court implicitly suggested that its holding was also applicable to long term care pharmacies. Because Florida statutes do not always distinguish between pharmacists practicing in retail settings and those practicing in institutional settings, and because the definition of "pharmacy" includes both community (retail) and institutional (long term care) pharmacies, this case could have significant implications for long term care pharmacies. See Fla. Stat. § 465.003(11)(a).

The Fourth District's decision in *Powers*, as it now stands, has serious ramifications for long term care pharmacies. As noted above, these entities dispense prescriptions from centralized facilities, often distant from the nursing home site, and do not come into contact with the residents who ultimately take the prescription medications. The face-to-face pharmacist-patient contact upon which *Powers* is predicated simply does not take place in the long term care world. Thus, the Fourth District's decision is plainly unworkable in the context of long term care pharmacies.



Many nursing home residents are frail and/or cognitively impaired.<sup>1</sup>

Requiring long term care pharmacists to warn nursing home residents about potential adverse effects of the drugs they dispense is simply impossible without mandating that each nursing home install an in-house pharmacy (at great cost to the Florida Medicaid program). Indeed, the Fifth District noted the differences between a long term care pharmacy and a retail pharmacy in framing the issues in *Sharp*: “In the present case the Estate seeks to hold the nursing home’s pharmacists liable for the administration of medications that were provided to Ms. Sharp by the nursing home, or that were prescribed by her physicians.” *Sharp*, 879 So. 2d at 36. Accordingly, the LTCPA has a substantial interest in preserving the well-settled Florida law that pharmacists have no general duty to warn, and that the Fourth District’s decision is quashed.

## **SUMMARY OF ARGUMENT**

The Supreme Court of Florida should quash the Fourth District’s ruling that the Complaint in *Powers v. Thobani* states a cause of action for negligence against

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<sup>1</sup> Nursing home residents typically have three medical conditions, with 45 percent having four or more, and 10 percent having more than six medical conditions. They take on average 6 drugs, with 45 percent taking seven or more drugs, and 20 percent taking more than 10 drugs. Over half of nursing home residents have abnormal cognitive function. See R. Bernabei, *et al.*, *Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*, 54 J. Gerontol. A Bio. Sci. Med. Sci. M25 (1999).

the Petitioners for failure to warn a customer of the risks of filling certain repeated prescriptions. Neither this state's common law nor statutory law recognizes an independent cause of action for negligence against a pharmacist who properly fills a legal prescription in accordance with a physician's orders. The Fourth District's creation from whole cloth of a new "policy," purportedly predicated upon excerpts from Florida statutes and Board of Pharmacy regulations, is contrary to law, and is out of step with both policy considerations and the overwhelming trend of the courts in the country to limit a pharmacist's duties to correctly filling prescriptions. If the *Powers*' holding is upheld, the Florida health care system will be significantly harmed, and the carefully balanced long term care pharmacy system serving the State's frail, elderly, and most vulnerable citizens will be severely impaired. Such serious policy concerns should be considered after full deliberation and consideration by the Florida Legislature, not by the Fourth District without benefit of any record whatsoever concerning long term care. Thus, this Court should quash *Powers* and reaffirm the long standing rule in Florida that pharmacists have no duty to warn.

## **ARGUMENT**

### **Standard Of Review**

In negligence cases, the question of whether a duty exists is one of law. *McCain v. Florida Power Corp.*, 593 So. 2d 500 (Fla. 1992). Questions of law are

reviewed *de novo* by this Court. *Fayad v. Clarendon Nat. Ins. Co.*, 899 So. 2d 1082 (Fla. 2005).

**I. The Fourth District Incorrectly Interpreted Statutes And Regulations To Create Its New “Policy.”**

**A. Florida Statutes And Regulations Do Not Create A Pharmacist’s “Duty” To Warn.**

In Florida, it has been well settled for over forty years that a pharmacist’s responsibilities are limited to warranting 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 v. W.S. Merrell Co.*, 174 So. 2d 736, 739 (Fla. 1965). This holding has been correctly and consistently upheld in subsequent rulings, including *Johnson v. Walgreen Co.*, 675 So. 2d 1036, 1038 (Fla. 1<sup>st</sup> DCA 1996); *Sharp*, 879 So. 2d at 36; and *Pysz v. Henry’s Drug Store*, 457 So. 2d 561, 561-62 (Fla. 4<sup>th</sup> DCA 1984), and should not be disturbed in the absence of any intervening legislative action.

The Fourth District, however, has taken it upon itself to change this forty-year-old rule notwithstanding its explicit concession that “Florida’s pharmaceutical regulatory statutes and administrative codes do not create a private cause of action against pharmacists.” *Powers*, 903 So. 2d at 279. The court below determined

that, because pharmacists are “specifically charged with general knowledge of prescription medication and the risks presented by taking particular prescription drugs,” a strong policy reason supported the imposition of a pharmacist’s duty to warn – a policy reason the Legislature somehow never saw fit to address. *Id.* (citing Fla. Stat. § 465.003; Fla. Admin. Code R. 64B16-27.300, 64B16-27.820).

A review of Florida pharmacy practice statutes reveals that the Fourth District was correct that no statute or regulation imposes a duty on pharmacists above and beyond the appropriate dispensing of a prescription. The Legislature has made clear that its purpose in enacting Fla. Stat. Chapter 465 was to establish licensure requirements and to regulate the practice of pharmacy, not to create a private cause of action against pharmacists for breach of a duty to warn.

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. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

Fla. Stat. § 465.002 (emphasis added).

Unfortunately, the Fourth District confused a standard of practice in a licensing statute with a duty.<sup>2</sup> It then relied upon the statutory definition of the

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<sup>2</sup>The violation of a licensing statute is not proof of negligence unless the violation is directly related to the incident giving rise to a claim of negligence. *McFarland*

term “dispense” as supporting its policy basis for the creation of a duty to warn. *Powers*, 903 So. 2d at 279. However, this definition addresses the pharmacist’s responsibility to assess whether the prescription that is dispensed is consistent with the drug prescribed by the physician. Rather than establishing a duty to warn, this statutory definition leaves to the discretion of the pharmacist the determination of whether counseling the patient on proper drug dosage is necessary, nothing more. Clearly, if the Florida Legislature intended to impose a duty to specifically warn customers of the risks associated with prescriptions pharmacists dispensed, it could certainly have done so directly, explicitly, and unambiguously.

This conclusion was clearly recognized in *Johnson*, 675 So. 2d at 1038, where the First District held that section 465.003(6) did not give rise to a private cause of action against a pharmacist for failure to warn of these types of risks. Wisely, the First District decided that policy determinations for imposing civil liability on a pharmacist were best left to the Legislature. *Id.* Following that

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*& Son, Inc. v. Basel*, 727 So. 2d 266 (Fla. 5<sup>th</sup> DCA 1999). In addition, licensing statutes created for the protection of the general public do not create a duty of care for a specific individual who happens to benefit from the statutes. *Holodak v. Lockwood*, 726 So. 2d 815,816 (Fla. 4<sup>th</sup> DCA 1999). Moreover, courts in other states have been quick to point out that a statute regulating pharmacists may not be used as evidence of the existence of a duty and should not alter the common law. *See Morgan v. Wal-Mart Stores, Inc.*, 30 S.W. 3d 455, 466-67 (Tex. Ct. App. 2000); *Saukas v. Walker Street Pharmacy*, No. 260560, 2005 WL 1846289, at \*2 (Mich. Ct. App. Aug. 4, 2005) (a professional standard would not have the effect of altering the common law).

decision, the Fifth District in *Sharp* revisited, and again rejected, the argument that Chapter 465 imposes a duty on a dispensing pharmacy providing services to a nursing home pursuant to a contract. *Sharp*, 879 So. 2d at 36.

The Fourth District also cited Fla. Admin. Code R. 64B-16-27.820 (“Patient Counseling”) as support for creation of a new duty. That section of the Code requires Florida pharmacists to make an offer to counsel the patient or the patient’s agent. Absent a refusal of counseling, the pharmacist shall discuss with the patient or the patient’s agent “matters that will enhance or optimize drug therapy” and this discussion “shall include appropriate elements of patient counseling.” Fla. Admin. Code R. 64B16-27.820(1). The regulation then lists elements that this discussion “may include, in the professional judgment of the pharmacist.” *Id.* (emphasis added). Thus, the Fourth District, finding no statute or regulation that imposed a duty to warn, created one out of an offer to counsel. Moreover, this new duty applies to long term care pharmacies even though there is no way a long term care pharmacist is in a position to counsel a patient and there is no guarantee the patient will understand such counseling. The Fourth District gave no consideration whatsoever to these or any other issues unique to long term care.

Similarly, the Fourth District relied upon Fla. Admin. Code R. 64B16-27.810 (“Prospective Drug Use Review”) which lists items to be identified by the pharmacist as part of the prospective drug use review, but does not specify a duty

to warn either the prescriber or patient. Fla. Admin. Code R. 64B16-27.810(1)(a-g). That regulation states that “[u]pon recognizing any of the above [list of items], the pharmacist shall take appropriate steps to avoid or resolve the potential problems, which shall, if necessary, include consultation with the prescriber.” Fla. Admin. Code R. 64B16-27.810(2) (emphasis added). The pharmacist, therefore, is to use his or her professional judgment to assess whether any of the situations listed in Fla. Admin. Code R.64B16-27.810(1)(a-g) exist, and only if he or she concludes that it is necessary, consult with the prescriber. This is not a duty to consult with the prescriber, nor is there any mention whatsoever of a duty to warn the patient. Thus, of all of the Respondent’s allegations in *Powers*, none is required as a duty under Fla. Admin. Code R. 64B16-27.810.

Finally, the Fourth District cited Fla. Admin. Code R.64B-16-27.300 (“Continuous Quality Improvement Program”) as creating a policy foundation for a duty to warn. The Continuous Quality Improvement Program, however, is a pharmacy peer-review program. There is no language requiring a pharmacist or pharmacy to report its findings on quality-related events to a prescriber or to a patient. Indeed, no patient’s name or employee’s name is to be included in a summary of these events, and “[r]ecords are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.” Fla. Admin. Code R. 64B16-27.300(5). The obvious intent of these regulations is to

create a tool for pharmacists and pharmacies to improve the quality of the services they offer, not to create a private right of action against pharmacists or pharmacies.

Neither the Respondent nor the court below has established a statutory basis for a pharmacist's duty to warn a customer. Respondent, therefore, has failed to meet the required elements of a negligence claim.<sup>3</sup> Instead of serving as a policy foundation for the establishment of a pharmacist's duty to warn, Florida pharmacy statutes and regulations were distorted by the Fourth District to justify a break with the common law that has served pharmacy customers well for years.

**B. Florida Statutes And Regulations Place The Duty To Warn On The Physician, Not The Pharmacists**

As noted above, the Fourth District was correct in one respect – Florida statutes and regulations do not impose a duty to warn on the pharmacist. Instead, the statutes, regulations, and even decisional case law of this State have consistently held that “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; *see also Sharp*, 879 So. 2d at 36; *McLeod*, 174 So. 2d at 739 (“Obviously, 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

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<sup>3</sup> A claim for negligence must allege: (1) a duty of care; (2) breach of that duty; (3) proximate cause; and (4) damages. *See Clampitt v. D.J. Spencer Sales*, 786 So. 2d 570, 573 (Fla. 2001).



physician who prescribed the remedy.”). Both statutes and regulations clearly recognize the differences between physicians and pharmacists and the different roles that each play in the health care process. *See* Fla. Stat. 456.065(1) (“[T]he unlicensed practice of a health care profession or the performance or delivery of medical or health care services to patients in this state without a valid, active license to practice that profession, regardless of the means of the performance or delivery of such services, is strictly prohibited.” (emphasis added)). Pharmacists, and others, risk civil and administrative sanctions as well as criminal penalties if they perform a medical service related to the prescribing of a drug. *See* Fla. Stat. 456.065(2)(d)(1-2). Indeed, even when the Florida Legislature expanded its definition of the “practice of the profession of pharmacy” to include “other pharmacy services” to enable pharmacists to monitor and assist the patient in the management of drug therapy and communicate with the physician in certain situations (a service not at issue in *Powers*), the Legislature limited the responsibilities of pharmacists. Nothing that constitutes the practice of pharmacy can serve to alter “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.” Fla. Stat. § 465.003(13).

Most relevant to the facts of this case, the differences between pharmacist and physician responsibilities are exemplified by the distinct regulations for Standards of Practice for Dispensing of Controlled Substances for the Treatment of Pain (applicable to pharmacists) and a separate regulation establishing Standards for the Use of Controlled Substances for the Treatment of Pain (applicable to physicians). Fla. Admin. Code R. 64B16-27.831(2), for pharmacists, is focused upon anti-diversion and only requires that pharmacists verify that a prescription for pain medication has been written for a legitimate medical purpose if: (1) there is frequent loss of controlled substance medications; (2) only controlled substances are being prescribed; (3) prescriptions are presented by one person with different patient names; (4) two or more prescribers prescribe the same or similar controlled substances; and (5) the patient always pays cash or insists on a name brand product. There is no requirement in this regulation for the pharmacist to warn a customer about the risks of the controlled substances the pharmacist dispenses.

In contrast, the regulation that applies to physicians requires the doctor to document a valid medical need for the controlled substance and a treatment plan. Fla. Admin. Code R. 64B8-9.013(1)(b). The physician is also obligated to adjust the quantity and frequency of doses according to the intensity and duration of the pain, and must recognize that a patient's tolerance and physical dependence on a prescription are "normal" consequences of the sustained use of these prescriptions.

Fla. Admin. Code R. 64B8-9.013(1)(c.) The physician must evaluate the patient by taking a complete medical history and conducting a physical examination, develop a written treatment plan, obtain the informed consent of the patient for the treatment plan, conduct periodic reviews of the course of treatment, refer the patient, as necessary, for additional evaluation and treatment, and keep accurate and complete medical records. Fla. Admin. Code R. 16B8-9.013(3)(a-f). These standards reflect the physician's training, his or her knowledge of the patient, and the physician-patient treatment goals for that patient. They are not the standards for a pharmacist.

Had the Fourth District appropriately evaluated these standards, it would have recognized that it is the doctor, not the pharmacist, who has the training and skill to prescribe the medication in the first instance, and who is the sole health care professional qualified to provide patient warnings. The regulations themselves make clear that the pharmacist has little to do with this process other than to dispense the medication that the doctor has prescribed, and to ensure to the extent possible that inappropriate diversion is avoided. To require the pharmacist to question and second-guess decisions made by the doctor would force the pharmacist to intrude into areas the Legislature reserved for physicians.

Creation of a new rule that pharmacists have a duty to warn would have extremely negative policy implications for pharmacists, physicians, and patients in the Florida health care system. Pharmacists would be considered co-practitioners with physicians, with the ability to provide alternative information to a patient and to challenge prescriptions written by the patient's physician. For example, if a pharmacist disagreed with the amount of pain medication a physician had prescribed, the pharmacist would be able to convey this information to the customer, thereby potentially interfering with a medically necessary treatment plan and undermining the customer's trust and confidence in his or her physician.

## **II. To The Extent A Policy Change Should Be Considered, It Should Be Considered By The Legislature**

The Fourth District, in seeking to make policy in the absence of a statutory or regulatory basis for a pharmacist's duty to warn, has deprived stakeholders of the opportunity for fair and open discussion of the issue before legislative committees charged with the policy making process. The Fourth District violated the Legislature's intended "sole purpose" for creating Chapter 465, failed to recognize that the regulatory responsibilities for physicians and pharmacists are different, and opened a "Pandora's Box" of ramifications for the health care system in Florida and long term care pharmacies in particular.

This type of policy decision is legislative in nature and the State Legislature has never made the decision to impose upon pharmacists a duty to warn customers of the risks of repeated and unreasonable prescriptions with potentially fatal consequences. Rather, the Legislature has left it to the discretion of patients whether to accept an offer to counsel and pharmacists whether to use their professional judgment on the content of the counseling.

### **III. A Duty to Warn is Incompatible With Long Term Care Pharmacies' Services**

The impact of a new duty to warn would be extremely harsh on long term care pharmacists, and the manner in which long term care pharmacy services are provided in Florida would cease to exist. Instead of using centralized institutional pharmacies to prepare and dispense drugs to many different nursing homes in an area, a long term care pharmacy would have to literally set up shop in each nursing home so that it could interact with every resident, or his or her legal representative, when dispensing a prescription. It is inconceivable how such a rule would work with a population that is among the most frail and cognitively impaired of all patients, and often has legal representatives who live in other states.

Importantly, the fact that the existing centralized dispensing process of a long term pharmacy does not require face-to-face contact with a patient has been recognized and accepted by the Centers for Medicare and Medicaid Services

(CMS) for the new Medicare Prescription Drug Program that will begin nationwide on January 1, 2006. “As provided in [42 CFR] § 423.120(a)(5) of our final rule, we will require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure convenient access to prescription drugs for institutionalized beneficiaries within the service area.” 70 Fed. Reg. 4251. Long term care pharmacies in Florida and other states have negotiated contracts with prescription drug plans using existing service models to provide prescription drug services to Medicare beneficiaries residing in nursing homes. To impose a duty to warn on pharmacists in Florida at this juncture would likely create chaos within the Medicare Prescription Drug Program in Florida.

Finally, the Court in *Sharp* noted that it was inappropriate to hold a pharmacist dispensing drugs to residents of a nursing home responsible for the actions of prescribing physicians or nursing home staff administering the drugs. *See Sharp*, 879 So. 2d at 36. The extreme policy implications of creating a pharmacist’s duty to warn warrant the type of extensive debate and consideration that only the legislative process offers.

#### **IV. The Majority of Jurisdictions Hold That Pharmacists Have No General Duty to Warn**

As justification of its decision, the Fourth District relied, in part, on the fact that other jurisdictions have recognized negligence liability of pharmacies.

*Powers*, 903 So. 2d at 279. However, the Fourth District ignored the holdings of the majority of jurisdictions that pharmacies do not have a general duty to warn.<sup>4</sup> Moreover, the trend of the most recent cases is that there is no duty to warn. While the Court acknowledged the holding in *Morgan*, 30 S.W. 3d at 466-69, that pharmacists do not have a general duty to warn customers of potential hazards or side effects of prescribed drugs, the Fourth District did not mention that the Texas Court of Appeals also noted that a majority of courts have held that a pharmacist has no duty to warn against side effects “when the prescription is proper on its face and neither the physician nor the manufacturer has required that the pharmacist give the customer any warning.” *Id.* at 461. Upon careful consideration of recent case law, the court commented that there are some limited situations where a

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<sup>4</sup> See, e.g., *Chamblin v. K-Mart Corp.*, 612 S.E. 2d 25 (Ga. Ct. App. 2005) (pharmacists do not have a duty to warn customers about every potential side effect of a drug); *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881 (Ala. 2004) (the learned intermediary rule forecloses the existence of a duty upon pharmacists to warn consumers of the risks or potential side effects of prescribed medication); *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885 (W.D. Ark. 1999) (pharmacists have no general duty to warn customers of potential drug side effects); *Coyle v. Richardson-Merrell, Inc.*, 584 A. 2d 1383 (Pa. 1989)(a pharmacist has no duty to warn of risks associated with prescription drugs); *McKee v. Am. Home Prods., Corp.*, 782 P. 2d 1045 (Wash. 1989) (a pharmacist has no duty to warn of adverse side effects of prescription drugs). In fact, one court explicitly adopted the standard set forth in *McLeod* when it found that the defendant pharmacy did not have a duty to warn the plaintiff of hazards associated with a certain drug. *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 88 (E.D. Pa. 1986).

pharmacist could be held liable for negligence, but that the court could not “discern from relevant case law a trend towards imposing a more general duty.” *Id.* at 466.

More recently, in *Cottam v. CVS Pharmacy*, 764 N.E. 2d 814, 817 (Mass. 2002), the Massachusetts Supreme Court addressed whether a pharmacy has a duty to warn customers of the potential side effects of prescriptions drugs. In an extensive commentary on cases from other jurisdictions, the court noted that, while a pharmacy has a duty to fill prescriptions correctly, “the overwhelming majority [of jurisdictions] hold that, in general, a pharmacy has no duty to warn its customers of side effects.” *Id.* at 819. Likewise, the Massachusetts Supreme Court held that, “generally, a pharmacy has no duty to warn its customers of the side effects of prescription drugs.” *Id.* Thus, there is no reason for this Court to abandon its well-established rule.

The court in *Cottam* also noted that many jurisdictions have held that pharmacists have no duty to warn by extending the “learned intermediary rule,” to pharmacies. *Id.* at 820. The learned intermediary rule was originally applied to drug manufacturers and provided that a prescription drug manufacturer’s duty to warn of the dangers associated with its product ran only to the physician, and not the ultimate consumer. *Id.* As applied to pharmacists, it is the physician’s duty to warn the patient because a physician can consider the history and needs of the



patients and the qualities of the drugs prescribed. *Id.* (citing *McKee v. Am. Home Prods. Corp.*, 782 P. 2d at 1049)<sup>5</sup>; *see also Ramirez.*, 628 F. Supp. at 88 (“To impose a duty to warn on the pharmacist, however, would be to place the pharmacist between the physician who, having prescribed the drug presumably knows the patient’s present condition as well as his or her complete medical history, and the patient.”). The Massachusetts Supreme Court in *Cottam* specifically adopted as Massachusetts law the learned intermediary doctrine in the context of pharmacies. *Id.* at 821. This doctrine has been effectively adopted in Florida with respect to pharmacists, *Pysz*, 457 So. 2d at 562; *Sharp*, 879 So. 2d at 36; *McLeod*, 174 So. 2d at 739; and has been explicitly adopted with respect to manufacturers, *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989).

In the most recent opinion on a pharmacist’s duty to warn, the Michigan Court of Appeals affirmed the district court’s holding that the defendant pharmacy owed the plaintiff no duty to warn of the side effects of a properly prescribed drug. *Saukas*, 2005 WL 1846289, at \*1. There, the Michigan Court of Appeals followed its prior line of cases which held that “a pharmacist has no duty to warn the patient

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<sup>5</sup> The court based its decision in part on policy reasons that: (1) imposing the duty to warn would undermine the doctor-patient relationship; (2) the physician is in the best position to decide what information is pertinent to the patient based on a physician’s knowledge of the patient’s medical history and unique condition; (3) imposing a duty to warn would place too heavy a burden on pharmacists; and (4) a pharmacist does not have the discretion to alter or refuse to fill a prescription. *Id.*

of possible side effects of a prescribed medication where the prescription is proper on its face and neither the physician nor the manufacturer has required that any warning be given to the patient by the pharmacist.” *Id.* (citing *Stebbins v. Concord Drugs*, 164 Mich. App. 204, 416 N.W. 2d 381 (1987)). Similarly, this Court should not overturn the established line of Florida cases, starting with this Court’s *McLeod* decision, and reaffirm that no duty to warn exists on the part of pharmacists that would give rise to a cause of action for negligence.

## **CONCLUSION**

For the foregoing reasons, as well as those set forth by Petitioners, this Court should quash the decision of the Fourth District and reaffirm the well established rule that, in Florida, a pharmacist has no duty to warn prescribers or customers of the adverse effects of the drugs they dispense pursuant to valid and lawful prescriptions. No such duty should be imposed on retail pharmacists, and certainly no such duty should be imposed on long term care pharmacists.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a copy of the foregoing has been furnished this  
\_\_\_\_ day of \_\_\_\_\_, 2005, to all persons on the attached service list.

Respectfully submitted,

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**CERTIFICATE OF FONT SIZE**

I HEREBY CERTIFY that the type size and style used throughout this Brief is the 14 Point Times New Roman Proportionally-spaced Font.

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