UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 12-60025-CIV-ROSENBAUM

JASON HOSLER and SANDRA HOSLER,

Plaintiffs,

v.

ALCON LABORATORIES, INC., a Texas corporation, and TOM BRADBURY, an individual pharmaceutical sales representative for ALCON LABORATORIES, INC.,

Defendants.
_____/

ORDER ON DEFENDANTS' MOTIONS TO DISMISS

This matter is before the Court upon Defendant Tom Bradbury's Motion to Dismiss Plaintiffs' Second Amended Complaint [D.E. 40] and Defendant Alcon Laboratories, Inc.'s Motion to Dismiss Plaintiffs' Second Amended Complaint [D.E. 41] ("Defendants' Motions to Dismiss"). The Court has reviewed Defendants' Motions and all supporting and opposing filings. In addition, the Court held oral arguments in this matter on September 21, 2012. For the following reasons, the Court now denies Defendants' Motions to Dismiss.

I. BACKGROUND

Plaintiffs Jason and Sandra Hosler filed a six-count Second Amended Complaint against Alcon Laboratories, Inc. ("Alcon"), a pharmaceutical company, and Tom Bradbury ("Bradbury"), an Alcon sales representative. *See* D.E. 38.[1] Plaintiffs' Second Amended Complaint arises out of

[1] Plaintiffs sought leave to amend their initial and first amended complaints after Defendants moved to dismiss both complaints.

a photorefractice keratectomy ("PRK") surgical eye procedure that Plaintiff Jason Hosler underwent in April 2008. *See* D.E. 38 at 3. After the surgery, Mr. Hosler's doctor, G. Richard Cohen, prescribed him Nevanac eye drops, manufactured by Alcon, "to treat pain and inflammation related to the PRK surgery." *Id.* Nevanac is approved by the Food and Drug Administration ("FDA") for use after cataract surgery. According to Plaintiffs, Alcon, through Defendant Bradbury, encouraged the use of Nevanac for a purpose other than its FDA-approved use. *Id.* Specifically, Plaintiffs contend that Alcon suggested that Dr. Cohen prescribe Nevanac for patients recovering from PRK surgery. *Id.* In this regard, Plaintiffs assert that Bradbury visited Dr. Cohen and provided him with Alcon articles promoting this use of Nevanac, "despite the fact that there was no substantial evidence or substantial clinical experience to support the use of Nevanac for the treatment of pain and inflammation associated with PRK surgery, as opposed to cataract surgery." *Id.*

In addition, Plaintiffs aver that, at the time Bradbury touted Nevanac to Dr. Cohen, Alcon was aware of studies demonstrating "that use of Nevanac post-PRK surgery impeded epithelial healing and presented an unreasonable risk of corneal scarring" but that the company did not provide those studies to Dr. Cohen. *Id.* at 4. Mr. Hosler alleges that his use of Nevanac caused him to developed corneal scarring and that, had Defendants "given Dr. Cohen adeqeuate and appropriate information ," he would not have prescribed Nevanac to Mr. Hosler. *Id.*

After Mr. Hosler's alleged injuries, he and his wife filed their six-count Second Amended Complaint against Defendants. Plaintiffs bring Counts I through IV against Alcon for negligence, negligent misrepresentation, strict liability (design defect), and strict liability (failure to warn). *See id.* at 5-14. In Count V, Plaintiffs charge negligent misrepresentation against Bradbury. *See id.* at 14-17. Mrs. Hosler asserts a loss-of-consortium claim against both Alcon and Bradbury in Count

VI. *See id.* at 17.

In response to Plaintiffs' Second Amended Complaint, both Defendants filed separate Motions to Dismiss, in which they each seek to dismiss the claims against them. *See* D.E. 40-41. Both Defendants argue that Plaintiffs' Second Amended Complaint should be dismissed pursuant to Rules 8(a), 9(b), and 12(b)(6), Fed. R. Civ. P.

II. DISCUSSION

A. Standard on a Motion to Dismiss

Rule 12(b)(6), Fed. R. Civ. P., governs motions to dismiss for failure to state a claim. It provides, in relevant part,

> **(b) How to Present Defenses.** Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:
> **(6)** failure to state a claim upon which relief can be granted; . . . .

Id. Thus, the Court considers the Federal Rules of Civil Procedure as they set forth the requirements for stating a claim.

Rule 8(a)(2), Fed. R. Civ. P., demands that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While a complaint need not provide detailed factual allegations, the standard "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 958 (11th Cir. 2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Similarly, "naked assertion[s] bereft of "further factual enhancement" do not suffice. *Twombly*, 550 U.S. at 555, 557. As the Supreme Court has explained, a complaint's

"[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555. "Moreover, the facts supporting the claim must be 'consistent with the allegations in the complaint.'" *Wilchombe*, 555 F.3d at 958 (quoting *Twombly*, 550 U.S. at 562).

Finally, Rule 9(b), Fed. R. Civ. P., provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." The purpose of this particularity requirement is to "alert[ ] defendants to the precise misconduct with which they are charged and protect[ ] defendants against spurious charges of immoral and fraudulent behavior." *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001) (internal quotation marks omitted). Rule 9's heightened pleading standard also applies to common-law negligent-misrepresentation claims. *See In re Mirabilis Ventures, Inc.*, 2010 WL 415315, at *3 (M.D. Fla. Jan. 27, 2010). The Rule must be read, however, in conjunction with Rule 8's directives that a complaint need only provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 8(a)(2), Fed. R. Civ. P.; *see also Friedlander v. Nims*, 755 F.2d 810, 813 n.3 (11th Cir. 1985) ("[A] court considering a motion to dismiss for failure to plead fraud with particularity should always be careful to harmonize the directives of rule 9(b) with the broader policy of notice pleading" found in Rule 8.). In this case, the heightened Rule 9 standard applies to the negligent-misrepresentation claims against Alcon and Bradbury (Counts II and V); the remaining claims are each governed by Rule 8.

When reviewing a motion to dismiss, a court, as a general rule, must accept the plaintiff's allegations as true. *Bell v. J.B. Hunt Transp., Inc.*, 427 F. App'x 705, 707 (11th Cir. 2011) (citing *Hishon v. King & Spalding*, 467 U.S. 69, 72 (1984)). The Court must also draw all reasonable inferences in the plaintiff's favor. *Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1194 (11th Cir. 2007). But "[c]onclusory allegations, unwarranted deductions of facts or legal conclusions masquerading

as facts will not prevent dismissal." *Bell*, 427 F. App'x at 707 (quoting *Jackson v. BellSouth Telecomm'ns*, 372 F.3d 1250, 1263 (11th Cir. 2004) (internal quotation marks omitted)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949-51 (2009). In short, the allegations in a complaint "must . . . contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1289 (11th Cir. 2010) (quoting *Twombly*, 550 U.S. at 570). With these standards in mind, the Court now considers Plaintiffs' six claims.

B. Claims Governed by Rule 8

Plaintiff Jason Hosler raises three claims governed by Rule 8 against Defendant Alcon: (1) negligence; (2) strict liability (design defect); and (3) strict liability (failure to warn). His wife, Sandra Hosler, asserts a loss-of-consortium claim against Alcon and Bradbury. The Court addresses each of these claims in turn.

1. Negligence (Count I)

To state a products-liability claim based on negligence, including negligent design or manufacture, a plaintiff must show all of the following: (1) the defendant owed a duty of care towards the plaintiff; (2) the defendant breached that duty; (3) the breach was the proximate cause of the plaintiff's injury; and (4) the product was defective or unreasonably dangerous. *Cook v. MillerCoors, LLC*, 829 F. Supp. 2d 1208, 1217 (M.D. Fla. 2011). In this case, the Second Amended Complaint sufficiently pleads each element.

With respect to the first element, Mr. Hosler alleges that Alcon owed him several specific duties, including "[t]he duty to design an ophthalmic suspension which was reasonably safe for its foreseeable use, including [the] off-label uses [Alcon] promoted;" "[t]he duty to design,

manufacture, test, and/or inspect the ophthalmic suspension for safe use under normal and expected conditions, included off-label uses [Alcon] promoted;" and "[t]he duty to . . . inspect the ophthalmic suspension for safe use under [Alcon's] recommended off-label uses." D.E. 38 at ¶ 27.

Mr. Hosler further asserts that Alcon breached these duties in particular ways, such as "failing to adequately warn medical professional[s] and potential patients of dangers presented by [Nevanac] for treatment post-PRK surgery, including but not limited to corneal scarring" and "[e]ngaging in off-label promotion of benefits of Nevanac post-PRK surgery when in fact there was not substantial competent evidence to support said use." *Id.* With regard to failure to warn, the Second Amended Complaint details that Nevanac's label is "necessarily inadequate to warn of the risk of corneal scarring when used in connection with PRK surgery because there is NO warning related to that use because the label does not reference PRK surgery." *Id.* at ¶ 22 (emphasis in original); *id.* at 5 ("realleg[ing] and reaver[ring] Paragraphs 1-23 as if fully set forth").

Plaintiff supports his breach-of-duty allegation as it relates to the promotion of off-label uses of Nevanac by stating, "[C]linical studies of which Defendant . . . was aware demonstrated as early as 2006 that use of Nevanac post-PRK surgery impeded epithelial healing and presented an unreasonable risk of corneal scarring. Those studies were not provided to Plaintiff's treating physician Dr. Cohen."[2] *Id.* at ¶ 18; *see also id.* at ¶17 (alleging, "Defendant Bradbury represented

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[2]This allegation takes on even more significance in light of Plaintiff's contention that

> [o]n October 20, 2006[,] [t]he Department of Health and Human Services sent . . . Alcon a warning letter regarding the false or misleading sales aids of Nevanac. In particular as relates to this case, the Department found that representations made by . . . Alcon were misleading because they suggested that Nevanac was effective for post-operative pain and inflammation for <u>any</u> eye surgery when in fact there was no substantial evidence or

to Dr. Cohen that Nevanac was safe and appropriate for use post-PRK surgery when in fact Defendant Alcon has no competent evidence to support that representation and in fact said representation is false."). In addition, Mr. Hosler avers that despite such circumstances, Alcon, through Bradbury, nonetheless "recommended the use of Nevanac for post-PRK" and "supplied Dr. Cohen with free samples of Nevanac to encourage and promote his off label use of the drug." *Id.* at ¶¶ 14, 16; *see also id.* at ¶ 25 ("Defendant . . . represented to . . . Dr. Cohen that Nevanac was safe and appropriate for post-surgical treatment of PRK when, in fact, Nevanac is not safe and appropriate for patients after PRK surgery"). Contrary to Alcon's suggestions, these allegations are factual contentions, not legal conclusions, and they are sufficiently specific to satisfy *Twombly* and *Iqbal*.

With respect to the third element, Mr. Hosler contends that Alcon's negligence directly and proximately caused his injuries because "Dr. Cohen's decision to recommend and prescribe Nevanac to the Plaintiff . . . for use after PRK surgery was based upon reliance on Defendants' off-label marketing of Nevanac. Without Defendants' off-label marketing if Nevanac, Dr. Cohen would not have prescribed and Plaintiff . . . would not have used Nevanac as part of his post-PRK treatment plan." *Id.* at ¶ 19. The Second Amended Complaint further explains that Dr. Cohen "was not aware of the unreasonable risk of corneal scarring posed by the use of Nevanac when used post-PRK

> substantial clinical experience to support the use of Nevanac for the treatment of pain and inflammation associated with any eye surgery as opposed to cataract surgery.

D.E. 38 at ¶ 9. Alcon's contention that allegations like this one and those that refer to Alcon's promotion of Nevanac's off-label uses turn Plaintiff's claim into an attempt to state a private cause of action under the Food, Drug, and Cosmetic Act is similarly unavailing. *See infra.* Rather, this contention goes to Alcon's knowledge of the allegedly misleading nature of its labeling, and, thus, to the allegedly misleading nature of the labeling itself.

surgery," *id.* at ¶ 21, and elaborates, "If Defendant[s] Alcon and Bradbury had given Dr. Cohen adequate and appropriate information regarding the risk of corneal scarring when Nevanac is used post-PRK surgery, he would not have prescribed Nevanac for Plaintiff . . . because of the unreasonable risk of corneal scarring which exists when the drug is used in connection with PRK surgery." *Id.* at ¶ 20. Under Florida's learned-intermediary doctrine, these allegations sufficiently establish proximate cause if true. *See Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104-05 (Fla. 1989) (explaining the "learned intermediary" doctrine and its role in determining proximate cause).

Finally, these allegations as a whole provide the necessary factual basis for Plaintiff's contention that Nevanac is defective or unreasonably dangerous for use in post-PRK-surgery patients. In short, the Court disagrees with Alcon's view that the allegations supporting Plaintiff's negligence claim are conclusory and general. Moreover, at the motion-to-dismiss stage, Rule 8 does not require a higher level of specificity than that contained in Mr. Hosler's allegations. Accordingly, the Court denies the Motion to Dismiss as it relates to Count I.

2. Strict Liability (Design Defect) (Count III)

To state a claim in Florida for strict products liability based on a design defect, a plaintiff must allege all of the following: "(1) that a defect was present in the product; (2) that it existed at the time the manufacturer parted possession with the product; and (3) that it caused the injuries of which the Plaintiff complains." *Barrow v. Bristol–Myers Squibb*, 1998 WL 812318, at *27 (M.D. Fla. Oct. 29, 1998); *see also Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1143 (Fla. 1st DCA 1981). A design defect is present "where unforeseen hazards accompany normal use of the product created according to design." *See Cassisi*, 396 So. 2d at 1145. When a design-defect claim is based on negligence, the plaintiff must demonstrate that the manufacturer "has a duty to exercise reasonable

care so that its products will be reasonably safe for use in a foreseeable manner, and the manufacturer has breached that duty." *Barrow*, 1998 WL at *27. In contrast, when a plaintiff asserts that a defendant is strictly liable for a design defect, the plaintiff "must show that, when the product left the manufacturer's control, it was in a defective condition unreasonably dangerous to foreseeable users and bystanders." *Id.*

The Court finds that Mr. Hosler has stated a claim for strict liability based on a design defect. He alleges that Nevanac, as designed, contains a defect that results "in corneal scarring when used for treatment post-PRK surgery." D.E. 38 at ¶ 52. Nor, as Alcon argues, is Plaintiff's strict-liability claim insufficient because it fails to identify a "specific defect" in the product. *See* D.E. 41 at 14-15. The Second Amended Complaint asserts that "clinical studies of which . . . Alcon was aware demonstrated as early as 2006 that use of Nevanac post-PRK surgery impeded epithelial healing and presented an unreasonable risk of corneal scarring." D.E. 38 at ¶ 18.

In a comparable case from the Middle District of Florida, the plaintiff alleged that he was injured by a defective surgical mesh patch. *See Krywokulski v. Ethicon, Inc*., 2010 WL 326166, at *2 (M.D. Fla. Jan. 21, 2010). Specifically, the patient had undergone surgery during which the mesh patch had been installed. Following the surgery, the plaintiff experienced an infection, which required that the mesh patch be removed. The plaintiff sued the manufacturer of the patch, contending that the patch was defective and that it had caused his infection. Among other theories, the plaintiff asserted a strict-liability claim. To support this cause of action, the plaintiff alleged, among other things, that the patch contained design and manufacture defects, specifically, that the "defective patches delaminated and/or malfunctioned, thus making the patches unsafe and dangerous for use." *Id.* at *2. In other words, the plaintiff suggested that the patch did not work right, which

made the patch unsafe and dangerous for use in that it caused the plaintiff's infection.

The defendants contended in a motion to dismiss that the plaintiff had not provided enough factual support for his allegations. *Id.* The court disagreed with the defendants, finding that, at the motion-to-dismiss stage, where "only the pleadings have been filed and no evidence has been placed of record," the plaintiff must "allege [only] the existence of a defect or that the defect has led to an unreasonably dangerous condition . . . ." *Id.* The court continued, explaining that a plaintiff cannot reasonably be expected "to prove the existence of a product defect at the pleading stage of trial." *Id.* In addition, the court noted that, so early in the case, the plaintiff was not even required to identify whether the alleged defect stemmed from the product's design, manufacture, or warning. *Id.* at 3. Indeed, the Eleventh Circuit has observed that "it would be difficult at such an early stage in the litigation for [a] plaintiff to know whether a defect was due to a product's design or manufacture." *Bailey v. Janssen Pharmaceutica*, 288 F. App'x 597, 605 (11th Cir. 2008). Instead, a plaintiff's "allegation of a defect alone is sufficient, as mere knowledge of a defect gives defendant enough notice to produce a proper response which may include discussion of a manufacturing or design-based defect." *Krywokulski*, 2010 WL at *3 (citing *Bailey*, 288 F. App'x at 608).

Similarly, in *Bailey*, the Eleventh Circuit considered the standard of pleading pertaining to a strict-liability claim under Florida law. 288 F. App'x 597. In that case, a fentanyl patch had been prescribed to the decedent after surgery. The patch was supposed to release a controlled dose of fentanyl, a powerful opiate, to its wearer over a 72-hour period. *Id.* at 599. The decedent's estate claimed that the patch had malfunctioned and instead delivered the entire dose of fentanyl to the decedent at one time, as opposed to administering it slowly over a 72-hour period. *Id.* at 599-600. Based on these allegations, the plaintiff alleged in a single count alternative theories of strict liability

based on design defect, manufacturing defect, and failure to adequately warn. *See id.* at 606-09. The Eleventh Circuit upheld the design-defect and manufacturing-defect theories but found that the failure-to-warn theory was inadequately pled.

In reaching these conclusions, the court noted that the complaint alleged "in a conclusory fashion that the patch reached [the decedent] in an unreasonably dangerous condition." *Id.* at 607. But the court nonetheless upheld the strict-liability claim because it further found that the complaint went on "to suggest several possible defects existing at the time of [the decedent's] use of the . . . patch." *Id.* More specifically, the court pointed to the allegations in the complaint that the patch "suffered from a malfunction in its 'protective liner and functional layers,' which 'leaked and failed to deliver fentanyl from the drug reservoirs at the declared constant amount per unit of time of 75 mcg/hour.'" *Id.* The complaint did not purport to identify what part of the "protective liner and functional layers" (a description that would seem to include all of the layers, or the entirety, of the patch) allegedly malfunctioned or how the liner and layers supposedly malfunctioned other than to state that they had caused the 72-hour dose to be delivered unevenly. In other words, the complaint basically alleged that some unidentified part of the patch had caused overly large amounts of fentanyl to be dispensed at once, thereby resulting in the decedent's death. The Eleventh Circuit determined that these allegations in the complaint were "sufficient to allow defendants to frame a responsive pleading directed at a defect in either the design or manufacturing of the patch's layers that caused a leak resulting in the delivery of a fatal dose of fentanyl." *Id.* at 608.

Plaintiff here alleges as much as the *Krywokulski* and *Bailey* plaintiffs. Specifically, Mr. Hosler asserts that the design of Nevanac "resulted in corneal scarring when used for treatment post-PRK surgery." D.E. 38 at ¶ 52. Plaintiff further contends that "use of Nevanac post-PRK surgery

impeded epithelial healing and presented an unreasonable risk of corneal scarring." *Id*. at ¶ 18. These contentions are at least as specific as the *Krywokulski* plaintiff's effective averment that the patch had a design or manufacturing defect because, when used as intended, it caused his infection and the *Bailey* plaintiff's allegation that similarly amounted to an assertion that the patch involved in that case suffered from a design or manufacturing defect because it caused the decedent's overdose death.

Here, Mr. Hosler has supplied Alcon with enough factual allegations for the company to formulate a response to the Second Amended Complaint. He does not contend generally that the defect could be based on either the design or manufacturing of Nevanac; instead, he specifies that Nevanac suffered from a design, rather than manufacturing, defect. *See* D.E. 38 at 11. Moreover, although he does not set forth the precise chemical, biological, or other process by which Nevanac allegedly causes corneal scarring in post-PRK patients, Mr. Hosler does place Alcon on notice of the type of harm the product allegedly causes. When discovery has not commenced and the parties have not yet sought expert opinions, it would be unreasonable to expect Mr. Hosler to identify the exact chemical, biological, or other process that allegedly results in corneal scarring when Nevanac is administered post-PRK surgery. Instead, as Plaintiffs have suggested, summary judgment or trial will be the appropriate stage at which "to test the existence of the defect," and "discovery in this matter, together with expert testimony, will flesh out precisely why [and if] Nevanac causes corneal scarring in post-PRK patients." D.E. 48.

And, contrary to Defendants' suggestion, *Gomez v. Pfizer, Inc*., 675 F. Supp. 2d 1159 (S.D. Fla. 2009), does not require a different outcome. In *Gomez*, the plaintiff took a combination of what was apparently over-the-counter Motrin, over-the-counter Tylenol, prescription Motrin, and

prescription Tylenol and subsequently developed Stevens-Johnson Syndrome. She sued several defendants, including the manufacturers of Tylenol and Motrin and alleged that the products were "defectively designed and/or manufactured because [their] intended use resulted in a substantial and unreasonable likelihood of causing Stevens–Johnson syndrome, which rendered [them] unreasonably dangerous for [their] intended use." *Id.* at 1163. Describing these assertions as "no more than bare legal conclusions," the court dismissed the claim for strict liability. *Id.* Significant to the court's discussion of the complaint's deficiencies was the background against which it occurred. In particular, among other shortcomings, the complaint also lacked any factual allegations putting the different manufacturers on notice of what product or products allegedly were defective. *Id.* And the complaint also failed to identify under which theory of strict liability the plaintiff sought to proceed. *Id.* In short, the *Gomez* complaint was wholly deficient.

The Second Amended Complaint in this case does not suffer from the same problems. It is clear from the pleading that Plaintiff sues Alcon and it representative for corneal scarring allegedly caused by using Nevanac post-PRK surgery. Unlike in *Gomez*, there is no question left here by the Second Amended Complaint as to which drug allegedly suffers from a strict-liability defect. And no issue arises as to proximate cause, as implicitly did in *Gomez*, where some unidentified combination of drugs supposedly was ingested before the plaintiff developed Stevens-Johnson Syndrome. In addition, the Second Amended Complaint specifically describes the defect alleged in this case as a design defect. Against this background, unlike in *Gomez*, the Second Amended Complaint's allegations of corneal scarring and impaired epithelial healing when Nevanac is used post-PRK surgery sufficiently identify a defect to put Defendants on notice regarding Plaintiff's strict-liability claim based on design defect.

Returning to the other elements of a strict-liability claim, Plaintiff also states that Alcon placed Nevanac into the stream of commerce with the defect already present in the product, *see* D.E. 38 at ¶ 50, and that the defect caused his corneal scarring and other injuries. *See id.* at ¶ 53. While Alcon argues that Mr. Hosler has not sufficiently alleged that a defect in Nevanac was the proximate cause of his injuries, this Court disagrees.

To prove the existence of proximate causation, a plaintiff must demonstrate that the defective product was the "but-for" cause of his injuries. *See Jones v. Utica Mut. Ins.*, 463 So. 2d 1153, 1156 (Fla. 1985). Here, Mr. Hosler pleads that the allegedly defective nature of Nevanac directly and proximately caused him to develop corneal scarring and resulting injuries. *See* D.E. 38 at ¶ 53. Alcon dismisses Mr. Hosler's statement as "a bare legal conclusion," D.E. 41 at 15, citing to *Gargano v. Phillip Morris USA, Inc*., 2011 WL 2445869, at *3 (S.D. Fla. June 20, 2011).[3]

In *Gargano*, the plaintiff, a longtime smoker who *had not* been diagnosed with lung cancer, argued that his use of cigarettes aggravated his lung-cancer risk. *Id.* at 2. The court dismissed the plaintiff's design-defect claim, finding that he failed to adequately plead proximate causation. *Id.* While the plaintiff used the term "proximate cause," the court explained that the but-for standard required the plaintiff to allege that his injury would not have occurred with a non-defective product. *Id.* In other words, the plaintiff did not sufficiently allege that he would not have suffered from an increased lung-cancer risk had he smoked "non-defective cigarettes" and not smoked the defendant's cigarettes. Instead, he stated that "non-defective cigarettes" would have merely decreased the risk,

[3] Alcon also cites to *Rink v. Cheminova, Inc*., 400 F.3d 1286 (11th Cir. 2005), and *Barati v. Aero. Indust. Inc.*, 579 So. 2d 176 (Fla. 5th DCA 1991). In both cases, the courts addressed whether the plaintiff had *proven* (rather than alleged) proximate causation for purposes of summary judgment. At the motion-to-dismiss stage, however, Mr. Hosler is not yet required to prove his case.

impliedly acknowledging that the risk would exist in either situation. *Id.* at 3.

Gargano is inapposite to the instant case. Here, Mr. Hosler argues that the allegedly defective design of Nevanac directly caused his injuries. Unlike the *Gargano* plaintiff, Mr. Hosler does not concede that he would have been at risk for the same injuries even without use of Defendant's product. Moreover, also unlike the plaintiff in *Gargano*, Mr. Hosler does not contend that Nevanac has increased his risk for an illness that has not yet developed. As discussed above, the Court cannot presently expect Mr. Hosler to state exactly *how* the design of Nevanac caused the corneal scarring; he will be required to prove causation in a motion for summary judgment or at trial. At this stage, though, the Court finds that Mr. Hosler has sufficiently alleged that, but for a defect in Nevanac's design, he would not have been injured. Thus, the Court will not dismiss Count III.

3. Strict Liability (Failure to Warn) (Count IV)

Drug manufacturers generally have a duty to warn of a drug's dangerous side effects. *See Hoffman-La Roche, Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009). In Florida, a prescription-drug manufacturer fulfills its duty to warn when it provides adequate warnings to a physician, rather than directly to the consumer. *Id.* "[T]he prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." *Felix v. Hoffman-La Rouche, Inc*., 540 So. 2d 102, 104 (Fla. 1989). The manufacturer, therefore, "will not be held liable in Florida where it can show that it provided the medical community with an adequate warning of the risks associated with the product." *Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 851 (S.D. Fla. 1990).

In order to state a claim in Florida for strict liability based on a drug's insufficient warnings,

then, the plaintiff must allege all of the following: "(1) that the warnings accompanying the item were inadequate; (2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and (3) that Plaintiff in fact suffered an injury by using the product." *Colville v. Pharmacia & Upjohn Co., LLC*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008). With regard to the first element, Mr. Hosler alleges that Nevanac's warnings were inadequate because they were vague and incomplete, and they did not "adequately warn of the unreasonably dangerous risks presented by the off-label use of Nevanac . . . ." D.E. 38 at 13. He further argues that the warnings were insufficient to "alert prescribing physicians, as well as consumer patients, of the actual risks presented by the off-label use of the drug" and did not contain adequate information "regarding all known or reasonably knowable potential side effects associated with the recommended off-label use of Nevanac." *Id.* Finally, Plaintiffs claim that "[t]he label for Nevanac is necessarily inadequate to warn of the risk of corneal scarring when used in connection with PRK surgery because there is NO warning related to that use because the label does not reference PRK surgery." D.E. 38 at ¶ 22 (emphasis in original).

Next, Mr. Hosler contends that the lack of warnings proximately caused his injury because, if Alcon had given "a proper and adequate warning . . . , Plaintiff's treating physician would not have recommended or prescribed Nevanac for use by Plaintiff and he would not have suffered the corneal scarring which resulted from such use." *Id.* at 14. Finally, he asserts that he has in fact "sustained serious injuries" from his use of Nevanac. *Id.*

Alcon argues that the failure-to-warn claim is inadequate because it does not identify what was lacking in Nevanac's warning, "other than that it [did] not mention PRK." *See* D.E. 41 at 9. Mr. Hosler, in response, contends that the lack of warning for post-PRK patients was exactly what

rendered the warning inadequate. *See* D.E. 48 at 6, 11; *see also* D.E. 38 at ¶ 22 ("The label for Nevanac is necessarily inadequate to warn of the risk of corneal scarring when used in connection with PRK surgery because there is NO warning related to that use because the label does not reference PRK surgery.") (emphasis in original). This sufficiently identifies what Plaintiff believes was lacking in Nevanac's warning. Moreover, Plaintiff has pled proximate causation and injury in fact, as required by the second and third elements of a failure-to-warn claim. Accordingly, the Court will not dismiss Count IV.

5. Loss of Consortium (Count VI)

Plaintiff Sandra Hosler asserts a loss-of-consortium claim against both Alcon and Bradbury. *See* D.E. 38 at 17. When a wife sues her husband's alleged tortfeasors for loss of consortium, "her right of action is a derivative right and she may recover only if her husband has a cause of action against the same defendant." *Gates v. Foley*, 247 So. 2d 40, 45 (Fla. 1971). Thus, if the husband fails to state a claim against the defendant, the wife's loss-of-consortium claim must fail as well. In this case, however, for the reasons set forth elsewhere in this Order, the Court declines to dismiss Mr. Hosler's claims against Alcon and Bradbury. As a result, Mrs. Hosler's claim will stand.

C. Claim Governed by Rule 9

Mr. Hosler raises negligent-misrepresentation claims against Defendants Alcon and Bradbury. Both Defendants argue that the negligent-misrepresentation claim should be dismissed because Mr. Hosler has failed to comply with Rule 9(b)'s heightened pleading requirements. *See* D.E. 40 at 6-10; D.E. 41 at 12-13.

To state a claim for negligent misrepresentation in Florida, a plaintiff must allege the following: "(1) a misrepresentation of material fact; (2) that the representor either knew or should

have known was false or made without knowledge of truth or falsity; (3) the representor intended to induce another to act on the misrepresentation; and (4) resulting injury to a party acting in justifiable reliance on the misrepresentation." *MeterLogic, Inc. v. Copier Solutions, Inc*., 126 F. Supp. 2d 1346, 1363 (S.D. Fla. 2000); *see also Hoon . Pate Constr. Co.*, 607 So. 2d 423, 427 (1992).

Mr. Hosler has sufficiently stated a claim for negligent misrepresentation against both Alcon and Mr. Bradbury. In the Second Amended Complaint, Mr. Hosler contends that Alcon, through Mr. Bradbury, represented to Dr. Cohen "that Nevanac was safe and appropriate for treatment post-PRK surgery and that independent reliable studies supported the use of Nevanac post-PRK surgery." D.E. 38 at ¶ 33. He further alleges that Defendants knew or should have known, at the time that these representations were made, that they were false, misleading, and contradicted by clinical studies. *See id.* at ¶¶ 35,67. In addition, Mr. Hosler avers that Alcon "intended to induce justifiable reliance by Plaintiff's treating physician and Plaintiff" himself. *Id.* at ¶ 32. Finally, Mr. Hosler argues that he was injured as a result of his reliance on Alcon's representations. *Id.* at ¶47.

With respect to Mr. Bradbury, Mr. Hosler alleges that the sales representative misrepresented the safety of Nevanac for post-PRK patients and that he knew or should have known "of the serious risks and dangers associated with such use of the product . . . ." D.E. 38 at ¶¶ 69-72. In addition, he contends that Mr. Bradbury made these statements with the intention of inducing Dr. Cohen, and, ultimately, patients such as Mr. Hosler, to rely on them.[4] *Id.* at ¶ 73. Finally, he asserts that he

[4] Defendant Bradbury cites to *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1289 (S.D. Fla. 2009), in support of his argument that Mr. Hosler's negligent-misrepresentation claim suffers from fatal deficiencies. In that case, the court dismissed a negligent-misrepresentation claim because the plaintiff did not "properly allege that a defendant made a knowingly or recklessly false statement to another and that the person receiving the statement reasonably relied upon it, and that such reliance injured the receiving party." Here, Mr. Hosler has clearly alleged that Defendants misrepresented the safety of

sustained serious injuries as a result of the alleged misrepresentations. *Id.* at ¶ 78.

Alcon and Bradbury argue that Mr. Hosler has not met Rule 9(b)'s heightened pleading standard because he has not stated "precisely what statements were made by Mr. Bradbury regarding the use of Nevanac for post-PRK," nor has he identified "precisely what documents Mr. Bradbury provided to Dr. Cohen . . . ." D.E. 40 at 9. In response, Mr. Hosler argues that the Second Amended Complaint "is very clear about what misrepresentation [his] claim is based upon; to wit: Defendant Bradbury told Dr. Cohen that Nevanac is safe and appropriate for use post-PRK surgery when in fact it is not safe and appropriate for use post-PRK surgery." D.E. 47 at 7-8. In addition, Mr. Hosler argues that the Second Amended Complaint "gives a time frame for the misrepresentations" — some time between January 2008 and March 2008 — and identifies Dr. Cohen's office as the location where the misrepresentations were allegedly made. *Id.* at 8. Mr. Hosler reasons, "When oral representations, as opposed to written representations, are made to a third party, it is, of course, virtually impossible to be precise." *Id.* During oral argument, however, counsel for Plaintiff confirmed that Dr. Cohen has stated that words to the effect set forth in the Second Amended Complaint were spoken to him by Defendant Bradbury.[5]

Rule 9(b) requires nothing more. Neither the Court nor Defendants can reasonably expect Mr. Hosler to set forth the exact words stated during a conversation at which he was not present and

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Nevanac for post-PRK patients, that Mr. Hosler relied on those misrepresentations, and that he was injured as a result of his reliance. Thus, *Southeast Laborers Health & Welfare Fund* is not instructive here.

[5]Counsel for Alcon also conceded that if Plaintiffs could prove that Mr. Bradbury represented to Dr. Cohen that "Nevanac was safe and appropriate for treatment post-PRK surgery and that independent reliable studies supported the use of Nevanac post-PRK surgery," the allegation to this effect in the Second Amended Complaint would satisfy Rule 9(b)'s particularity requirement.

which Dr. Cohen had no reason to know would become important at a later date. The purpose of Rule 9(b)'s particularity requirement is to "alert[ ] defendants to the precise misconduct with which they are charged . . . ." *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001) (internal quotation marks omitted).

Mr. Hosler's allegations sufficiently plead the substance of the alleged conversations between Bradbury and Dr. Cohen and contain enough detail to put Defendants on notice of the type of misconduct Mr. Hosler charges. Indeed, courts in this district, applying Florida law, have previously held that a plaintiff may state a claim for fraud by identifying "the individuals who made the alleged misrepresentations, the time of the alleged fraud, and the place of the alleged fraud" and "quot[ing] *or paraphras[ing]* the alleged fraudulent misrepresentations made by the defendant." *MeterLogic, Inc. v. Copier Solutions, Inc*., 126 F. Supp. 2d 1346, 1360 (S.D. Fla. 2000) (emphasis added).

Moreover, while the Court does not do so in this case, courts sometimes apply the specificity requirements less stringently "where 'strict application of Rule 9(b) could result in substantial unfairness to private litigants who could not possibly have detailed knowledge of all the circumstances surrounding the alleged fraud.'" *Id.* at 361 (quoting *NCR Credit Corp. v. Reptron Elecs., Inc.*, 155 F.R.D. 690, 692 (M.D. Fla. 1994)). Were the Court to require a negligent- or fraudulent-misrepresentation plaintiff to plead the precise statements allegedly spoken, it would often amount to an impossible barrier in cases where a defendant's alleged misrepresentations were made to a third party rather than to the plaintiff himself — a problem prone to arise in cases involving drugs prescribed to patients by their physicians. This would result in the "substantial unfairness" contemplated by the *MeterLogic* court. Accordingly, the Court will not dismiss Mr. Hosler's negligent-misrepresentation claims because he cannot state precisely each exact word of each alleged

conversation between Mr. Bradbury and Dr. Cohen.

6. Off-Label Promotion Under the Food, Drug, and Cosmetics Act

Both Defendants contend that Plaintiffs impermissibly attempt to bring a private cause of action for alleged violations of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301, *et seq.* ("FDCA"). *See* D.E. 40 at 4-5; D.E. 41 at 16-19. The Court is not persuaded by this argument.

While the FDCA bars off-label marketing of drugs by their manufacturers, it creates no private cause of action for violations of its provisions. *See Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999). A private plaintiff may, however, assert a claim such as negligence or negligent misrepresentation that is based in part on a defendant's conduct that happens to occur in violation of the FDCA. *See In re Neurontin Mktg. & Sale Practices Litig.*, 244 F.R.D. 89, 92 n.6 (D. Mass. 2007).

Here, Plaintiffs do not purport to base their claims on an alleged violation of the FDCA. Instead, their claims are based, in part, on the alleged statements that Defendants made regarding off-label use of Nevanac and the resulting injuries Plaintiffs claim to have suffered. In the state claims that Plaintiffs have pled, the significance of the off-label marketing stems from the fact that that is the context in which the alleged misrepresentations occurred, as opposed to appearing on the labeling. In order to explain why a doctor might rely on such statements, Plaintiffs set forth the context in which they were allegedly made. This fact does not somehow convert state causes of action into attempted private FDCA causes of action, though. Indeed, as Plaintiffs observe in their Response to Bradbury's Motion, the Second Amended Complaint asserts that Defendants "were aware that not only was their marketing 'an impermissible off-label promotion *but also that it was not supported by medical and scientific evidence' and was 'false*.'" D.E. 47 at 9 (quoting D.E. 38

at 10, 17) (emphasis added). Plaintiffs' claims will not fail simply because the acts that they allege, if true, may also constitute a violation of the FDCA.

III. CONCLUSION

For the foregoing reasons, Defendant Tom Bradbury's Motion to Dismiss Plaintiffs' Second Amended Complaint [D.E. 40] and Defendant Alcon Laboratories, Inc.'s Motion to Dismiss Plaintiffs' Second Amended Complaint [D.E. 41] are hereby **DENIED**.

DONE and **ORDERED** at Fort Lauderdale, Florida this 9th day of October 2012.

ROBIN S. ROSENBAUM
United States District Judge

copies: Counsel of Record