HEADNOTE

Gourdine, et al v. Crews, et al

No. 1190, September Term, 2006

Appellee Crews suffered an insulin induced seizure while driving, thus causing a collision in which Gourdine was killed. Suit was filed against numerous parties, including Eli Lilly, Inc. manufacturer of the insulin medications.

The Circuit Court granted summary judgment in favor of Lilly on two grounds: (1) Lilly owed no duty to Gourdine; and (2) federal preemption.

The learned intermediary rule imposes a duty on a drug manufacturer to warn physicians of the potential danger of particular medications. Since a manufacturer owes no duty to the patient, it follows that there is no duty to a non-user of the drug.

Moreover, it was not reasonably foreseeable to Lilly that Crew's use of the medications would result in ultimate injury to Gourdine.

REPORTED

IN THE COURT OF SPECIAL APPEALS

OF MARYLAND

No. 1190

September Term, 2006

MARY GOURDINE, INDIVIDUALLY,
etc.

v.

ELLEN CREWS, et al

Salmon,
Adkins,
Sharer,

JJ.

Opinion by Sharer, J.

Filed: November 29, 2007

This appeal stems from a tort action filed by appellants, Mary S. Gourdine, the widow and personal representative of the estate of Issac J. Gourdine ("Gourdine"), and their two children, Monica J. and Lamar T., against appellee, Eli Lilly and Company ("Lilly"), and others.

The Circuit Court for Prince George's County (Hon. Steven I. Platt) granted Lilly's motion for summary judgment, the other defendants having been dismissed from the suit. Appellants pose four questions for our review, which we have condensed and rephrased as:[1]

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[1] In their brief, appellants ask:

> 1. Did the circuit court err in granting summary judgment to Lilly on Count I of [appellants'] Complaint on the basis that Lilly owed no legal duty to protect Gourdine, an innocent bystander, from harm caused by Lilly's sale of the drugs Humulin NPH and Humalog in a defective and unreasonably dangerous condition?
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> 2. Did the circuit court err in entering summary judgment against [appellants] holding that tortfeasors are liable only to the persons to whom their misrepresentations are made or upon whom they commit fraud - not innocent bystanders such as Gourdine?
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> 3. Did the circuit court err in granting summary judgment to Lilly and denying [appellants] discovery based on the FDA's opinion that common law tort claims involving prescription drug injuries are preempted?
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> 4. Did the circuit court err in granting summary judgment to Lilly with respect to [appellants'] punitive damages count (Count XII of the Complaint), in ruling that Lilly owed no legal duty to the [appellants], that [appellants'] claims were preempted and that, therefore, [appellants'] request for punitive damages was without merit?

1. Whether the circuit court erred in granting Lilly's motion for summary judgment.

2. Whether the circuit court erred in determining that federal law preempted state law failure to warn claims involving prescription drugs.

For the reasons that follow, we shall hold that the circuit court correctly granted summary judgment on the basis that "Lilly did not owe a duty to Mr. Gourdine." In light of our holding, we need not address appellants' federal preemption argument.

FACTUAL and PROCEDURAL BACKGROUND

At the time of the motor vehicle accident giving rise to this litigation, Ellen Crews was a type 1 diabetic.[2] On the morning of February 25, 2002, Crews took a combination therapy of Humalog, a rapid-acting insulin, and Humulin N, a long-acting neutral protamine hagedorn ("NPH") insulin, both of which are manufactured and distributed by Lilly. Later that morning, just before 11:00 a.m., while driving south on the Capital Beltway, Crews experienced hypoglycemia or low blood sugar. Near Indian Head Highway, Crews, whom eyewitnesses described as driving erratically, struck the rear of a vehicle driven by Isaac J. Gourdine, pushing Gourdine's vehicle into the back of a tractor-trailer rig parked illegally on the shoulder of the Beltway. Gourdine suffered a fatal head injury as a result of the collision.

[2] Type 1 diabetes results from the body's failure to produce insulin. Diabetes patients may be susceptible to hyperglycemia (high blood sugar) or hypoglycemia (low blood sugar).

On January 7, 2005, appellants filed a complaint,[3] in the Circuit Court for Prince George's County, against Crews, Lilly, Joseph Scott, the driver of the tractor-trailer, F&S Contract Carrier, Inc., the owner of the truck tractor, and ESF Trailer Systems, LLC, the owner of the trailer.[4] The complaint alleged the following against Lilly: (1) "Strict Liability in Tort for Sale of a Misbranded Drug with False and Misleading Advertising and Labeling;" (2) "Negligent Failure to Warn of Dangers Associated with the Use of the Drug Humalog as Directed;" (3) "Conscious Misrepresentation and Fraud;" (4) "Wrongful Death;" (5) "Damages ... Resulting from the Survival Act;" and (6) "Punitive Damages."

All of appellants' claims against Lilly were based on their contention that Humalog and Humulin N combination therapy caused increased rates of hypoglycemia between 6 a.m. and 12 p.m., and that Lilly knowingly failed to include a warning to that effect in its labeling and advertising.

Lilly moved for summary judgment on all counts on May 19, 2006, to which appellants filed their opposition on June 2, 2006. The circuit court heard oral arguments on June 8, 2006, and, after holding the matter *sub curia*, issued an order granting Lilly's motion for summary judgment on June 12, 2006. The court's memorandum opinion, "stating the

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[3] Appellants' complaint was captioned as a "Complaint for Wrongful Death and Survival Action and for Compensatory and Punitive Damages for Sale of a Defective Product, Fraud, Conscious Misrepresentation, Negligence and Breach of Warranty."

[4] By order of court on May 9, 2006, the claims against Joseph Scott, F&S Contract Carrier, Inc., and ESF Trailer Systems, LLC, were dismissed with prejudice. Crews was likewise dismissed from this case.

reasons for [the] order," was filed on July 5, 2006.

In his memorandum opinion, Judge Platt reasoned.

> The existence of a legal duty is a question of law, to be decided by the court. *Doe v. Pharmacia & Upjohn Co., Inc.* 338 Md. 407, 414, 879 A.2d 1088, 1092 (2005).
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> In this case the issue is what duty is owed the public by a drug manufacturer in a failure to warn case. With respect to prescription drugs, Maryland courts have adopted the "Learned Intermediary Rule," which states that a prescription drug manufacturer has a duty to warn **physicians** of potential risks associated with taking a drug, but does not have a duty to warn patients. *Hunt v. Hoffmann-LaRoche, Inc.* 785 F. Supp. 547, 550 (D. Md. 1992). It follows that if a pharmaceutical manufacturer does not have a duty to give patients using their products warnings, they do not have a duty to warn the people with whom those patients interact.
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> In this case, Ellen Crews was taking Humalog, a prescription drug, and Humulin N, a drug that Ms. Crews was taking by prescription, but which was also available over-the-counter. With over-the-counter medications, pharmaceutical manufacturers do owe a duty to warn the patient directly. However, even if this duty were applicable in this case, this duty does not extend to Mr. Gourdine.
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> [Appellants] concede in their Memorandum of Points and Authorities in Opposition to [Appellee's] Motion for Summary Judgment that Eli Lilly had no duty to warn Mr. Gourdine directly. Instead they argue that it was foreseeable that not warning patients of an increased risk of hypoglycemia between 6 a.m. and 12 p.m. could cause people to suffer from hypoglycemia or neuroglycopenia, and if that occurred while the patient was driving a vehicle, that they could seriously injure other users of the road. [Appellants] argue that this foreseeability extends a duty to users of the road and so to Mr. Gourdine. This Court declines to extend that duty to Eli Lilly.

> Instead this trial court echoes what the Maryland Court of Appeals said in *Doe v. Pharmacia & Upjohn Co., Inc.,* 388 Md. 407, 879 A.2d 1088 (2005), "the imposition of duty of care in this case would create an indeterminate class of potential plaintiffs." *Id.* at 421, 1096. In *Pharmacia & Upjohn*, the plaintiff was the wife of a laboratory technician who had contracted HIV from his employment in a laboratory. The Court held that the employer did not owe a duty to the wife, because that would create an indeterminate class of potential plaintiffs, including spouses, sexual partners, and then anyone the employee could possibly pass the disease onto [sic]. Certainly, if this were an indeterminate class of people, then expanding duty to users of the highway, as [appellants] strenuously urge this Court to do in the instant case, would create an equally large and amorphous indeterminate class of Plaintiffs.
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> [Appellants] would have us interpret *Valk Mfg. Co. v. Rangaswamy* as authority to impose a liability on Eli Lilly on this case. *Id.*, 74 Md. App. 304, 537 A.2d 622 (1988). In *Rangaswamy*, the Court held that "bystanders... are protected under the doctrine of strict liability in tort." *Id.* at 323, 632. However, in the sentence immediately preceding, the *Rangaswamy* Court cited W. Keeton, *Prosser and Keeton on Torts* 704 (5th ed. 1984), to explain that the effect of an expanded duty to bystanders was to put 'strict liability on the same footing as negligence, as to all foreseeable injuries.' *Rangaswamy*, 74 Md. App. at 323, 537 A.2d 632. It is this Court's opinion in this case, that Eli Lilly did not owe a duty to [appellants] even in the negligence claim, and so *Rangaswamy* does not aid [appellants] in their strict liability claim.

(Emphasis in original) (footnote omitted).

This timely appeal followed.

STANDARD of REVIEW

Our review of a circuit court's grant of summary judgment is *de novo*. *Aventis Pasteur, Inc. v. Skevofilax*, 396 Md. 405, 440 (2007). "We determine whether the circuit

court properly concluded that there was no dispute of material fact, and, if so, whether the circuit court's decision that the moving party was entitled to summary judgment was legally correct." *Cruickshank-Wallace v. County Banking & Trust Co.*, 165 Md. App. 300, 310 (2005), *cert. denied*, 391 Md. 114 (2006); *see* Md. Rule 2-501(f). "On appeal from an order entering summary judgment, we review only the legal grounds relied upon by the trial court in granting summary judgment." *Cochran v. Norkunas*, 398 Md. 1, 12 (2007).

Our review is likewise premised on the basis that, in the case *sub judice*, the parties concede the lack of dispute of a material fact.

DISCUSSION

In granting summary judgment, the circuit court found that "Eli Lilly did not owe a duty to Mr. Gourdine[.]" "The existence of a legal duty is a question of law, to be decided by the court." *Doe v. Pharmacia & Upjohn Co.,* 388 Md. 407, 414 (2005). Our analysis of whether a duty is owed to a plaintiff in a failure to warn case is the same whether recovery is sought under a negligence or a strict liability in tort theory. *See Mayor & City Council of Baltimore v. Utica Mut. Ins. Co.*, 145 Md. App. 256, 287-88 (2002)(describing negligence and strict liability failure to warn theories as "nearly identical.").

With respect to prescription drugs,[5] "Maryland law recognizes the 'learned intermediary' doctrine, which provides that manufacturers need only warn the prescribing

[5] Although Humulin N was available over-the-counter, Crews was taking the drug by prescription. Thus, for purposes of our analysis, Humulin N and Humalog are prescription drugs.

physician and not the patient directly." *Ames v. Apothecon, Inc.*, 431 F.Supp. 2d 566, 572 (D.Md. 2006); *see also Nolan v. Dillon*, 261 Md. 516, 523 (1971). Stated alternatively, under the learned intermediary doctrine, the manufacturer of a prescription drug has no duty to directly warn patients. Diane S. Kane, Annotation, CONSTRUCTION AND APPLICATION OF LEARNED-INTERMEDIARY DOCTRINE, 57 A.L.R. 5th 1 (1998). It follows, therefore, that since there is no duty on the part of prescription drug manufacturers to directly warn users of the drug of possible adverse effects, the manufacturer has no duty to warn a nonuser such as Gourdine. *See Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987)(applying the learned intermediary doctrine and holding that drug manufacturers owed no duty to warn a third party who was injured by a patient using their products).

Appellants nonetheless maintain that it was foreseeable that failing to warn patients of an increased risk of hypoglycemia between 6 a.m. and 12 p.m. could cause them to suffer from hypoglycemia, and if that occurred while a patient was driving a vehicle, that the patient could seriously injure other users of the road. According to appellants, the foreseeability of the injuries here at issue extended a duty to warn all users of the road and, thus, Gourdine.

Appellants correctly state that "liability for injuries which are foreseeable resulting from a defective product extends to bystanders who are put in peril by the defect." *See e.g. Valk Mfg. Co. v. Rangaswamy*, 74 Md. App. 304, 322-23 (1988), *rev'd on other grounds sub nom. Montgomery County v. Valk Mfg. Co.*, 317 Md. 185 (1989). Even assuming, *arguendo*, that the warnings rendered about the drugs were defective, the injuries sustained by Gourdine

were not reasonably foreseeable. It cannot be said that Lilly should have reasonably foreseen that Crews, with her history of hypoglycemia, would ignore her doctor's orders to discontinue her morning insulin, drive a car, suffer a hypoglycemic episode, lose control of her car, strike Gourdine's car, push it into the back of an illegally parked tractor-trailer, and fatally injure Gourdine. Indeed, to impose a duty on Lilly in these circumstances "would create an indeterminate class of potential plaintiffs." *Pharmacia & Upjohn Co., supra*, 388 Md. at 421.

JUDGMENT OF THE CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY AFFIRMED;

COSTS ASSESSED TO APPELLANT.