COURT OF APPEAL

STATE OF LOUISIANA

FIRST CIRCUIT

2007 CA 2080

HOWARD STANLEY, ENID SHAWN POOLE GORRINGE, ERIN MARIE POOLE, EVE ARCULEER STANLEY LONDO AND STEPHANIE ANN STANLEY

VERSUS

WYETH, INC. A/K/A WYETH COMPANY, WYETH PHARMACEUTICALS, INC., SANDOZ, INC., NOVARTIS PHARMACEUTICALS CORPORATION, TARGET CORPORATION OF MINNESOTA D/B/A TARGET STORE 1876 AND PHARMACIST ELIZABETH HUGHES SMITH

Consolidated With

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Judgment rendered: MAY - 2 2008

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On Appeal from the 22nd Judicial District Court
Parish of St. Tammany, State of Louisiana
Case Numbers 2006-11011 and 2007-10687; Division J
The Honorable William J. Knight, Judge Presiding

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BEFORE: PARRO, KUHN AND DOWNING, JJ.

DOWNING, J.

At issue in this appeal is whether the trial court erred in entering judgment sustaining Wyeth, Inc. and Wyeth Pharmaceuticals, Inc.'s (Wyeth) exception of no cause of action and dismissing the claims filed by Howard Stanley, Enid Gorringe, Erin Poole, Eve Londo, and Stephanie Ann Stanley, the decedent's relatives (Stanley Family), with prejudice. For the following reasons, we affirm the trial court judgment.

According to the petition, Mrs. Stephanie Arculeer Stanley was prescribed Cordarone as a medication for a non-life-threatening heart condition. Cordarone is Wyeth's brand name for a drug it developed, amiodarone.[1] On March 9, 2005, Mrs. Stanley's cardiologist, Dr. Jose Silva, wrote her a prescription for Cordarone, but the pharmacist filled the prescription with the generic version of amiodarone made by Sandoz, Inc. Mrs. Stanley took the medication as prescribed, developed severe liver complications, allegedly a side-effect from the drug, underwent two liver transplants, and ultimately died.

The Stanley Family filed suit against Wyeth alleging that it is liable for: (1) failing to warn of the dangers associated with amiodarone; (2) understating the drug's nature and adverse effects; (3) actively promoting the drug for off-label uses including atrial fibrillation; (4) misleading physicians and pharmacists regarding the risks of amiodarone, and downplaying the severity and duration of side effects; and (5) marketing, promoting and pushing amiodarone as a drug suitable to treat non-life-threatening heart conditions. The Stanley Family does not assert that Mrs. Stanley ingested Cordarone or any other Wyeth product.

In response to the petition, Wyeth filed a peremptory exception raising the objection of no cause of action. The function of a peremptory exception is to have the plaintiff's action declared legally nonexistent or barred by effect of law; hence,

[1] Cordarone is the only form of amiodarone sold by Wyeth.

this exception tends to dismiss or defeat the action. LSA-C.C.P. art. 923. After the trial court sustained Wyeth's exception, the Stanley Family appealed, raising one assignment of error that presented two questions for review: (1) whether LSA-9:2800.51 applies,[2] and (2) whether there is a cause of action based on negligence.

This is a suit against a manufacturer in which the Stanley Family claims to have been injured by Wyeth's misrepresentations about its product. The Stanley Family alleges that Wyeth, through its sales representatives, misrepresented the serious side effects to the medical community. They do not allege that they directly relied upon these misrepresentations. The Stanley Family filed this suit pursuant to LSA-C.C. arts. 2315 and 2316, arguing that this is a negligent misrepresentation action and not an action under the LPLA. They do not assert that the product was inadequately labeled or that the warning on the drug information sheet was inadequate. Citing **Cypress Field Oil Contractors, Inc. v. McGoldrick Oil Company, Inc.**, 525 So.2d 1157 (La.App. 3 Cir. 1988), they contend that privity of contract between plaintiff and defendant is not a requisite for negligent misrepresentation claims.

Louisiana's case-by-case development of negligent misrepresentation has not been restricted to a set theory and has been broadly used to encompass situations from non-disclosure in fiduciary relationships to situations of direct disclosure to non-clients. **Barrie v. V.P. Exterminators, Inc.**, 6225 So.2d 1007, 1016 (La. 1993). The **Barrie** court stated that a case-by-case application of the duty/risk analysis adequately protects the misinformer and the misinformed because the initial inquiry is whether, as a matter of law, a duty is owed to this particular plaintiff to protect him from this particular harm. **Id.** The duty is

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[2] The Louisiana Products Liability Act (LPLA) provides the specific authority for claims against manufacturers for damages allegedly caused by their products. LSA-R.S. 9:2800.52 states that the LPLA is the exclusive basis of liability against manufacturers for damages from injuries caused by their products. Under the LPLA the first element that must be proven by the claimant is that the defendant is the manufacturer of the product causing plaintiff's harm. **Matherne v. Poutrait-Morin/Zefal-Christophe, Todson, Inc.**, 02-2136, p. 8 (La.App. 1 Cir. 12/12/03), 868 So.2d 114, 119. Therefore, the LPLA cannot apply to these facts.

imposed by law based upon policy considerations due to the tortfeasor's knowledge of the prospective use of the information, which expands the bounds of his duty of reasonable care to encompass the intended user. **David v. Guidry**, 94-0096 (La.App. 1 Cir. 11/10/94), 645 So.2d 1234, 1237.

Therefore, the lynchpin of the Stanley Family's claim is whether they can extend the duty Wyeth may have owed to the doctor prescribing Cordarone to themselves. Generally, a drug manufacturer has no duty to warn the consumer directly of any risks or contraindications associated with its product. **Mikell v. Hoffman-LaRoche, Inc.**, 94-0242 (La.App. 1 Cir. 12/22/94), 649 So.2d 75, 79; **Cobb v. Syntex Laboratories, Inc.**, 444 So.2d 203, 205 (La.App. 1 Cir. 1983).

Here, the court must consider whether a manufacturer has a duty to a person who neither ingested the product nor relied upon a manufacturer's representations. As this question is novel to Louisiana, we have reviewed recent decisions in other jurisdictions and reviewed the cases cited by Wyeth and the Stanley Family. We note that the Stanley Family cited no authority to support its claim against a product manufacturer for representations made about its product when a generic form of the product actually caused the injury. Wyeth, on the other hand, cited numerous cases where the negligent misrepresentation claims were either preempted by the FDA or a state's enactment of products liability law,[3] or the court ruled that a manufacturer could not be held liable for the alleged injuries caused by another company's generic product, because there was no duty.[4]

In **Foster v. American Home Products Corp.**, 29 F.3d 165, 171 (4th Cir. 1994), the court held that to impose a duty upon a manufacturer for damages caused by the generic bioequivalent would stretch the concept of foreseeability too

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[3] *See* **Tarver v. Wyeth**, 2005 WL 4052382 (W.D. La. 6/07//05) (unpublished slip opinion); **Block v. Wyeth, Inc.**, 2003 WL 203067 (N.D. Tx. 1/28/03); **Possa v. Eli Lilly and Company**, No. 05-1307 (M.D. La. 5/10/06)(unpublished).

[4] *See* **Goldych v. Eli Lilly and Company**, 2006 WL 2038436 (N.D.N.Y.), /19/06, 66 Fed.R.Ser.3d 799 (unpublished).

far because a manufacturer "cannot reasonably expect that consumers will rely on information they provide when actually ingesting another company's drug." The **Foster** court also found that when a manufacturer of a generic equivalent drug blindly accepts the brand name manufacturer's representations, it does so at its own risk. **Id.**

In **Colaciccio v. Apotex**, 432 F.Supp.2d 514 (E.D. Pa. 2006), the court confronted a somewhat analogous factual situation to the one before us. Mr. Colaciccio sued GlaxoSmithKline after his wife committed suicide by ingesting a generic version of its antidepressant drug, Paxil. Plaintiff asserted claims based on a failure to warn, reasoning that the warnings, which were published by GlaxoSmithKline, were inadequate to inform users of the suicide risks associated with the drug. **Id.** The labeling was prepared solely by the brand name and adopted by Apotex, the generic drug manufacturer. **Id.** The **Colaciccio** court dismissed the suit, but examined in depth the duty of care that brand name manufacturers owe to consumers of a manufacturer's generic drug products. It held "that a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug." **Id.** at 538-39.

In Louisiana, to recover damages for negligent misrepresentation, there must be a legal duty on the part of the defendant to supply correct information, a breach of that duty, and damage to the plaintiff caused by the breach.[5] **Hughes v. Goodreau**, 01-2107, p. 19 (La.App. 1 Cir. 12/31/02), 836 So.2d 649, 663.

Accepting as true all allegations of fact set forth in the Stanley Family's petition for damages, we conclude that the trial court did not err in holding that there is no viable cause of action alleged, since the Plaintiffs failed to show that

[5] Negligent misrepresentation cases are evaluated using the duty/risk analysis on a case-by-case basis. **Smith v. Roussel**, 00-1028, p. 5 (La.App. 1 Cir. 6/22/01), 809 So.2d 159, 164-65. To meet the burden of proof the plaintiff must show (1) that the conduct in question was a cause-in fact of the resulting harm, (2) that the defendant owed a duty of care to the plaintiff, (3) that the requisite duty was breached by the defendant, and (4) that the risk of harm was within the scope of protection afforded by the duty breached. **Id.**

Wyeth owed them a legal duty, regardless of the theory of recovery asserted. After reviewing the controlling and persuasive jurisprudence, we conclude that, as a matter of law, Wyeth owed no duty to Mrs. Stanley to protect her from this particular harm. In Louisiana, a drug manufacturer has no duty to warn the consumer directly. *See* **Cobb**, 444 So.2d at 205. As noted in **Foster,** a manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug. **Foster**, 29 F.3d at 171. Therefore, as in **Colaciccio,** we hold that a name brand drug manufacturer owes no legal duty to the consumer of a generic equivalent of its drug. **Colaccio**, 432 F.Supp. 2d at 538-39. Accordingly, since Wyeth had no duty to the Stanley Family the petition failed to state a cause of action against Wyeth.

Ordinarily, when the grounds of an objection pleaded by a peremptory exception can be removed by amendment of the petition, the judgment sustaining the exception shall order such amendment within the delays allowed by the court. If, however, the grounds of an objection cannot be so removed, the action shall be dismissed. LSA-C.C.P. art. 934.

Here, Mrs. Stanley did not use Wyeth's product, so the plaintiffs cannot proceed with a products liability claim. Neither did they show that Wyeth owed them a duty of care, nor that they relied on representations made by Wyeth. Thus, the grounds of the objection cannot be removed. Accordingly, the trial court judgment dismissing plaintiffs' claims against Wyeth is affirmed. The costs of this appeal are assessed to plaintiffs/appellants, Howard Stanley, Enid Gorringe, Erin Poole, Eve Londo, and Stephanie Ann Stanley. This memorandum opinion is issued in accordance with Uniform Rules-Courts of Appeal, Rule 2-16.3B.

AFFIRMED