IN THE DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FIFTH DISTRICT JULY TERM 2007

MARISOL FONTANEZ,

Appellant/Cross-Appellee,

v. Case No. 5D06-1363

PARENTERAL THERAPY ASSOCIATES, INC.,

Appellee/Cross-Appellant.

_____/

Opinion filed December 28, 2007

Appeal from the Circuit Court
for Orange County,
Donald Grincewicz, Judge.

Kenneth P. Hazouri and T. Kevin Knight, of de Beaubien, Knight, Simmons, Mantzaris & Neal, L.L.P., Orlando, for Appellant/Cross-Appellee.

Michael R. D'Lugo, of Wicker, Smith, O'Hara, McCoy, Graham & Ford, P.A., Orlando, for Appellee/Cross-Appellant.

EVANDER, J.

Marisol Fontanez, personal representative of the estate of Eduina Zayas, brought a wrongful death action against Parenteral Therapy Associates, Inc., alleging that Ms. Zayas' death was the result of the defendant providing Zayas with a contaminated nutrient solution. The plaintiff initially sought damages under theories of strict liability, breach of implied warranty of merchantability, breach of implied warranty of fitness for a

particular purpose, and negligence. The trial court granted partial summary judgment in favor of appellee on the strict liability and warranty theories, finding that such theories did not apply to a retail prescription pharmacist. The plaintiff then amended her complaint and, referencing the Florida Supreme Court's decision in *McLeod v. W.S. Merrell Co., Div. of Richardson-Merrell, Inc.,* 174 So. 2d 736 (Fla. 1965), alleged that the defendant had breached the implied warranties of a pharmacist. The trial court also dismissed this count. The case proceeded to a jury trial on plaintiff's negligence count where the jury found in favor of the defendant. On appeal, plaintiff contends that, under the facts of this case, she should have been permitted to proceed under her theories of strict liability and breach of a pharmacist's implied warranties We affirm the trial court's decision granting summary judgment on plaintiff's strict liability count. However, we find the trial court erred in dismissing plaintiff's count for breach of a pharmacist's implied warranties.

In 1989, Zayas was diagnosed with short bowel syndrome, necessitating surgery to remove a large portion of her small intestine. Thereafter, she was unable to digest normal portions of food. Accordingly, Zayas primarily nourished herself with total parenteral nutrient ("TPN"), a prescription medication composed of water and nutrients, compounded by a pharmacist, which is infused intravenously into the blood stream. Zayas infused her TPN on a nightly basis while she slept. Specifically, she would connect a bag of TPN to a line that ran through an infusion pump and then through an in-dwelt catheter inserted in her vein.

On May 24, 2000, a pharmacy technician employed by the defendant compounded seven bags of TPN for Zayas. Shortly after starting the infusion that night,

Zayas developed extreme chills, vomiting, and diarrhea. She was transported by a family member to the hospital where she later went into respiratory arrest and lapsed into a coma. Zayas was diagnosed as having severe sepsis.[1] There was also evidence that her blood sugar level had dropped to 1 – an exceedingly low level likely to cause death. (There was expert testimony that the normal range for blood sugar level is between 85 and 125.) Through the efforts of her treating physicians, Zayas eventually emerged from her coma 5 or 6 days later and was discharged from the hospital almost two months later. However, her health and physical condition had severely deteriorated as a result of the aforesaid events. She died the following year.

Prior to being transported to the hospital on the evening of May 24, 2000, Zayas told her grandson that she believed there was something wrong with the TPN. He brought the TPN bag to the hospital for testing. The hospital tested that bag, as well as three other TPN bags which had been prepared by the defendant and delivered to Zayas on May 24th.

At trial, the parties presented conflicting expert testimony. The plaintiff introduced evidence reflecting that all four TPN bags tested positive for potentially harmful bacteria and that one bag also contained a small amount of insulin. (Insulin was not prescribed to be in the TPN solution.) The plaintiff presented expert testimony that (1) Zayas' illness was caused by contaminated TPN, and (2) Zayas' dangerously low blood sugar level was caused by insulin in the TPN. It was the plaintiff's contention that the TPN was likely contaminated during the compounding process by "touch contamination." Touch contamination occurs when a non-sterile object actually touches

[1] Sepsis is the presence of pathogenic organisms or their toxins in the blood or tissues. *American Heritage Dictionary*, at 1118 (2d College Ed. 1982).

and contaminates a sterile object. It was also the plaintiff's contention that the insulin's presence must necessarily have been caused by a mistake occurring during the compounding process.

The defendant's primary expert witness disputed that the bags were contaminated and opined that the source of Zayas' infection was her catheter. The defendant acknowledged that Zayas had a low sugar level upon her admission to the hospital, but challenged the validity of a blood sugar level of 1. The defendant disputed the claim that there was insulin in the TPN and presented expert testimony that Zayas' low blood sugar testimony was likely the result of the sepsis and not the introduction of insulin into her body from an outside source.

The defendant also presented the testimony of the pharmacy technician who prepared Zayas' TPN bags. Defense counsel requested the pharmacy technician to "explain, describe, and illustrate so that the ladies and gentlemen of the jury will understand how it is that you are making sure that you *don't introduce bacteria* and describe the process of compounding TPN" (emphasis added). The pharmacy technician testified extensively about her experience, her training, the sterile environment in which she prepared the TPN, and the efforts she made to ensure that the TPN was not contaminated by bacteria. She also testified that she did not introduce insulin into the TPN during the compounding process and, indeed, that there was no insulin kept in the room in which she prepared the TPN. In closing argument, defense counsel reminded the jury:

> This is a negligence case. If the defendant uses reasonable care, we win. We win. They have to demonstrate a departure from reasonable care.

Defense counsel went on to argue that the plaintiff had failed to meet its burden of proving that defendant's pharmacy technician did not use reasonable care in the preparation of Zayas' TPN.

Both parties seek support for their respective position from the Florida Supreme Court's decision in *McLeod*. In *McLeod,* the plaintiff's physician prescribed a certain drug on the plaintiff's behalf. The drug was manufactured by W.S. Merrell Company. The manufacturer sold the product to retail pharmacists for resale to the public only on prescription of medical doctors. It was undisputed that the two defendant retail druggists sold the drug to the plaintiff in the original unbroken containers that they had received from the manufacturer. The plaintiff apparently suffered severe side effects from his use of the drug and brought an action against the manufacturer and the two retail pharmacists. As to the two retail pharmacists, the plaintiff attempted to proceed on the theory that the retail druggists had breached implied warranties of merchantability and fitness for a particular purpose. The supreme court found that the trial court had properly dismissed plaintiff's warranty counts against the pharmacists.

In rejecting the plaintiff's implied warranty of merchantability claim, the court first observed that a warranty of merchantability applies only when goods are offered for consumption by the public generally. The court found that an implied warranty of merchantability would not exist for prescription drugs because these drugs are available only to a very limited segment of the public, to wit: those individuals "who had previously been seen by their personal physician and who presented their doctor's prescription directing that the drug be supplied." *Id*. at 738-39.

In rejecting the plaintiff's implied warranty of fitness for a particular purpose theory, the court observed that this type of warranty is conditioned upon the buyer's reliance on the skill and judgment of the seller to supply a commodity suitable for the intended purpose. The court held that McLeod relied upon the skill and judgment of his physician, not the pharmacist, in deciding to purchase the prescribed drug. *Id.* at 739.

The court went on to state that "[t]he concept of a strict liability without fault should not be applied to the prescription druggist in the instant case." Instead, the court found that a consumer's rights could be protected by finding that a pharmacist who sells a prescription drug makes certain warranties to the patient-purchaser.

> Rather it appears to us, that the rights of the consumer can be preserved, and the responsibilities of the retail prescription druggist can be imposed, under the concept that a druggist who sells a prescription warrants that (1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug has not been affected with some adulterating foreign substance.

Id.

The plaintiff contends that *McLeod* reflects an attempt by the supreme court to carefully balance the rights of pharmacists and consumers by imposing limited implied warranties on pharmacists in lieu of strict product liability. The defendant argues that *McLeod* should be read to permit only actions for negligence against a pharmacist. The defendant suggests that the supreme court's reference to a pharmacist's warranties was solely to set forth the extent of a pharmacist's duties to a patient – not to establish a cause of action for breach of an implied warranty. We agree with the plaintiff.

First, the supreme court specifically stated that a failure of a pharmacist to satisfy the second warranty [failure to use due care in filling a prescription] "might *also* give rise to an action in negligence" (emphasis added). If the supreme court's intent was to limit actions against pharmacists to negligence claims, it would make little sense to use the above-referenced language. An alternative cause of action is quite obviously not an exclusive one.

The supreme court's decision also recognizes the distinction between the "compounding" of a prescribed drug and the "dispensing" of a prescription drug. The United States Supreme Court has defined compounding as a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. *Thompson v. Western States Med. Ctr.,* 535 U.S. 357, 360-61 (2002).[2] When a pharmacist merely resells a drug that he or she

[2] Rule 64B16-27-700, F.A.C. provides in relevant part:

> "Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or his agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal products as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.
>
> 1. Compounding includes:

has received from a manufacturer, the pharmacist is playing no role in the preparation of the product, but is simply dispensing the drug. The *McLeod* court found that the imposition of strict liability on a pharmacist simply dispensing a prescription drug would improperly convert retail pharmacists into insurers of the safety of the manufactured drug.

On the other hand, when a pharmacist compounds a drug, he is actively involved in the preparation of the end product. Under these circumstances, the *McLeod* decision recognizes that a plaintiff harmed by an adulterated compound drug should not be limited to pursuing an action based on a negligence theory. By permitting a plaintiff to proceed on a warranty theory, *McLeod* recognizes, *inter alia,* that the risk of harm associated with the use of a drug which somehow became contaminated during the compounding process should be borne by the one best able to implement procedures to prevent the contamination, not by a consumer who is powerless to protect himself or herself.

Furthermore, it is unreasonable to require a plaintiff who has been harmed by an adulterated product to have the burden of proving the specific manner in which a drug became contaminated during the compounding process. The unfairness of placing this burden on the plaintiff is clearly demonstrated in the instant case. The only evidence as to the precise manner in which Zayas' TPN was prepared, the condition of the room in which the TPN was compounded on the day in question, and the location of the insulin

---

> (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

came, not unexpectedly, from the defendant's employees. Generally, pharmacy employees will have exclusive knowledge of the events surrounding the compounding of a particular drug.

In the present case, we find that the amended complaint adequately alleged a breach of a pharmacist's implied warranties. The plaintiff specifically alleged that the defendant had compounded and delivered to Zayas, TPN that 1) was contaminated with E-Coli and other bacteria and 2) was improperly laced with insulin. Accordingly, it was error for the trial court to dismiss this count.

The defendant next argues that dismissal of the warranty count was harmless error because the trial court instructed the jury as to the standards of care imposed on pharmacists.

> The standards of care that are imposed on pharmacists are as follows: he will compound the drug prescribed. He will use due and proper care in filling the prescription. Proper methods will be used in compounding the drug. The drug will not be infected with an adulterating foreign substance while compounding dispensing or delivering it.

The defendant's argument ignores the fact that the trial court also instructed the jury that the plaintiff had the burden to prove that the defendant failed to exercise that level of care that a reasonably careful pharmacy would use under like circumstances. Under a warranty theory, the plaintiff would only be required to establish that the TPN was contaminated with an adulterating foreign substance when it was delivered to Zayas and that the contamination caused her illness and/or death.[3] Defense counsel understandably argued to the jury that the plaintiff had failed to prove that the pharmacy

[3] *See Green v. American Tobacco Co.,* 154 So. 2d 169 (Fla. 1963), discussing requisites for establishing implied warranty claim.

technician did not use reasonable care in the preparation of the TPN. Clearly, plaintiff' was prejudiced by the trial court's dismissal of the warranty count.

Based on our conclusion that the trial court erred in dismissing plaintiff's breach of a pharmacist's implied warranties claim, we find it unnecessary to address the other issues raised on appeal and cross-appeal.

REVERSED and REMANDED for a new trial.

SAWAYA and TORPY, JJ., concur.