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Carol E. Higbee, P.J.Cv.

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SUPERIOR COURT OF NEW JERSEY

COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

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MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE: **Ruby Edna Coundouris v. Wyeth, et al. – ATL-L-1940-10**

Barbara Danziger v. Wyeth, et al. – ATL-L-4513-10

Basil and Emily Downer v. Wyeth, et al. – ATL-L-0843-11

Kamile Drake and Atay Kural v. Wyeth, et al. – ATL-L-0262-11

Joyce M. Lorber v. Wyeth, et al. – ATL-L-1973-11

Craig G. Lynn v. Wyeth, et al. – ATL-L-6357-10

Catherine R. Monroe v. Wyeth, et al. – ATL-L-0257-11

Diane and Arnold Riback v. Wyeth, et al. – ATL-L-1927-11

DATE: **June 26, 2012**

MOTION: **Brand Manufacturers' Joint Motion to Dismiss**

ATTORNEYS: **Ezra D. Rosenberg, Esq., Dechert LLP – Attorney for Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Wyeth Holdings Corporation**

Tracy McDevitt Hagan, Esq., Reilly, Janiczek & McDevitt, P.C. – Attorney for Defendants Alaven Pharmaceutical LLC, and Schwarz Pharma, Inc.

Theodore Oshman, Esq., Oshman & Mirisola, LLP – Attorney for Plaintiffs

Having carefully reviewed the papers submitted and any response received, I have ruled on the above Motion as follows:

Defendants Wyeth LLC, Wyeth Pharmaceuticals Inc., and Wyeth Holdings Corporation (together, "Wyeth"), Schwarz Pharma, Inc. ("Schwarz"), and Alaven Pharmaceutical LLC ("Alaven") (collectively, "Brand Defendants") filed this Motion seeking to dismiss the actions brought against them by Plaintiffs Ruby Coundouris, Barbara Danziger, Basil and Emily Downer, Kamile Drake and Atay Kural, Joyce Lorber, Craig Lynn, Catherine Monroe, and Diane and Arnold Riback (collectively, "Plaintiffs"). Plaintiffs filed an opposition, and Brand Defendants filed a reply. Oral argument was held.

I. Background

Metoclopramide is a prescription drug approved by the FDA to treat gastroesophageal reflux disease and diabetic gastroparesis. Metoclopramide is available in both brand-name (Reglan®) and generic formulations.

The Brand Defendants manufactured and distributed Reglan®. Wyeth manufactured and distributed Reglan® tablets until late 2001, at which time it sold rights and responsibilities concerning Reglan® to Schwarz. Thereafter, Schwarz manufactured and distributed Reglan® tablets until 2008. Alaven purchased the right to Reglan® tablets from Schwarz in 2008 and sold Reglan® tablets until June 2011.

Plaintiffs never took Reglan®, but instead ingested generic metoclopramide manufactured by various companies other than the Brand Defendants.[1] Plaintiffs assert claims

[1] Plaintiffs all ingested generic metoclopramide. However, Craig Lynn alleges that he used brand-name Reglan® manufactured by both Wyeth and Schwarz, and some generic metoclopramide manufactured by a division of Wyeth, ESI Lederle ("Lederle"). Barbara

against the Brand Defendants for conscious misrepresentation, negligent misrepresentation, and negligence. Plaintiffs Lorber and Lynn also allege design and manufacturing defect claims under the PLA. Breach of express warranty claims have also been brought by some of the Plaintiffs against some or all Brand Defendants.

II. Legal Standard

Pursuant to Rule 4:6-2(e), a defendant may move to strike all or part of a complaint for "failure to state a claim upon which relief can be granted." Such a motion entails scrutiny of the complaint to determine whether any viable cause of actions exists. "[T]he test for determining the adequacy of a pleading [is] whether a cause of action is 'suggested' by the facts . . . . At this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint." Printing Mart-Morristown v. Sharp Elec. Corp., 116 N.J. 739, 746 (1989) (quoting Velantzas v. Colgate-Palmolive Co., 109 N.J. 189, 192 (1988)).

III. Discussion

The parties have agreed that New Jersey law applies for purposes of the resolution of this motion only.

Danziger admits that she ingested only generic metoclopramide but alleges that some of the generic product was manufactured by Lederle.

Brand Defendants have jointly moved to dismiss all claims that are asserted against them based on Plaintiffs' theory that the Brand Defendants are liable because they manufactured Reglan®, even though they did not manufacture the generic metoclopramide that Plaintiffs ingested.

Brand Defendants have adopted this motion with the following qualifications: (1) Wyeth moves to dismiss all claims of Plaintiffs except Craig Lynn and Barbara Danziger, against whom Wyeth moves to dismiss only Counts I, II, and VII; (2) Schwarz moves to dismiss the claims of all Plaintiffs except Craig Lynn; (3) Alaven moves to dismiss all claims of all Plaintiffs except Barbara Danziger, who has agreed to dismiss her claims against Alaven based on the fact that she stopped taking metoclopramide before Alaven acquired any rights associated with Reglan®.

In support of their Motion to Dismiss, Brand Defendants argue that the New Jersey Products Liability Act ("PLA") governs Plaintiffs' claims, and that pursuant to the PLA and New Jersey case law, manufacturers of a brand-name drug may not be held liable for injuries caused by a plaintiff's use of a generic drug manufactured by another company.

In opposition, Plaintiffs argue that their claims against Brand Defendants are not products liability claims governed by the PLA, but are instead negligence claims governed by New Jersey common law. Plaintiffs contend that the Brand Defendants owed a duty to those ingesting generic metoclopramide to exercise reasonable care in either disseminating accurate, non-misleading information about metoclopramide or adequately warning doctors and patients as to the risk of the drug.

Under the PLA, a "product liability action" is defined as "*any* claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim." N.J.S.A. § 2A:58C-1(b)(3) (emphasis added). The PLA defines "harm" to include "personal physical illness, injury or death"; "pain and suffering, mental anguish or emotional harm"; and "any loss of consortium or other services or other loss deriving from any type of harm described." N.J.S.A. § 2A:58C-1(b)(2).

As the New Jersey Supreme Court has explained, "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." Sinclair v. Merck & Co., Inc., 195 N.J. 51, 66 (2008); In re Lead Paint Litig., 191 N.J. 405, 436-37 (2007).

The Court finds that Plaintiffs' cases are products liability actions governed by the PLA. The central focus of Plaintiffs' claims is that the Brand Defendants were aware of dangers associated with metoclopromide, and either failed to disseminate accurate information about the drug, or failed to adequately warn as to the dangers of its usage. Such a classic articulation of

tort law duties falls squarely within the theories included in the PLA. See In re Lead Paint Litig., supra, 191 N.J. at 437 (finding that the duties to warn of, or make safe, were squarely within the theories included in the PLA). In light of the clear intention of our Legislature to include all such claims within the scope of the PLA, the Court finds no ground on which to conclude that the claims being raised by Plaintiffs, regarding a prescription drug used by patients, were excluded from the scope of the PLA.

Having concluded that the Plaintiffs' claims are governed by the PLA, the Court finds that Plaintiffs' action must fail because they did not ingest a product made or sold by the Brand Defendants. In New Jersey, "it is well-settled that in products-liability litigation, [a plaintiff] must demonstrate that his or her injuries were caused by...defendant's...product." Gannon v. Am. Home Products, Inc., 414 N.J. Super. 507, 525 (App. Div. 2010) (quoting Vassallo v. Am. Coding & Marking Ink Co., 345 N.J. Super. 207, 214 (1993)) (internal quotations omitted). "[P]roof of causation-in-fact is ordinarily an indispensible ingredient of a *prima facie* case...." Ibid. (quoting Shackil v. Lederle Labs., 116 N.J. 155, 163 (1989); see also Namm v. Charles E. Frosst & Co., 178 N.J. Super. 19, 27 (App. Div. 1981) ("It is a fundamental principle of products liability law that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product which caused injury.")

This Court's decision in Rossi v. Hoffman-LaRoche, No. ATL-L-690-05 (N.J. Super. Ct. Jan 3. 2007), is instructive. In Rossi, the plaintiff brought suit against the brand-name manufacturer, Hoffman-LaRoche, Inc., for misrepresentations, claiming damages purportedly caused by the plaintiff's ingestion of a generic version (mefloquine) of the brand-name manufacturer's product (Lariam®). This Court declined to create a duty on the part of the name-brand manufacturer to the consumers of a generic drug and dismissed the plaintiff's action against Hoffman-LaRoche. In reaching its decision, this Court noted that there was "no

evidence" that "the New Jersey legislature intended for prescription drug liability to extend to the name-brand manufacturer when the alleged victim ingested a generic equivalent manufactured and sold by another company." In addition, this Court found that the PLA reflected the Legislature's intent to limit liability to specific parties -- namely the manufacturer or seller of a product.

Consistent with New Jersey precedent, other trial courts have reached a similar conclusion when confronting this issue. See Sloan v. Wyeth, No. MRS-L-1183-04 (N.J. Super. Ct. Oct. 13, 2004) (granting summary judgment against a negligent misrepresentation claim brought by plaintiffs suing drug manufacturer for harm caused by ingestion of another company's generic metoclopramide); Westerlund v. Wyeth, Inc., No. MID-02174-05, 2008 WL 5592753, at *3 (N.J. Super. Ct. Oct. 20, 2008) (declining to extend liability against drug manufacturer where plaintiff did not use their product).

The United States Supreme Court's decision in Pliva v. Mensing, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011) does not change New Jersey law. In Mensing, the Supreme Court found that federal regulations applicable to generic manufacturers preempted state law failure to warn claims against those manufacturers. The practical effect of Mensing's holding is that generic manufacturers who comply with the FDA requirement that they mimic the brand-name manufacturers' warning labels cannot be held liable under state tort law for failure to warn. However, Mensing did not address or impact the issue currently before this Court -- namely, whether a brand-name manufacturer owes a duty to a patient who ingested a drug that the brand-name manufacturer did not make or sell. Because Mensing did not alter New Jersey law, the PLA and case law continue to govern.

To be sure, the Court recognizes cases from other jurisdictions, such as Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008), which have extended a brand-name manufacturer's

duty to warn to patients whose doctors rely on the brand-name manufacturer's product information when prescribing metoclopramide, whether the prescription is written for or filled with Reglan or its generic equivalent. Nonetheless, this Court is bound by the statutory and case law of the State of New Jersey. Our courts have made clear that an essential element of a plaintiff's prima facie products liability action case is proof that the manufacturer actually produced the product which gave rise to the plaintiff's injury.

Where Plaintiffs never ingested metoclopramide manufactured or sold by the Brand Defendants, they are unable to establish an essential element of their *prima facie* case under New Jersey law, and their claims against the Brand Defendants must be dismissed.

In these cases, all claims against Wyeth are dismissed, with the exception of Craig Lynn and Barbara Danziger, against whom only Counts I, II, and VII are dismissed. All claims against Schwarz are dismissed, with the exception of Craig Lynn. All claims against Alaven are dismissed, with the exception of Barbara Danziger.

CAROL E. HIGBEE, P.J.Cv.