UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
OWENSBORO DIVISION

CIVIL ACTION NO. 4:16CV-00103-JHM

ESTATE OF JERRY DEMOSS, by and through CYNTHIA DEMOSS as Administratrix, and CYNTHIA DEMOSS Individually **PLAINTIFFS**

V.

ELI LILLY AND COMPANY **DEFENDANT**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on a motion by Defendant, Eli Lilly and Company, to dismiss the complaint pursuant to Fed. R. Civ. P. 8(a), 9(b), and 12(b)(6) [DN 13]. Fully briefed, this matter is ripe for decision.

I. STANDARD OF REVIEW

Upon a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiff[]," League of United Latin American Citizens v. Bredesen, 500 F.3d 523, 527 (6th Cir. 2007), "accept all well-pled factual allegations as true," id., and determine whether the "complaint . . . states a plausible claim for relief," Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). Under this standard, the plaintiff must provide the grounds for his or her entitlement to relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A plaintiff satisfies this standard only when he or she "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. A complaint falls short if it pleads facts "'merely consistent with' a defendant's liability," id. at 678 (quoting Twombly, 550 U.S. at 557), or if the alleged facts do not "permit the court to

infer more than the mere possibility of misconduct," id. at 679. Instead, the allegations must "'show[ ] that the pleader is entitled to relief.'" Id. at 679 (quoting Fed. R. Civ. P. 8(a)(2)). It is against this standard that the Court reviews the following facts.

II. BACKGROUND

This case arises from the death of Jerry DeMoss following his use of Effient, a prescription medication approved by the Food and Drug Administration ("FDA") for the treatment of patients with acute coronary syndrome ("ACS") to reduce the risk of thrombotic cardiovascular events, including heart attack, stroke, or blood clot. In July 2009, Effient was approved by the FDA for use in patients with ACS with unstable angina or non-ST-elevation myocardial infarction, or patients with ST-elevation myocardial infarction. Approval of Effient was based on a series of clinical trials derived from the TRITON-TIMI 38 trial, a 13,608 patient, multicenter, international, randomized, double-blind, parallel-group study comparing Effient (prasugrel) and Plavix (clopidogrel). (Complaint at ¶ 22.) The TRITON-TIMI 38 trial indicated that Effient was superior to Plavix for preventing ischemic events, but "that Effient (prasugrel) was associated with significantly increased risk of bleeding, including fatal bleeding, as compared to Plavix (clopidogrel)." (Id. at ¶ 22.) Plaintiffs allege that the TRITON-TIMI 38 trial made clear that the benefits of Effient should be balanced with its increased associated risk for bleeding events. Plaintiffs further contend while Defendant marketed Effient as a new antiplatelet treatment alternative to Plavix, its promotional materials failed to highlight the increased risk of bleeding, to disclose to patients and members of the medical community that there is no drug, agent, or means to reverse the effects of Effient, and to disclose that the use of Effient, as opposed Plavix, placed patients at greater risk for bleeding events. Additionally, Plaintiffs allege that Defendant sought and had FDA panelist Dr. Sanjay Kaul removed from the advisory panel because of his reservations regarding the safety of Effient.

Including June 2015, a total of 12,281 Effient-associated adverse reports had been filed with the FDA, including 171 hemorrhages and 153 deaths. (Id. at ¶ 30.) Plaintiffs allege that, despite the reported adverse events, the Defendant failed to perform further investigation and studies into the safety of Effient; failed to disclose its knowledge that Effient was associated with or could cause life-threatening bleeding; and failed to provide adequate warnings and instructions. (Id. at ¶¶ 31-39.)

DeMoss began taking Effient on or about April 2014 (id. at ¶8) and subsequently suffered a massive cerebral hemorrhage and died on July 19, 2014. (Id. at ¶10.) Plaintiffs filed this action in Hopkins Circuit Court on July 19, 2016. Defendant removed this action on August 24, 2016. Plaintiffs contend that Defendant designed, manufactured, and promoted a drug it knew to be highly dangerous based on clinical trials funded by Defendant; promoted it as "better" than Effient's safer, competitor drugs, such as Plavix; and failed to adequately warn users of the unreasonably significant risk of intracranial hemorrhage without any opportunity for reversal. Plaintiffs assert claims for negligence (design defect, manufacturing defect, and failure to warn); strict products liability (design defect, manufacturing defect, and failure to warn); breach of implied warranties; negligent misrepresentation; violation of the Kentucky Consumer Protection Act; and loss of consortium.

Defendant moves the Court to dismiss Plaintiffs' claims arguing that the causes of action are unsustainable as a matter of Kentucky law and fail to meet the pleading standards articulated by the Supreme Court in Iqbal and Twombly.

III. DISCUSSION

A. Strict Liability Claims

Plaintiffs have asserted strict liability claims based on the theory that Effient was defective in its design and manufacture and because the Defendant failed to warn of the risk of

injury caused by the medication. (Complaint at ¶¶ 55-78.)

1. Strict Liability Design Defect Claim

Under Kentucky law, to prevail in a strict products liability action, a plaintiff must establish: "(1) that there is a product, which is (2) in a defective condition unreasonably dangerous to the user or consumer or his property, and (3) which reaches the user or consumer without substantial change in the condition in which it is sold; (4) that the product is sold by one who is engaged in the business of selling such a product which (5) results in physical harm to the ultimate user or consumer or his property." Bosch v. Bayer Healthcare Pharms., Inc., 13 F. Supp. 3d 730, 740 (W.D. Ky. 2014) (citations omitted). A plaintiff also must establish that there was "an alternative, safer design that is practicable under the circumstances." Id. Defendant contends that Effient falls within the ambit of comment k to section 402A of the Restatement (Second) of Torts because the FDA's approval of Effient for the treatment of acute coronary syndrome conclusively demonstrates that the benefits of Effient exceed the potential risks. Thus, Defendant argues it is not subject to design defect liability, and the Court should dismiss this claim.

Kentucky follows the Restatement (Second) of Torts, including comment k to section 402A. Prather v. Abbott Labs., 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (citing McMichael v. American Red Cross, 532 S.W.2d 7, 9-11 (Ky. 1975)). Comment k "provides an exception to the general rule of strict liability for 'apparently useful and desirable product[s], attended with a known but apparently reasonable risk.'" Id. (quoting Restatement (Second) of Torts § 402A cmt. k). Where comment k applies, a prescription drug manufacturer "is not subject to strict liability for design defects. Instead, the manufacturer's liability is limited to manufacturing defects, for those cases in which the [drug] given had been improperly prepared, and warning defects, where a manufacturer's failure to market a drug . . . without adequate warnings of its dangers renders

the product defective." Snawder v. Cohen, 749 F. Supp. 1473, 1476 (W.D. Ky. 1990); see Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003). In Kentucky, the scope of comment k is determined on a case-by-case basis. Prather, 960 F. Supp. 2d at 707; see Weiss v. Fujisawa Pharm. Co., 2006 WL 3533072, *1, *3-4 (E.D. Ky. Dec. 7, 2006)(extends "comment k protection when the apparent benefits of the drug exceed the apparent risks, given the scientific knowledge available when the drug was marketed"). Courts consider such factors as "(1) the drug's overall usefulness and benefit; (2) the likelihood and seriousness of injury; (3) the availability of a substitute product at the time of sale and distribution; (4) the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness; and (5) the expense involved in eliminating the unsafe character of the product." Weiss, 2006 WL 3533072, at *3.

Here, Plaintiffs allege that the benefits of Effient did not outweigh its risks given the clinical trials Defendant conducted, and that Defendant failed to adequately warn end-users of the risks associated with Effient. Further, Plaintiff contends that Defendant sought and had FDA panelist Dr. Sanjay Kaul removed from the advisory panel because of his reservations regarding the safety of Effient. Because the Court must accept as true Plaintiffs' allegations at this stage of the proceeding and because the analysis under comment k is highly fact dependent, see Weiss, 2006 WL 3533072, at *4, the Court declines at this stage to dismiss Plaintiffs' strict liability design defect claim based on comment k. See House v. Bristol-Myers Squibb Co., 2017 WL 55876, *3 (W.D. Ky. Jan. 4, 2017)(denying motion to dismiss because the analysis under comment K is fact dependent and because the cases relied upon by defendants were addressing comment k in the context of motions for summary judgment).

Defendant also argues that Plaintiffs' strict liability defective design allegations are deficient. According to Defendant, Plaintiffs have not identified what aspect of the drug's design

was allegedly defective, instead simply regurgitating generic elements of a strict liability claim. (Compl. ¶¶ 59, 60, 64.) Further, Defendant contends that Plaintiffs fail to explain how any alleged defect caused Mr. DeMoss's injuries. Accordingly, Defendant maintains that the Plaintiffs' defective design claim should be dismissed because Plaintiffs merely recite the elements of a design defect claim and do not adequately plead or support how Defendant's design is defective, in what way Defendant could have remedied the defect, or how the alleged defect caused his particular injuries.

The Court disagrees. The allegations in the complaint state a plausible claim for relief for a strict liability design defect claim. Plaintiffs sufficiently allege that Effient posed a significantly higher bleeding risk as compared to other competing drugs, like Plavix, and that no antidote exists for Effient, making it more dangerous than other drugs used for similar purposes. (Complaint ¶¶ 25, 26, 34.) Further, Plaintiffs allege that DeMoss died of a massive cerebral hemorrhage caused by Effient. (Id. at ¶40.) Essentially, Plaintiffs allege that Effient was defective because it created an unreasonably high bleeding risk without any reversal agent available to account or compensate for the increased bleeding risk and that DeMoss died as a result of that injury. Accordingly, the Court denies Defendant's motion to dismiss the strict liability design defect claim.

2. Strict Liability Manufacturing Defect

Defendant argues that Plaintiffs' strict liability manufacturing defect claim is insufficiently pleaded. Under Kentucky law, a plaintiff alleging a manufacturing defect must show that the product was "in a defective condition because it was not manufactured or assembled in accordance with its specifications" and that the condition caused the alleged injuries. See Greene v. B.F. Goodrich Avionics Sys., Inc., 409 F.3d 784, 788 (6th Cir. 2005) (applying Kentucky law); Bosch v. Bayer Healthcare Pharm., Inc., 13 F. Supp. 3d 730, 743–44

(W.D. Ky. 2014). A manufacturing defect claim requires the jury to determine whether the product failed because of an error in the process of manufacture or assembly. Id. Kentucky has adopted Restatement (Second) of Torts § 402A. See Dealers Transport Co. v. Battery Distrib. Co., 402 S.W.2d 441, 446–47 (Ky. App. 1965). "Under § 402A, the defendant is held strictly liable if the plaintiff proves the product was 'in a defective condition unreasonably dangerous to the user or consumer.'" Greene, 409 F.3d at 788–89 (quoting Montgomery Elevator Co. v. McCullough by McCullough, 676 S.W.2d 776, 780 (Ky. 1984)). "Unreasonably dangerous" means "a product that is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" Greene, 409 F.3d at 789 (quoting Restatement (Second) of Torts § 402A cmt. i). "Defective" means "that the product does not meet the reasonable expectations of the ordinary consumer as to its safety." Greene, 409 F.3d at 789 (quoting Worldwide Equip., Inc. v. Mullins, 11 S.W.3d 50, 55 (Ky. Ct. App. 1999)). See also Waltenburg v. St. Jude Med., Inc., 33 F. Supp. 3d 818, 835 (W.D. Ky. 2014); Bosch, 13 F. Supp. 3d at 743–744.

In this case, Defendant argues that Plaintiffs have failed to allege facts to support a manufacturing defect claim, instead offering only a formulaic recitation of the claim's elements. Although Plaintiffs allege that "Effient . . . manufactured . . . by Defendants was manufactured defectively in that Effient was in a defective condition and was unreasonably dangerous to its intended users" (complaint at ¶ 67), Plaintiffs fail to allege specific facts to support their manufacturing defect claim. They do not allege any specific manufacturing defect or failure that occurred with the Effient product. They similarly do not allege how Effient deviated from Defendant's specifications. Due to the lack of factual allegations, the Court holds that Plaintiffs have failed to properly state a manufacturing defect claim. Plaintiffs' manufacturing defect

claim is dismissed without prejudice.

3. Strict Liability Failure to Warn Claim

To plead a failure to warn claim in a prescription drug case, a plaintiff must allege facts for the Court to infer that (1) the manufacturer failed to provide his prescribing physician with adequate warnings about risks of which it knew or should have known and (2) the inadequate warnings proximately caused his injuries. Prather, 960 F. Supp. 2d at 708-09. Here, Plaintiffs adequately allege how the warnings provided were defective and how they caused his injury. Specifically, Plaintiffs allege that Defendant made, distributed, marketed, and sold Effient without adequate warning to Plaintiff's prescribing physicians or DeMoss that Effient was associated with and/or could cause life-threatening bleeding and presented a risk of life-threatening bleeding in patients who used it, especially as compared to similar antiplatelet drugs, such as Plavix. Additionally, Plaintiffs contend that Defendant's failure to adequately test and study the life-threatening bleeding risk further rendered the warnings for this medication inadequate. (Complaint at ¶¶36-40, 71-73.) As a result, DeMoss suffered death as a result of the massive cerebral hemorrhage caused by Effient. Contrary to Defendant's argument, these statements are not conclusory and comply with the Iqbal and Twombly standard.

For these reasons, the Court denies Defendant's motion to dismiss Plaintiffs' claims for strict liability design defect and failure to warn. Plaintiffs' strict liability manufacturing defect claim is dismissed without prejudice.

B. Negligence Claims

Plaintiffs allege that the Defendant negligently designed, manufactured, promoted, marketed, sold, and distributed Effient in an unreasonably dangerous condition. (Complaint ¶¶ 42-54.) Under Kentucky law, to succeed on a negligence claim, Plaintiff must establish that: (1) Defendant owed a duty of care to DeMoss; (2) Defendant breached its duty; and (3) the breach

proximately caused DeMoss's damages. Bosch, 13 F. Supp. 3d at 741 (citing Mullins v. Commonwealth Life Ins. Co., 839 S.W.2d 245, 247 (Ky. 1992)). Because Plaintiffs' negligent design, manufacture, and failure to warn claims essentially are premised on the same allegations as their strict liability claims, much of the Court's analysis above is equally applicable here. Accordingly, the Court finds that Plaintiffs' claims of negligent design and failure to warn comply with the standards of Iqbal and Twombly.

With respect to the negligent manufacture claim, the Court finds that Plaintiffs have not included any factual allegations as to how Defendant breached the duty of care as to manufacturing of Effient or how Effient deviated from the Defendant's intended design. See Bosch, 13 F. Supp. 3d at 741–42 (dismissing negligent manufacture claim because plaintiffs failed to "allege how their specific [intrauterine contraceptive] devices were defective due to manufacturing" and otherwise failed to assert "any facts to support" their conclusory allegations); see also Guidry v. Janssen Pharmaceuticals, Inc., 2016 WL 633673, *4 (E.D. La. Feb. 17, 2016) (dismissing manufacturing defect claim where plaintiff failed to allege any facts as how the Invokana she ingested deviated from the intended design). Therefore, Plaintiffs' negligent manufacture claim is dismissed without prejudice

Furthermore, in as much as Defendant argues that Plaintiffs' cause of action for negligence is redundant and duplicative of Plaintiffs' strict liability claims, the case law supports Plaintiffs ability to assert multiple theories of liability. "'Under Kentucky law, a plaintiff can advance both a strict-liability claim and a negligence claim against the manufacturer of a product for injury suffered by that product.'" Stanley v. Bayer Healthcare Pharm. Inc., 2015 WL 4511973, *2 (W.D. Ky. July 24, 2015)(quoting Waltenburg v. St. Jude Medical, Inc., 33 F. Supp. 3d 818, 836 (W.D. Ky. 2014)). "Strict liability typically focuses on the condition of the product while a negligence inquiry examines whether the [defendant] exercised the proper degree of care

to protect against foreseeable dangers when [designing or] manufacturing the product for the consumer." Prather v. Abbott Laboratories, 960 F. Supp. 2d 700, 712 (W.D. Ky. 2013)(citing Ostendorf v. Clark Equip. Co., 122 S.W.3d 530, 535 (Ky. 2003)). See also Montgomery Elevator Co. v. McCullough, 676 S.W.2d 776, 780 (Ky. 1984); Shea v. Bombardier Recreational Prod., Inc., 2012 WL 4839527, *4 (Ky. Ct. App. Oct. 12, 2012)("Negligence and strict liability theories of recovery overlap to the degree that, in either instance, the plaintiff must prove the product was defective and the legal cause of the injury."); Holbrook v. Rose, 458 S.W.2d 155, 157 (Ky. 1970)(whether the action involves negligent design, negligent failure to adequately warn, or the sale of a defective product that is unreasonably dangerous because of an inherent defect or inadequate warning, in every instance, the product must be a legal cause of the harm).

Finally, in response to the motion to dismiss, Plaintiffs note that they do not assert a separate and independent claim for "failure to test," but simply allege that Defendant's failure to adequately test its products supports Plaintiffs' products liability claims. Kentucky courts have treated failure to properly test pharmaceutical drugs as subsumed by a failure to warn claim. See Baird v. Bayer Healthcare Pharmaceuticals, Inc., 2013 WL 5890253, *2 (E.D. Ky. Oct. 31, 2013); Bosch, 13 F. Supp. 3d at 747.

For these reasons, the Court denies Defendant's motion to dismiss Plaintiffs' claims for negligent design defect and failure to warn. Plaintiffs' claim for negligent manufacturing defect is dismissed without prejudice.

C. Breach of Implied Warranty

Defendant argues that Plaintiffs' claim for breach of implied warranty (Complaint ¶¶ 79-89) must be dismissed because there is no privity of contract between the parties. Under Kentucky law, privity of contract is an essential element of a claim for breach of an implied warranty. Baird, 2013 WL 5890253, at *3; Brown Sprinkler Corp. v. Plumbers Supply Co., 265

S.W.3d 237, 240 (Ky. Ct. App. 2007). "As a rule, privity of contract does not extend beyond the buyer-seller setting, and an intervening purchaser destroys privity." Gaunce v. CL Med. Inc., 2015 WL 893569, at *2 (E.D. Ky. Mar. 2, 2015) (citing Compex Intern. Co. Ltd. v. Taylor, 209 S.W.3d 462, 465 (Ky. 2006)). Plaintiffs contend that the implied warranty claim survive because they allege in the complaint that Defendant distributed Effient to Mr. DeMoss, and that Mr. DeMoss died from a massive cerebral hemorrhage caused by Effient. (Complaint ¶¶ 9, 56.) Plaintiffs further argue that Defendant made direct warranties to DeMoss regarding efficacy and safety of Effient through its labeling, advertising, marketing, and promotional materials and, as a result, the warranty runs "directly to the intended consumer." Naiser v. Unilever United States, Inc., 975 F. Supp. 2d 727, 739 (W.D. Ky. 2013).

Plaintiffs have alleged no facts to support the conclusion that privity existed. Plaintiffs allege that the drug is a prescription drug that was prescribed to DeMoss by his doctor. (Compl. ¶ 8.) Plaintiffs do not allege facts indicating that DeMoss purchased Effient from Defendant. Because the Complaint fails to show that DeMoss and Defendant were in a buyer-seller relationship, DeMoss was not in privity with Defendant. See Bosch, 13 F. Supp. 3d at 749. See also House v. Bristol-Myers Squibb Co., 2017 WL 55876, at *2–7 (W.D. Ky. Jan. 4, 2017). Furthermore, Plaintiffs' reliance on Naiser v. Unilever U.S., Inc., 975 F. Supp. 2d 727 (W.D. Ky. 2013) is misplaced. Naiser involved a breach of express warranty claim which Plaintiffs have not asserted in this case. "The Court's ruling in Naiser had no impact on the privity of contract requirement with respect to implied warranty causes of action." Bosch v. Bayer Healthcare Pharmaceuticals, Inc., 13 F. Supp. 3d 730, 749 (W.D. Ky. 2014). Accordingly, Plaintiffs' breach of implied warranty claim is dismissed without prejudice.

D. Negligent Misrepresentation

Defendant argues that Plaintiffs' claim for negligent misrepresentation (Complaint ¶¶ 90-

97) must be dismissed because it is not a viable claim and is inappropriate in the context of product liability claims. Defendant relies upon Bland v. Abbott Labs. Inc., 2012 WL 524473, *1-2 (W.D. Ky. Feb. 16, 2012), in support of its argument that negligent misrepresentation does not encompass instances involving defective products and statements in product advertising and packages. Alternatively, Defendant argues that Plaintiffs' negligent misrepresentation claim should be dismissed because it is not adequately pled and does not state a claim for relief under Iqbal and Twombly.

Initially, with respect to Defendant's reliance upon Bland and similar cases, more recent precedent reflects that the Restatement (Third) of Torts § 9 now governs. In Morris Aviation, LLC v. Diamond Aircraft Indus., Inc., the Sixth Circuit pointed to the Kentucky Supreme Court's acknowledgement in Giddings & Lewis v. Industrial Risk Insurers of Section 9 of the Restatement (Third) of Torts: Products Liability, which provides:

> One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.

Morris Aviation, LLC v. Diamond Aircraft Indus., Inc.,536 Fed. Appx. 558, 567-68 (6th Cir. 2013) (quoting Giddings & Lewis v. Industrial Risk Insurers, 348 S.W.3d 729, 746 n. 11 (Ky. 2011)). See also Stanley v. Bayer Healthcare Pharm. Inc., 2015 WL 4511973, at *3–4 (W.D. Ky. July 24, 2015). Accordingly, with the adoption of the Restatement (Third) of Torts § 9, Kentucky law provides for negligent misrepresentation claims associated with the sale of a product, and the Bland reasoning does not compel its dismissal.

Notwithstanding, Plaintiffs' allegations do not state a claim for negligent misrepresentation. Under Kentucky law, a plaintiff must identify the false or misleading information provided by the specific defendant. See Gaunce, 2015 WL 893569, at *2–3;

Giddings & Lewis, 348 S.W.3d at 746. Additionally, a plaintiff must demonstrate: (1) the subject plaintiff was a reasonably foreseeable recipient of the information; (2) he justifiably relied on the information; (3) he exercised reasonable care in relying on the information; and (4) the false statements allegedly made by the defendant were a proximate cause of the plaintiff's damage. Presnell Constr. Managers, Inc. v. EH Constr., LLC, 134 S.W.3d 575, 580 (Ky. 2004). A plaintiff alleging a negligent misrepresentation claim under Kentucky law must meet the heightened pleading requirements of Rule 9(b). Republic Bank & Trust Co. v. Bear Stearns & Co., Inc., 683 F.3d 239, 247-248 (6th Cir. 2012).

Here, Plaintiffs contend they have sufficiently advised Defendant of the basis of their claims and identified to whom the misrepresentations were made (Mr. DeMoss and his healthcare professionals), by whom they were made (Defendant who marketed and promoted Effient), where and when they were made (in the promotional materials provided to DeMoss and his healthcare providers), and why those representations were fraudulent (because the materials failed to identify the risks of Effient as compared to safe alternative drugs.). (Complaint ¶¶ 22, 23, 45(o), 93). Specifically, Plaintiffs allege that "Defendants negligently misrepresented Effient's high risk of unreasonable, dangerous side effects," "[concealed] information from Mr. DeMoss and Plaintiffs in knowing that Effient was unsafe, dangerous, and/or non-conforming with FDA regulations," and that "Defendants' promotional materials fail to highlight the increased risk of bleeding that cannot be reversed and can lead to death, as it did for Mr. DeMoss." (Id. at ¶¶ 93, 45(o), 23).

The Supreme Court of Kentucky in Giddings & Lewis, Inc. v. Indus. Risk Insurers, 348 S.W.3d 729 (Ky. 2011) has emphasized that the tort of negligent misrepresentation "requires an affirmative false statement; a mere omission will not do." Id. at 746 (quoting Republic Bank & Trust Co. v. Bear, Stearns & Co., Inc., 707 F. Supp. 2d 702, 714 (W.D. Ky. 2010)). See also

Restatement (Third) of Torts § 9 (requiring a "misrepresentation of material fact concerning the product.") Plaintiffs' allegations center on Defendant's failure to disclose the increase risk of bleeding, rather than any identified affirmative misrepresentation or statement. Accordingly, Plaintiffs have not properly stated a negligent misrepresentation claim, and Plaintiffs' negligent misrepresentation claim is dismissed without prejudice.

E. Violation of KCPA

Count V of the complaint alleges a claim for violation of the Kentucky Consumer Protection Act ("KCPA"). (Complaint at ¶¶ 98-108.) The KCPA declares unlawful "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS 367.170(1). Here, Plaintiffs assert that Defendant "misrepresented the alleged benefits of Effient, failed to disclose material information concerning known side effects of Effient, misrepresented the quality of Effient, and otherwise engaged in fraudulent and deceptive conduct which induced Mr. DeMoss to purchase and use Effient." (Complaint ¶ 102.) Plaintiffs further allege that Defendant "uniformly communicated the purported benefits of Effient while failing to disclose the serious and dangerous side-effects related to the use of Effient, its safety, its efficacy, and its usefulness, especially as compared to similar antiplatelet drugs." (Id. at ¶ 103.) Finally, Plaintiffs assert that the unfair and deceptive acts and practices include: "[p]ublishing instructions and product material containing inaccurate and incomplete factual information," "[m]isrepresenting the nature, quality, and characteristics about the product," and "[e]ngaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding." (Id. at ¶ 101.)

The KCPA provides a private right of action for "[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal" as a result of a violation of KRS

§367.170. KRS §367.220(1). Accordingly, the KCPA requires that privity of contract exist between the parties. See Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc., 836 S.W.2d 907, 909 (Ky. Ct. App. 1992). Courts have recognized that an exception to the privity requirement exists when express representations are alleged. Naiser, 975 F. Supp.2d at 743-744; Bosch v. Bayer Healthcare Pharmaceuticals, Inc., 13 F. Supp. 3d 730 (W.D. Ky. 2014). In Naiser, the Court analyzed this exception:

> In [Skilcraft Sheetmetal, Inc.], Kentucky's Court of Appeals analyzed whether K.R.S. § 367.220 allows an action by a person who has not purchased or leased goods from the person he claims to have violated the KCPA. The Court held that a subsequent purchaser could not "maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser." The Court went on to explain that while privity is generally required to assert a cause of action under the KCPA, it found certain situations "distinguishable . . . such as that presented in Ford Motor Co. v. Mayes, Ky. App., 575 S.W.2d 480 (1978), where the defendant (Ford Motor Company) provides warranties to the ultimate purchaser to repair the item purchased."

Naiser, 975 F. Supp. 2d at 743 (internal citations omitted). The plaintiffs in Naiser relied on this language in Skilcraft Sheetmetal, Inc. to argue that they should be allowed to maintain a KCPA cause of action since they alleged that the manufacturer made valid express warranties for the benefit of consumers. The Court agreed. See id. (representations that the product's "effects would last no longer than 30 days," when it "could be expected to last for months," and that "the product contained no formaldehyde," when it actually "contained a chemical known to release formaldehyde upon its use"). According to the Court in Naiser, since the plaintiffs had sufficiently alleged that the manufacturer made valid express warranties for plaintiffs' benefit, the exception outlined in Skilcraft Sheetmetal, Inc. was applicable. The plaintiffs were permitted to maintain a KCPA claim despite the absence of a direct buyer-seller relationship. See Bosch v. Bayer Healthcare Pharm., Inc., 13 F. Supp. 3d 730, 750–51 (W.D. Ky. 2014)

Defendant urges the Court to dismiss Plaintiffs' KCPA claims because there is no privity of contract between the parties. Plaintiffs respond that they have alleged that Defendant made specific representations that misrepresented the safety of Effient to its consumers, and, as a result, the exception to the privity requirement set forth in Naiser applies. Specifically, Plaintiffs allege that Defendant marketed, advertised and promoted Effient as "a new antiplatelet treatment alternative to clopidogrel (Plavix)," but failed to warn that "Effient created [a] significantly increased risk of bleeding as compared to its competitor Plavix." (Complaint ¶¶ 24, 25, 33.) Contrary to Plaintiffs' argument, Plaintiffs have not alleged any affirmations of fact or promises made by Defendant that would qualify as valid express warranties to fall within the Naiser exception. As the complaint fails to show that DeMoss was in privity with Defendant, the KCPA provides no recovery. Accordingly, the Court dismisses Plaintiffs' claim under the KCPA without prejudice.

F. Loss of Consortium

Dismissal of Mrs. DeMoss's claim for loss of consortium is not appropriate given portions of the complaint survive the motion to dismiss.

G. Leave to Amend Complaint

Finally, in response to the motion to dismiss, Plaintiffs request in the alternative that, if the Court finds the complaint defective in any way, they be granted leave to amend the complaint. The Court does not consider this request an appropriate motion to amend. If Plaintiffs want the Court to consider such a request, they should submit a properly supported motion, with a copy of the amended complaint attached, no later than twenty-one (21) days from the entry of this Memorandum Opinion and Order. Thereafter, Defendant may file its response, and the Court will address the merits of Plaintiffs' motion.

IV. CONCLUSION

For the reasons set forth above, **IT IS HEREBY ORDERED** that the motion by Defendant, Eli Lilly and Company, to dismiss the complaint pursuant to Fed. R. Civ. P. 8(a), 9(b), and 12(b)(6) [DN 13] is **GRANTED IN PART AND DENIED IN PART** consistent with this opinion. If Plaintiffs want the Court to entertain a motion to amend the complaint, **IT IS HEREBY ORDERED** that they shall submit their motion and amended complaint no later than twenty-one (21) days from the entry of this Memorandum Opinion and Order.

Joseph H. McKinley, Jr., Chief Judge
United States District Court

February 10, 2017

cc: counsel of record