IN THE FLORIDA SUPREME COURT

YOUR DRUGGIST, INC.

Petitioner,

v.

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

Respondent.
_____/

CASE NO: SC05-1191

LOWER COURTS
District Case No: 4D04-2061
Circuit Case No. 03-17380(12)

REPLY BRIEF OF PETITIONER, YOUR DRUGGIST, INC.

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SCOPE OF REPLY BRIEF

To avoid unnecessary duplication, the Petitioner Pharmacies have coordinated their replies to Powers' Answer Brief. Accordingly, Your Druggist adopts the arguments contained in The Medicine Shoppe's Reply Brief as if fully contained herein.

ARGUMENT

I. STATE AND FEDERAL STATUTES DO NOT IMPOSE A DUTY TO WARN ON PHARMACISTS WHEN FILLING LAWFUL PRESCRIPTIONS.

A. There Is No Duty To Warn Of Lawful Prescriptions Under Florida Statutes Or Regulations.

Florida statutes and regulations governing pharmacies do not create a legally enforceable duty to warn. Respondent contends that "[p]harmacy disciplinary statues 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 at the very least, [constitute] evidence of negligence (if not negligence per se)." Resp. Br. at 19. However, many courts have rejected the same argument in evaluating similar state regulatory statutes or rules promulgated by their state pharmacy boards. See Chamblin v. K-Mart Corp., 612 S.E.2d 25 (Ga. App. Ct. 2005); Morgan v. Wal-Mart Stores, Inc., 30 S.W. 3d 455 (Tex. App. Austin 2000); McKee v. American Home Products, Corp., 782 P.2d 1045 (Wash. 1989); Ingram v. Hook's Drugs, Inc., 476 N.E. 2d 881, 887 (Ind. Ct. App. 1985),

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discussed infra. These courts have concluded that such state statutes and regulations do not establish a legally enforceable standard of care, impose a general duty to warn, or create an independent cause of action.

In support of this argument, Respondent cites to the Florida Pharmacy Act claiming it "define[s] the applicable standard of care or serves as evidence of it." Resp. Br. at 24-25. According to Respondent, the Florida Pharmacy Act "specifically requires that every prescription be screened and that the appropriate corrective counseling be taken" citing section 465.003(6), Florida Statutes. Resp. Br. at 25. However, this section merely defines the term "dispens[ing]." One Florida court has already rejected Respondent's argument based on the same definition. See Johnson v. Walgreen Co., 675 So.2d 1036, 1037 (Fla. 1st DCA 1996).

In Johnson v. Walgreen Co., 675 So.2d 1036, 1037 (Fla. 1st DCA 1996), the court refused to recognize a cause of action or legal duty to warn of adverse drug interactions based on the Florida Pharmacy Act. In Johnson, the plaintiff unsuccessfully argued that section 465.003(5), Florida Statutes, imposed a duty and a cause of action on pharmacists because it required that: "[a]s an element of dispensing, the pharmacist shall … interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen he deems appropriate in the exercise of his professional judgment…. The pharmacist shall also provide

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counseling on proper drug usage, either orally or in writing, if in the exercise of his professional judgment counseling is necessary." Id. Fla. Stat. 465.003(5)(1986).[1] These are the same unpersuasive arguments raised by Respondent.

Respondent contends that Johnson would be decided differently today, even though the Johnson court evaluated the same language defining the same term "dispense." Resp. Br. at 35. See footnote 1, infra. Moreover, Johnson was decided in 1996, six years after the enactment of the Omnibus Budget Reconciliation Act of 1990 ("OBRA"). Respondent relies heavily on OBRA in arguing that a pharmacists' duty to warn of adverse drug interactions already exists.

Other courts have rejected the Respondent's argument that a state regulatory statute or rule promulgated by a pharmacy board establishes a duty to warn. In a recent case, Chamblin v. K-Mart Corp., 612 S.E.2d 25 (Ga. App. Ct. 2005), the court refused to find a duty to warn based on a rule enacted by the Georgia State Board of Pharmacy requiring pharmacists to advise customers of the potential side-effects of a drug. The subject rule required dispensing pharmacists to personally offer to discuss matters that would enhance or optimize drug therapy with each customer. The plaintiff in Chamblin had an extreme allergic reaction to a prescription filled at a K-Mart pharmacy. There were no allegations that the

[1] In 1999, § 465.003 of the Florida Pharmacy Act was amended. Subsection (5), defining the term "dispense", was renumbered as section 465.003(6). The language of subsection (5) is the exact language considered by the court in Johnson.

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pharmacy incorrectly filled the prescription, provided the plaintiff with incorrect instructions, or gave the drug in an incorrect strength or quantity. Nonetheless, the plaintiff claimed that the pharmacy had "a duty to warn her of any potential adverse effects of [the medication] based on the regulations of the Georgia State Board of Pharmacy requiring dispensing pharmacists to offer to counsel patients about their medication." Id. at 27. The court ruled against the plaintiff, reasoning that "while the rule requires that counseling be offered to a customer, the topics of discussion are determined entirely by the subjective judgment of the individual pharmacist, and the rule only refers to common side or adverse effects in its list of elements of discussion that may be included." Id. (emphasis added).

Similarly here, Respondent contends that "the standards of the Pharmacies' own profession impose duties … to intervene to avoid poor patient outcomes and to promote the therapeutic appropriateness of prescriptions." Resp. Br. at 25. This does not create a legally enforceable standard of care. As in Chamblin, the decision of when patient counseling is necessary is based on a pharmacist's "professional judgment." Fla. Stat. § 465.003(6). See Morgan v. Wal-Mart Stores, Inc., 30 S.W. 3d 455 (Tex. App. Austin 2000)(noting that while administrative rules adopted pursuant to the Texas Pharmacy Act demonstrate that pharmacists are trusted professionals with varied and important responsibilities, they impose no general duty to warn patients of the adverse effects of prescription drugs); McKee v.

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American Home Products, Corp., 782 P.2d 1045 (Wash. 1989)(statute defining "practice of pharmacy" does not create mandatory duty on all pharmacists to warn customers of all dangers associated with a drug).

Respondent also cites to § 465.0155, Florida Statutes, which gives the Florida Board of Pharmacy the right to define the standards of practice for pharmacists, claiming this creates a legally enforceable duty. Resp. Br. at 23. In Ingram v. Hook's Drugs, Inc., 476 N.E. 2d 881, 887 (Ind. Ct. App. 1985), a statute vesting the board of pharmacy with the authority to regulate and control the practice of pharmacy and a regulation requiring a pharmacist to include directions for use as contained in the prescription did not create a statutory duty on the part of pharmacists to warn customers of all hazards associated with a prescription drug. In rejecting the same argument made by Respondent, the Ingram court explained: "[o]ur examination of [the relevant statute] discloses no evidence of a mandatory duty on the part of pharmacists filling a prescription to warn a customer of all possible hazards associated with that drug." Thus, these rules do not create a legally enforceable standard of care. Additionally, rules promulgated under the Florida Pharmacy Act, do not create a private cause of action. See Amicus Brief of Long Term Care Pharmacy Alliance at 6-7.

Similarly, Respondent improperly attempts to rely on § 465.016(1)(i), Florida Statutes, which governs improper dispensing, such as dispensing medicine

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without a prescription. A violation of this statute may result in the revocation of a pharmacist's license, but it does not subject the pharmacist to civil liability.

In sum, Respondent misapplies the nature and purpose of the Florida statutes and regulations governing the practice of pharmacy in an effort to alter the common law.

B. Federal Law Does Not Establish A Duty To Warn

Similarly, Federal statutes and regulations do not create a duty to warn customers of potential risks in filling lawful prescriptions, nor do they establish a standard whereby pharmacists are required to warn customers of lawful prescriptions.

Respondent's reliance on 21 C.F.R. § 1306.04, in support of his argument that "federal law clearly imposes a 'responsibility' with the 'pharmacist who fills the prescription' for every controlled substance," is misplaced. Resp. Br. at 21. As explained in Ryan v. Dan's Food Stores, Inc., 972 P.2d 395, 406 (Utah 1998), "section 1306.04 does contain a … narrow [public policy], one which only prohibits pharmacists from *knowingly* filling an improper prescription. Violation of section 1306.04 'require[s] a willful violation.'" (emphasis in original)(internal citations omitted). There are no allegations here that Mrs. Powers' prescriptions were improper. Of importance, "[s]ection 1306.04 does not mandate or even authorize a pharmacist to question every prescription or to conduct an investigation

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to determine whether an otherwise facially valid prescription has been issued other than in the "usual course" of the doctor's practice. But when faced with a prescription that is irregular on its face—'no date, no physician signature, an obviously toxic dose'--section 1306.04 requires further inquiry." Id. (emphasis added). Thus, 21 C.F.R. § 1306.04 is entirely consistent with the Petitioner Pharmacies' position that a pharmacy's duty is to correctly fill lawful prescriptions. "[S]ection 1306.04 does not … establish a policy requiring pharmacists to verify prescriptions. Id.

Respondent also misapprehends the OBRA statute. Citing to OBRA, Respondent contends that "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. . . ." Resp. Br. at 22. Much of Respondent's brief relies on this contention as established fact, for example, "before OBRA greatly expanded pharmacists' duties." Resp.Br. at 35. See also Resp.Br. at 25, 27, 34, and 36. Respondent's argument misapprehends the nature and purpose of this section of OBRA. OBRA was never intended to establish a duty on pharmacists to "screen *all* prescriptions and counsel their customers." Rather, OBRA governs Medicaid payment for prescription drugs and was intended to, among other things, keep Medicaid costs down.

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The applicable statute, 42 U.S.C.§ 1396r-8, is titled "Payment for covered outpatient drugs." This means *Medicaid* covered outpatient drugs. The specific subsection relied upon by Respondent is (g) "Drug use review." Specifically, 42 U.S.C.§ 1396r-8(g)(1)(A) provides:

> *In order to meet the requirement of section 1396b(i)(10)(B) of this title,* a State shall provide . . . for a drug use review program described in paragraph (2) for covered outpatient in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results.

(emphasis added). This provision further states that the "program shall be designed to educate physicians and pharmacists to identify and reduce . . . fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. . . ." More importantly, the first sentence unambiguously states that the drug use review program is required in order to meet the requirements of 42 U.S.C. 1396b(i)(10)(B). This is the drug utilization program run by the Agency for Health Care Administration for Medicaid patients and has no application to this case. That statutory provision states that a state Medicaid program cannot pay for "an innovator multiple source drug," for instance, a brand name drug, if there is a less expensive alternative available. Thus, while the drug use review program does cover abuse, drug-drug interactions, and drug allergies, its main purpose is to ensure that the least costly medications are paid for under state Medicaid programs. More importantly, the OBRA mandated drug review was never intended to require

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pharmacists to screen all prescriptions, much less establish a legally enforceable standard of care. It was intended to be part of a state *Medicaid* reimbursement system.

Nonetheless, Respondent contends that one purpose of OBRA was "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." Resp. Br. at 21. This is not so. Respondent's contention is contradicted by the very words of the statute. The requirements that Respondent contends were made part of the expanded state pharmacy standards by OBRA are part of the prospective drug review described in 42 U.S.C. §1396r-8(g)(2)(A). Subsection (g)(2)(A)(ii), however, provides that "[a]s part of the State's prospective drug use review program under this subparagraph *applicable State law shall establish standards* for counseling of individuals receiving benefits under this subchapter by pharmacists . . . ." (emphasis added). Congress could not have expanded pharmacy practice standards through OBRA when OBRA itself relied upon applicable state law for standards.

Lastly, the Fourth District certified the decision below to be in conflict with Estate of Sharp v. Omnicare, Inc., 879 So.2d 34 (Fla. 5th DCA 2004), a case that involved a long term care pharmacy. OBRA provides, at 42 U.S.C. § 1396r-

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8(g)(1)(D), that drug use reviews need not be performed regarding drugs dispensed to residents of long term care facilities that are in compliance with 42 C.F.R. § 483.60. Subsection 483.60(c) provides for a monthly drug regimen review for each resident of the long term care facility by a licensed pharmacist. The pharmacist is required to report any "irregularities" to the attending physician and the director of nursing, "and these reports must be acted upon." The regulation, cited as sufficient in OBRA, requires no interaction with the patient at the time medications are dispensed, no counseling, and no warnings. It is difficult to believe that the same statute that explicitly endorsed 42 C.F.R. § 483.60 could possibly be read as expanding the duties of pharmacists.

II. POLICY CONSIDERATIONS OVERWHELMINGLY FAVOR LIMITING THE DUTY TO WARN OF ADVERSE SIDE-EFFECTS TO LICENSED PHYSICIANS.

Respondent misapprehends the impact of imposing on pharmacists a duty to warn patients and physicians of lawful prescriptions. Respondent claims that such a duty would be "minimal" because pharmacists regularly contact physician's offices to verify prescriptions." However, pharmacists are currently only required to contact physicians when it is clear, from the face of the prescription, that the prescription is unlawful. See Johnson v. Walgreen Co., 675 So.2d 1036, 1037 (Fla. 1st DCA 1996)(holding that pharmacists have no general duty to warn customers or their physicians of potential adverse prescription drug interactions). As a

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practical matter, imposing a duty on pharmacists to evaluate the reasonableness of every prescription would disrupt both the jobs of pharmacists and the practice of medicine.

Many courts have declined to impose on pharmacists a duty to warn, recognizing the profound impact that imposing this duty to warn would have on pharmacists. See Johnson, 675 So.2d at 1037 (Fla. 1st DCA 1996)(recognizing that while some public policy arguments can be made in favor of expanding a pharmacists' duty, that task should be left to the legislature); McKee v. American Home Products, Corp., 782 P. 2d 1045 (Wash. 1989)(noting that imposing a duty would "antagonize" the relationship between doctor and pharmacist).

The job of properly assessing the statewide impact of imposing such a vast duty on pharmacists should be left to the legislature since they have the resources and the ability to take evidence of demographic trends, to hear from economists and experts in the pharmaceutical and medical professions, and weigh the conflicting policies involved in recognizing such a vast duty. Thus, the legislature is better equipped than the courts or litigants to appropriately evaluate the statewide impact on both the practice of medicine, the practice of pharmacy, and the impact the expanded duty would have on Florida citizens, including the costs that will be borne by Florida elderly citizens.

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Respondent contends that the Petitioner Pharmacies did not have to know anything about Mrs. Powers' medical history to know that OxyContin was being prescribed inappropriately and was subject to abuse. Resp.Br. at 28. This argument ignores the well-recognized fact that pharmacists cannot determine the appropriateness of a particular drug regimen without having knowledge of the customer's medical history. "The propriety of a prescription depends not only on the propensities of the drug but also on the patient's condition. A prescription which is excessive for one patient may be entirely reasonable for the treatment of another." Eldridge v. Eli Lilly & Co., 485 N.E. 2d 551, 555 (Ill. Ct. App. 1985). It is the prescribing physician, not the pharmacist, who is in the best position to determine the appropriateness of a prescribed drug and monitor its use.

Essentially, Respondent is asking this Court to impose a duty that would require pharmacists to practice medicine without a license. Determining when a particular drug is being prescribed in excessive quantities is a medical judgment. "Determining which medication is to be utilized in any given case requires an individualized medical judgment, which … only the patient's physician can provide." Fakhouri v. Taylor, 618 N.E. 2d 518, 521 (Ill. App. Ct. 1999). Similarly, Respondent's reliance on McCain v. Florida Power Corp., 593 So.2d 500 (Fla. 1992) is misplaced. It is the doctor, not the pharmacist, who has the duty to foresee the consequences of prescribing a particular drug for a particular purpose.

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In arguing that pharmacists have a duty to warn customers of potentially adverse drug interactions, Respondent and his *amicus* completely ignore the essential role of physicians in determining what medication, dosage, and quantities to prescribe based on a patient's condition and unique medical history. Pharmacists are not licensed physicians. Patients rely upon their physicians, not pharmacists, to prescribe the correct drug and dosage and warn of the risks associated with the drug. Similarly, licensed physicians, not pharmacists, are gatekeepers of prescription drugs. See Adkins v. Mong, 425 N.W. 2d 151 (Mich. Ct. App. 1988)(pharmacists owe no legal duty to monitor customer's drug usage).

Respondent claims that the Petitioner Pharmacies are liable for failing to warn Mrs. Powers when dispensing Oxycontin because the FDA issued warnings to doctors and pharmacists that Oxycontin was dangerous and intended for use only as needed. Resp.Br. at 31-32. Again, Respondent ignores the role of Mrs. Powers' physician in determining what warnings, including FDA warnings, were appropriate based on her treatment of Mrs. Powers and Mrs. Powers' own individual medical history. The FDA's own warning states that treatment should be closely monitored by the prescribing physician. The Petitioner Pharmacists had no indication that Mrs. Powers was not being closely monitored by her physician. In fact, Schedule II controlled substances, such as Oxycontin, cannot be refilled and

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thus, by definition, Mrs. Powers was seen by her physician each time she obtained a prescription.

CONCLUSION

In sum, there is no basis under Florida or Federal law for imposing on pharmacists a general duty to warn their customers of potential adverse interactions when filling lawful prescriptions. The duty to warn must rest with the physician, because only he or she can determine what prescription drug regime is appropriate based on the patient's complaints, the physical examination of the patient, and the patient's medical history.

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CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing was served via Federal Express this 7th day of February, 2006 to all counsel listed on the attached service list.

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In compliance with Fla.R.App.P. 9.210(a)(2), and 9.100(1), undersigned counsel certifies that this brief is submitted in Times New Roman 14 point font.

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