NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION AND, IF FILED, DETERMINED

IN THE DISTRICT COURT OF APPEAL
OF FLORIDA
SECOND DISTRICT

JEANNE M. SORENSON, as executor of the Estate of DARRYL RAY SORENSON,)
Appellant,)
V.) Case No. 2D15-441
PROFESSIONAL COMPOUNDING PHARMACISTS OF WESTERN PENNSYLVANIA, INC., a Foreign Corporation; CHARLOTTE PAIN MANAGEMENT CENTER, INC.; ANZAOHEALTH CORPORATION, a Florida Corporation; LEONARD A. BENTON, M.D.; HAROLD E. SLEIGHT, II, M.D.; JOHN HUBICKI, PA-C; NANCY HARRIS, R.N.; GINA PROVENCAL; and JOHN DISTASIO,	
Appellees.)

Opinion filed May 11, 2016.

Appeal from the Circuit Court for Charlotte County; Donald H. Mason, Judge.

Christian D. Searcy of Searcy Denny Scarola Barnhart & Shipley, P.A., West Palm Beach; William E. Partridge and Patrick S. McArdle of Grossman Roth P.A., Sarasota; and David J. Sales of David J. Sales, P.A., Jupiter, for Appellant.

Shelley H. Leinicke of Wicker, Smith, O'Hara, McCoy & Ford, P.A., Ft. Lauderdale; and Michael R. D'Lugo of Wicker, Smith, O'Hara, McCoy & Ford, P.A., Orlando (substituted as counsel of record), for Appellee Professional Compounding Pharmacists of Western Pennsylvania, Inc.

No appearance for remaining Appellees.

SILBERMAN, Judge.

Jeanne M. Sorenson, as Executor of the Estate of Darryl Ray Sorenson, seeks review of the order dismissing with prejudice the claims in her wrongful death negligence suit against Professional Compounding Pharmacists of Western Pennsylvania, Inc. (the Pharmacist). The trial court dismissed these claims, which were set forth in counts VI and VII of the second amended complaint, for failing to allege a cognizable duty that the Pharmacist owed Mr. Sorenson. We conclude that count VI alleged a breach of a cognizable duty to use due and proper care in filling a prescription and reverse on this basis. We affirm the dismissal as it pertains to count VII.

The second amended complaint alleges that Mr. Sorenson was an Ohio resident who suffered from chronic low back pain caused by a car accident. Mr. Sorenson's physician was managing his pain by administering hydromorphone through a pain pump that had been inserted into his spinal canal. While vacationing in Florida in 2012, Mr. Sorenson visited Charlotte Pain Management Center, Inc. (Charlotte Pain), based on a referral from his physician. One of Charlotte Pain's physicians wrote a prescription for hydromorphone that increased the concentration from 10 mg/mL to 30 mg/mL. Charlotte Pain transmitted this prescription directly to the Pharmacist, and the Pharmacist compounded the medication and released it to Charlotte Pain. Charlotte

Pain then administered the medication to Mr. Sorenson through his pain pump. He died that same day.

Ms. Sorenson's wrongful death suit included medical negligence claims against Charlotte Pain, several of its health care providers, and the Pharmacist. Count VI of the second amended complaint alleged negligence of the Pharmacist by, among other things, "negligently preparing and dispensing" a prescription for hydromorphone that was "unreasonable on its face, due to the dosage strength." Count VII alleged negligence per se of the Pharmacist by filling the unreasonable prescription without being registered or licensed in Florida as required by law.

The question before this court is whether the trial court properly dismissed these counts for failing to allege a cognizable duty that the Pharmacist owed Mr.

Sorenson.¹ This court conducts a de novo review of an order dismissing claims for failing to state a cause of action. Ferguson Enters., Inc. v. Astro Air Conditioning & Heating, Inc., 137 So. 3d 613, 615 (Fla. 2d DCA 2014). However, our review is limited to the four corners of the complaint, and we are required to accept the allegations therein as true and to resolve any inferences in favor of the plaintiff. Id.

I. Count VI - Wrongful Death Negligence

In McLeod v. W.S. Merrell Co., 174 So. 2d 736 (Fla. 1965), the supreme court addressed the issue of a pharmacist's obligations to its customers in a breach of warranty case. The court concluded that

a druggist who sells a prescription warrants that (1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might

¹The counts against Charlotte Pain and the health care providers remain pending in the trial court, but they have been stayed until this appeal is decided.

also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug has not been infected with some adulterating foreign substance.

Id. at 739 (emphasis added). Our sister courts have relied upon this language to conclude that a pharmacist has a common law duty to use due and proper care in filling a prescription and that the failure to do so may give rise to an action for negligence.

See Oleckna v. Daytona Disc. Pharmacy, 162 So. 3d 178, 181-82 (Fla. 5th DCA 2015); Powers v. Thobhani, 903 So. 2d 275, 278 (Fla. 4th DCA 2005); Dee v. Wal-Mart Stores, Inc., 878 So. 2d 426, 427 (Fla. 1st DCA 2004).

These courts have also determined that this duty to use due and proper care may involve more than simply filling the prescription as written. Oleckna, 162 So. 3d at 182; Powers, 903 So. 2d at 278; Dee, 878 So. 2d at 427. A pharmacist may breach the duty of care even when he or she fills a prescription in accordance with the physician's instructions if the prescription is unreasonable on its face.

In <u>Dee</u>, the complaint alleged that a prescription for a Duragesic patch was unreasonable on its face because it was more than four months old and did not contain a time limit for filling or using it. 878 So. 2d at 427. Thus, a pharmacist who viewed the prescription would reasonably conclude that the patient is opioid-naive and not on the necessary drug regimen and that the patch would likely be fatal to the patient. <u>Id.</u> at 427-28. The First District concluded that the complaint stated a cause of action in negligence. <u>Id.</u> at 428.

In <u>Powers</u>, the complaint alleged that a pharmacist breached its duty by filling a patient's multiple prescriptions in too short a time frame, noting that some of the prescribed narcotics were contraindicated and that the drugs were being repeatedly

prescribed before preceding prescriptions would have been depleted. 903 So. 2d at 276-77. The Fourth District concluded that the complaint set forth a cognizable breach of the "duty to warn customers of the risks inherent in filling repeated and <u>unreasonable</u> prescriptions with potentially fatal consequences." Id. at 279 (emphasis added).

The complaint in <u>Oleckna</u> contained allegations of filling prescriptions that were unreasonable on their faces because the physician was overprescribing narcotics. 162 So. 3d at 179-80. The Fifth District determined that the complaint alleged a cognizable duty to use due and proper care. <u>Id.</u> at 182-83. The court explained that a pharmacist's duty of care "extends beyond simply following the prescribing physician's directions" and held that the duty could not be "satisfied by 'robotic compliance' with the instructions of the prescribing physician." <u>Id.</u> at 182.

We agree with our sister courts that a pharmacist's duty to use due and proper care involves more than simply filling the prescription as written. We share in the Fifth District's conviction that "robotic compliance" with a prescribing physician's instructions will not shield a pharmacist from liability when the prescription is unreasonable on its face.

The second amended complaint contains the following allegations regarding the Pharmacist's breach of the duty of care as set forth in count VI:

21. The Defendant PROFESSIONAL COMPOUNDING PHARMACISTS sent 40 ml of Hydromorphone in a preservative free solution at a concentration of 30 mg/ml to Defendant CHARLOTTE PAIN without confirming the previous concentration and dose; without reviewing the Decedent DARRYL RAY SORENSON's patient history to determine past dosing; and by failing to determine the pump type, the various settings, or the programming used to deliver the Hydromorphone, thereby negligently and inappropriately filling a prescription which was unreasonable

on its face due to the potency and strength of this highly controlled pain medication[.]

. . . .

- 46. At all times material hereto, Defendant PROFESSIONAL COMPOUNDING PHARMACISTS owed a duty by and through its agents, apparent agents, employees, and/or contractors to provide pharmacy and narcotic dispensing services in accordance with the prevailing professional pharmacy standards of care, which in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent and similar pharmacists in the same or similar community.
- 47. Notwithstanding the duty undertaken, Defendant PROFESSIONAL COMPOUNDING PHARMACISTS is independently and/or vicariously liable for doing, or by <u>failing</u> to do one or more of the following acts, any or all of which are departures from the acceptable professional pharmacy <u>standards of care</u> in Charlotte County, Florida, or any other similar pharmacy community:
- i. negligently preparing and dispensing an order for 30 mg/ml of Hydromorphone without a license in Florida, which Defendant PROFESSIONAL COMPOUNDING PHARMACISTS knew, or should have known was unreasonable on its face, due to the dosage strength of the medication, and was likely to result in serious injury or death to the decedent, DARRYL RAY SORENSON:
- ii. Negligently failing to inform DARRYL RAY SORENSON and/or his other healthcare providers that the pharmacy had no active license to compound drugs in Florida, which led to the filling of the prescription of 30 mg/ml of Hydromorphone, a prescription unreasonable on its face due to dosage strength, and likely to result in serious injury or death to the decedent DARRYL RAY SORENSON.

(Emphasis added.) Accepting these allegations as true and resolving inferences in favor of Ms. Sorenson, the Pharmacist knew or should have known that the prescribed concentration of hydromorphone was potentially fatal and nonetheless filled the

prescription without further inquiry. We conclude that these allegations of count VI set forth a cognizable duty that the Pharmacist owed Mr. Sorenson.

We recognize that the complaint is unartfully drafted. For example, the use of the word "thereby" in paragraph 21 could be read to limit the Pharmacist's negligent actions to those preceding that word: filling the prescription without confirming the previous concentration and dose, reviewing Mr. Sorenson's patient history, and inquiring into the details of the pump specifications. These allegations, standing alone, may not support a claim against a compounding pharmacist. However, when read in conjunction with the subsequent assertions in count VI, we conclude that the Pharmacist's allegedly negligent actions included filling a prescription that is claimed to be facially unreasonable and failing to consult the prescribing physician regarding that dosage strength.

This is where the dissent's argument misses the mark. The dissent frames the issue, as does the Pharmacist, solely as a question of negligence arising out of the Pharmacist's failure to inquire as to the patient's history and related information in order to determine whether the prescription was appropriate for the patient. But that reading of the complaint ignores the allegation of negligence in filling a prescription for hydromorphone at a concentration of 30 mg/mL, which the Pharmacist "knew, or should have known was unreasonable on its face, due to the dosage strength of the medication." By rejecting this allegation as "conclusory," the dissent appears to have decided that a prescription for hydromorphone in that concentration may be reasonable for other patients. However, the issue of whether the prescription concentration was, in fact, facially unreasonable is not an issue that can be resolved on a motion to dismiss.

<u>See Ferguson</u>, 137 So. 3d at 616 ("It is not for the court to speculate whether the allegations of the complaint are true or whether they can be proven.").

The Pharmacist argues that <u>Oleckna</u>, <u>Powers</u>, and <u>Dee</u> do not support a finding of a duty for the Pharmacist because the pharmacists in those cases were retail, as opposed to compounding, pharmacists. The Pharmacist asserts that, as a compounding pharmacist, it was two steps removed from Mr. Sorenson because it dispensed the medication to the prescribing physician who then administered it to Mr. Sorenson. We recognize that compounding pharmacists may have no direct contact with patients. However, we are not persuaded that the lack of direct patient contact shields a compounding pharmacist from its duty to use due and proper care in filling a prescription that is intended for administration to that patient. We also note that this duty arises not from a duty to warn the patient; rather it arises from the duty to not fill a facially unreasonable prescription without appropriate inquiry.

The Pharmacist also argues that count VI does not set forth a cognizable duty to inquire about the hyrdomorphone's concentration because the administering physician could reduce the concentration or reduce the dosage to compensate for the higher concentration. However, these asserted facts are beyond the four corners of the complaint and are therefore beyond this court's consideration. The complaint unequivocally asserts that the prescription as written was "likely to result in serious injury or death," and we are required to accept this allegation as true. Evidence to the contrary would at best present a question of fact to be resolved in later proceedings.

II. Count VII - Wrongful Death Negligence Per Se

Count VII of the second amended complaint asserts a cause of action for negligence per se by filling the prescription without being registered or licensed as required by law. See §§ 465.0156(1), 456.065, Fla. Stat. (2011). The complaint alleges that "[Mr. Sorenson] falls within the statute's protected class, namely a Florida resident who received treatment from an unlicensed health care provider that resulted in his death due to a lack of services at a high level of protection and competence." This language is taken from a line of cases recognizing a cause of action for negligence per se based on a violation of a "statute which establishes a duty to take precautions to protect a particular class of persons from a particular injury or type of injury." deJesus v. Seaboard Coast Line R.R. Co., 281 So. 2d 198, 201 (Fla. 1973); see also Lingle v. Dion, 776 So. 2d 1073, 1077 (Fla. 4th DCA 2001) ("A cause of action in negligence per se is created when a penal statute is designed to protect a class of persons, of which the plaintiff is a member, against a particular type of harm." (quoting Newsome v. Haffner, 710 So. 2d 184, 186 (Fla. 1st DCA 1998))).

The trial court rejected Ms. Sorenson's allegation that the statutes meet this standard and instead concluded that the failure to be licensed merely constitutes evidence of negligence. The court explained, "Although failure to be licensed or permitted may be evidence of negligence, this is relevant only after the law has imposed a duty of care which has been breached." The trial court concluded that Ms. Sorenson did not state a cause of action in count VII because she failed to allege the breach of a cognizable duty. We agree.

Ms. Sorenson's argument, relying on <u>deJesus</u> and its progeny, is misplaced. The question of whether a statute establishes a duty to take precautions to

protect or benefit a particular class of persons is no longer determinative on the question of whether a cause of action should be recognized. Murthy v. N. Sinha Corp., 644 So. 2d 983, 985 (Fla. 1994). "[L]egislative intent, rather than the duty to benefit a class of individuals, should be the primary factor considered by a court in determining whether a cause of action exists when a statute does not expressly provide for one." Id.

Chapter 456 was enacted to regulate lawful professions "for the preservation of the health, safety, and welfare of the public under the police powers of the state." § 456.003(1), (2). A pharmacist is a "health care practitioner" under section 456.001(4), which extends to chapter 465, the Pharmacy Act. And "[i]t is the legislative intent [of chapter 465] that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state." § 465.002.

"In general, a statute that does not purport to establish civil liability but merely makes provision to secure the safety or welfare of the public as an entity, will not be construed as establishing a civil liability." Murthy, 644 So. 2d at 986 (quoting Moyant v. Beattie, 561 So. 2d 1319, 1320 (Fla. 4th DCA 1990)). We can discern no language in either chapter suggesting an intent to create a private cause of action for the violation of its requirements. See Estate of Johnson ex rel. Johnson v. Badger Acquisition of Tampa, 983 So. 2d 1175, 1182 (Fla. 2d DCA 2008) (affirming summary judgment in favor of a pharmacist because the plaintiff had not established a duty of care arising from the Pharmacy Act and the Act did not set forth a legislative intent to create a private cause of action); Oleckna, 162 So. 3d at 183 n.4 ("The Florida pharmaceutical regulatory statutes and administrative codes do not create a private cause of action

against pharmacists."); <u>Johnson v. Walgreen Co.</u>, 675 So. 2d 1036, 1038 (Fla. 1st DCA 1996) (holding that the language and legislative history of the Florida Pharmacy Act "is devoid of any indication that the Legislature intended to create a private cause of action" for negligence). Accordingly, count VII does not set forth a private cause of action for negligence per se.

In conclusion, we reverse the dismissal of count VI of the second amended complaint because it alleged a breach of a cognizable duty to use due and proper care in filling a prescription. We affirm the dismissal of count VII because it sets forth no basis for a private cause of action for failing to be registered or licensed as required by law.

Affirmed in part, reversed in part, and remanded.

MORRIS, J., Concurs.

LaROSE, J., Concurs in part and dissents in part with opinion.

LaROSE, Judge, concurring in part and dissenting in part.

I concur, without reservation, in the court's affirmance of the trial court's decision to dismiss count VII of the second amended complaint. A cause of action for negligence per se cannot stand.

I respectfully dissent from the court's holding that the second amended complaint alleged facts sufficient to impose on the Pharmacist a duty to use due and proper care in filling a prescription for Mr. Sorenson's ultimate use. Certainly, there may

be cases where a compounding pharmacy owes a duty of care in filling a prescription for a patient. See McLeod v. W. S. Merrell Co., Div. of Richardson-Merrell, Inc., 174 So. 2d 736, 739 (Fla. 1965). This is not that case. In my view, the second amended complaint fails to allege ultimate facts showing any duty owed by the Pharmacist. See Fla. R. Civ. P. 1.110(b)(2); Mather v. Northcutt, 598 So. 2d 101, 101 (Fla. 2d DCA 1992) ("To state a cause of action in negligence, a complaint must allege ultimate facts which establish a relationship between the parties giving rise to a legal duty in the defendant to protect the plaintiff from the injury of which he now complains." (citing Ankers v. District School Bd. of Pasco Cty., 406 So. 2d 72, 73 (Fla. 2d DCA 1981))); Estate of Sharp v. Omnicare, Inc., 879 So. 2d 34, 36 (Fla. 5th DCA 2004) (concluding that the complaint's allegations failed to discern a duty that the pharmacy owed to the plaintiff).

The second amended complaint alleges that the Pharmacist failed to "reasonably determine [Mr. Sorenson's] medical history and condition prior to dispensing a highly potent prescription of a controlled substance " As I understand the allegations, I see no such duty. Unlike the situations in Oleckna v. Daytona Disc.

Pharmacy, 162 So. 3d 178 (Fla. 5th DCA 2015), and Powers v. Thobhani, 903 So. 2d 275 (Fla. 4th DCA 2005), there is no allegation that the Pharmacist had any prior dealings with Mr. Sorenson. Nothing indicates that the Pharmacist ever filled a prescription for Mr. Sorenson or on the order of Mr. Sorenson's pain management physician in Ohio. Allegedly, Mr. Sorenson's Ohio physician had previously prescribed hydromorphone for Mr. Sorenson in a concentration of 10 mg/mL. The second amended complaint does not allege that the Pharmacist filled that prescription.

We do know that Mr. Sorenson presented to the Charlotte Pain

Management Center as recommended by his Ohio physician. A physician at Charlotte

Pain prescribed hydromorphone. A copy of the prescription is not in our record. The

court reasonably assumes, however, that the Charlotte Pain physician ordered a

concentration of 30 mg/mL, three times higher than previously ordered by Mr.

Sorenson's Ohio physician. Allegedly, the Charlotte Pain physician forwarded the

prescription to the Pharmacist, who, in turn, filled it. The Pharmacist sent the allegedly

fatal concentration of hydromorphone to the Center. A physician at Charlotte Pain

administered the hydromorphone to Mr. Sorenson a couple of days after his initial visit.

The source of any alleged duty owed by the Pharmacist to Mr. Sorenson hinges on the conclusory allegation that the prescription was "unreasonable on its face due to the potency and strength" of the medication. Consequently, the Pharmacist, as the second amended complaint alleges, had a duty to determine Mr. Sorenson's health history, investigate his prior doses, ascertain the type of pain pump he used, and inquire about pain pump settings. Strikingly, the second amended complaint alleges no facts from which one could say that the prescription, as written, was inappropriate so as to trigger some duty on the part of the pharmacy. See Dee v. Wal-Mart Stores, Inc., 878 So. 2d 426, 427 (Fla. 1st DCA 2004) (alleging that the prescription rendered was unreasonable on its face because it lacked a time limit); Oleckna, 162 So. 3d at 182 (holding that allegations that the pharmacist filled too many prescriptions too close in time should have put pharmacist on notice). The second amended complaint fails to tell us why the Pharmacist should have hesitated. Despite what I see as a pleading deficiency, the court imposes an undue burden of investigation on a compounding

pharmacy. Even the cases relied upon by the court demonstrate the need for some factual setting from which to impose duties such as those claimed by the second amended complaint.

Taken to its logical conclusion, the court's decision will require a compounding pharmacy, upon receipt of a prescription for a new patient, to contact the prescriber to inquire about the patient's history and course of treatment, even if the prescription appears regular on its face. I know of no law or regulation that requires such a burdensome inquiry.