IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

Kimberly Centeno,

Plaintiff,

vs. **No. 3:14-cv-75-DRH-DGW**

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant.

MEMORANDUM AND ORDER

HERNDON, Chief Judge:

This matter is before the Court on Defendant Bayer HealthCare Pharmaceuticals Inc.'s ("Bayer") motion to dismiss (Doc. 9). Plaintiff Kimberly Centeno responded (Doc. 13). For the following reasons, Bayer's motion is **GRANTED IN PART AND DENIED IN PART.**

I. Background

On January 22, 2014, plaintiff filed this products liability case against Bayer concerning Bayer's product Mirena. Plaintiff filed an amended complaint on January 23, 2014. Mirena, a T-shaped polyethylene frame with a steroid reservoir that releases 20μg/day of levonorgestrel, is a prescription medication used as a contraceptive. Mirena is manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Bayer, Bayer OY, and Bayer Pharma AG. Bayer is a corporation organized under the laws of Delaware and having its principal place of

business at 6 West Belt Road, Wayne, New Jersey.

Plaintiff, a citizen of California, alleges the following. In June 2011, plaintiff had Mirena inserted. Her Mirena insertion was uncomplicated and properly placed. When she returned for an exam approximately six weeks after Mirena was inserted, she was again told that it was properly placed. However, plaintiff began experiencing severe cramping and pain approximately six months later. Her symptoms required additional medical care, treatment, and testing. Plaintiff subsequently requested that Mirena be removed due to severe pain. In May 2012, plaintiff was diagnosed with cysts on her right ovary.

Bayer now moves to dismiss plaintiff's complaint, asserting that the Court should apply California law and that plaintiff has failed to state a claim under California law. Plaintiff responds, arguing that New Jersey law should apply and that under New Jersey law she has sufficiently stated a claim. In the alternative, she argues that if the Court applies California Law, she has stated a claim under California law.

II. Legal Standard

A properly stated claim in a well-pleaded complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief and a demand for the relief sought." Fed. R. Civ. P. 8. A defendant may file a motion to dismiss the claim for failure to state a claim on which relief can be granted. Fed. R. Civ. P. 12(b)(6). Withstanding such a motion requires alleging enough facts to support a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678

(2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570). A claim is facially plausible "when the plaintiff 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. Although the plausibility standard does not require a showing of "probability," a mere showing of the possibility that the defendant acted unlawfully is insufficient. *Id*.

III. Analysis

A. Choice of Law

In a diversity case, the Court applies the choice of law rules of the state in which the district court sits. *Wachovia Securities, LLC v. Banco Panamericano, Inc.*, 674 F.3d 743, 751 (7th Cir. 2012). Illinois has adopted the choice of law analysis from the Second Restatement of Conflict of Laws. *Townsend v. Sears, Roebuck and Co.*, 879 N.E.2d 893, 903 (Ill. 2007). "The cornerstone of the Second Restatement is the 'most significant relationship' test, the objective of which is 'to apply the law of the state that, with regard to the particular issue, has the most significant relationship with the parties and the dispute.' " *Burlington N. & Santa Fe Ry. Co.*, 906 N.E.2d 83, 91 (Ill. App. Ct. 2009).

In conducting its analysis, the Court begins with section 146 of the Second Restatement. *Townsend, 879 N.E.2d at 903.* Section 146 directs the Court to apply the law of the place of injury unless another state has a more significant relationship with the occurrence and with the parties with respect to the particular issue. *Id.* In assessing which state has a more significant relationship, the Court

considers the following factors: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145, at 414 (1971). The Court does not simply count the contacts. Instead, the Court must consider these factors in light of the general principles embodied in Section 6 of the Second Restatement to determine whether those principles tip the scales against the presumption that the law of the place of the injury controls. *See Townsend,* 903-907.

Having weighed the relevant factors, the Court concludes that California has the most significant relationship to this case, not New Jersey. The Court infers that the plaintiff's injury occurred in her state of residence, California. Therefore, the Court presumes that California law applies unless, as asserted by the plaintiff, New Jersey has a more significant relationship to the occurrence. The product was manufactured and designed in New Jersey thus it is the place where the conduct causing the injury occurred. As previously indicated, plaintiff is a resident and citizen of California. Bayer is incorporated in the state of Delaware and has its principal place of business in New Jersey. Finally, the relationship between the parties is centered in the state where Mirena was inserted, likely also in California. *See Nichols v. G.D. Searle and Co.*, 668 N.E.2d 1101, 1103 (Ill. App. Ct. 1996) (holding, in product liability action involving intrauterine contraceptive device, the relationship between parties was centered in the state where each plaintiff "was

prescribed and used" the device). Considering these contacts in light of the general principles embodied in the Restatement, the Court cannot conclude that New Jersey's relationship to the facts of this case is greater than that of the place of plaintiff's injury. Accordingly, the Court concludes that Louisiana law controls. *See Townsend,* 227 Ill.2d at 164-171 (applying Illinois choice of law principles to determine which states law controlled when injury and conduct causing injury occurred in different states); *Nichols,* 668 N.E.2d 1101 at 1103 (same); [1] Restatement (Second) of Conflict of Laws § 146, Comment e (entitled "When conduct and injury occur in different states" and adopted by the Illinois Supreme Court in *Townsend*).

B. Sufficiency of Plaintiff's Complaint

1. First Cause of Action ("Defective Manufacturing")

A plaintiff alleging a manufacturing-defect claim must explain how the product deviated from its intended design. *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978). To survive a challenge to a manufacturing defect claim under Rule 12(b)(6), a plaintiff must explain how the product deviated from defendant's intended result/design or how the product deviated from other seemingly identical product models. *Id*.

[1] In this product liability action involving an intrauterine contraception device, the Illinois Appellate Court applied Illinois choice of law rules to determine where the plaintiffs' cause of action arose. The controlling presumption applied by the Appellate Court was that the law of the place of injury controlled unless some other jurisdiction had a greater relationship to the facts of the case (the same presumption applicable in the instant case). Illinois was the forum state. In addition, the product was developed and manufactured in Illinois and the manufacturer had its principle place of business in Illinois. Each plaintiff was injured in his or her home state. The Court further concluded that the relationship between the parties was centered in each plaintiff's home state (where the device was prescribed and used). Under these circumstances, the Appellate Court Concluded that Illinois (the state where the conduct causing the injury occurred and the defendant had its principle place of business) did *not* have a greater relationship to the facts of the case than the place of injury for each plaintiff.

Plaintiff's manufacturing defect claim fails because plaintiff does not allege facts that identify or explain how Mirena either deviated from defendant's intended result or design or how Mirena deviated from other seemingly identical Mirena models.

Accordingly, the First Cause of Action ("Manufacturing Defect") is DISMISSED with leave to amend.

2. Third Cause of Action ("Negligence")

Plaintiff's third cause of action sounds in negligence. Under California law, to maintain a negligence action, plaintiff must allege that defendant owed a legal duty, breached that duty, and that the breach proximately caused injury to the plaintiff. *Garcia v. W & W Cmty. Dev., Inc.*, 186 Cal. App. 4th 1038, 1044 (Cal. App. 2010). Bayer argues plaintiff's negligence claim is insufficiently pleaded because plaintiff does not allege sufficient facts and relies on bare legal conclusions to assert her negligence claim.

The Court holds that plaintiff has sufficiently alleged facts supporting a negligence claim. Construing the complaint in a light most favorable to the non-moving party and assuming the truth of non-conclusory, material allegations of fact contained therein.

Bayer also argues that it cannot be held liable for a failure to test Mirena because California law does not recognize an independent cause of action for failure to test. Bayer is correct. *See Valentine v. Baxter Healthcare Corporation*, 68 Cal. App. 4th 1467, 1485–86 (Cal. App. Ct. 1999). However, plaintiff argues that she is

not asserting an independent cause of action for failure to test. Instead, she contends the failure to test component is a factual allegation supporting her claim that defendants were negligent. This brings plaintiff's duty to test allegation within the ambit of *Valentine*, which recognizes that testing and inspection duties may be tied to liability for manufacture, design, and failure to warn, even if they are not maintainable as an independent duty. *Valentine*, 68 Cal. App. 4th at 1485.

Accordingly, because plaintiff has sufficiently pleaded a negligence claim, Bayer's motion to dismiss the Third Cause of Action for Negligence is DENIED.

3. Fourth Cause of Action ("Failure to Warn")

Bayer contends the complaint fails to allege sufficient factual detail to state a plausible failure to warn claim. The California Supreme Court has held that manufacturers of prescription drugs can be held strictly liable for failure to warn of knowable risks. *Brown v. Superior Court*, 44 Cal.3d 1049, 1069 (Cal. 1988). Plaintiff has alleged, *inter alia*, that Bayer was the manufacturer of Mirena, that Bayer failed to provide adequate warnings to physicians, pharmacies and consumers (including the plaintiff and the plaintiff's physician), and that Bayer failed to give appropriate warnings regarding all of the risks associated with its use. More specifically, plaintiff has alleged that Mirena's labeling fails to adequately warn of the risk of migration of the product post-insertion, uterine perforation post-insertion or the possibility that the device complications such as migration and perforation may cause abscesses, infections, require surgery for removal

and/or may necessitate hysterectomy, oophorectomy and other complications. Plaintiff further alleges that she suffered severe pain and was diagnosed with ovarian cysts as a result of Bayer's failure to warn. The Court concludes that the allegations are sufficient to survive a motion to dismiss.

Accordingly, the motion to dismiss plaintiff's Fourth Cause of Action is DENIED.

4. Eighth and Ninth Causes of Action – Fraud Based Claims

Bayer contends plaintiff's fraud based claims are not pled with sufficient particularity under Rule 9(b). The Court disagrees. The Court specifically notes the following allegations: Plaintiff alleges that Mirena's label fails to warn about spontaneous migration of the device, defendants have a history of overstating the efficacy of Mirena while understating the potential safety concerns, defendants made fraudulent representations regarding Mirena in December 2009 in their "Mirena Simple Style Statements Program," and defendants made misrepresentations regarding Mirena's propensity to cause serious physical harm. The Court finds that these allegations are sufficient to survive Bayer's motion to dismiss.

Accordingly, the motion to dismiss as to Causes of Action Eight and Nine is DENIED.

5. Second ("Design Defect") and Fifth ("Strict Liability") Causes of Action

Bayer contends that California law does not recognize a cause of action for strict liability design-defect in the pharmaceutical context. As a result, Bayer argues, the plaintiff's Second and Fifth Causes of Action are not cognizable claims and must be dismissed.

In California, "[s]trict products liability has been imposed for defects arising from flaws in the manufacturing process (manufacturing defects), defects in the design rendering a product unsafe (design defects) and inadequate warnings or failure to warn (warning defects)." *Garrett v. Howmedica Osteonics Corporation* 214 Cal. App. 4th 173, 182 (Cal. App. 2013). However, the California Supreme Court has held that a manufacturer of prescription drugs cannot be *strictly liable* for a design defect. *Brown v. Superior Court* 44 Cal. 3d 1049, 1057 (Cal. 1988). In California, strict liability for design defect is established using the risk-benefit test or the consumer expectations test. *Garrett,* 214 Cal. App. 4th at 182. The California Supreme Court has held that the consumer expectation test and the risk-benefit test should not be applied in the context of prescription drugs. *Id.*

While prescription drug manufacturers may not be held strictly liable for design defects, they may be liable for design defect claims sounding in negligence. *Garrett*, 214 Cal. App. 4th 173, 182 (Cal. App. 2013) ("the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves

an application of the ordinary negligence standard"). Under the negligence standard adopted by the California Supreme Court (reflected in comment K to section 402A of the Restatement Second of Torts), a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed. *Brown,* 44 Cal. 3d at 1059.

In the instant case, the plaintiff's Second Cause of Action ("Design Defect") appears to sound in strict liability (Doc. 5 ¶¶ 51,52) (asserting that the product was defectively designed under the risk-benefit test and/or under the consumer expectation test). Accordingly, the plaintiff's Second Cause of Action is not cognizable under California law and must be dismissed. The plaintiff's Fifth Cause of Action ("Strict Liability") seeks to impose liability for defects arising from alleged design defects (Doc. 5 ¶¶ 77, 78) and alleged warning defects (Doc. 5 ¶¶ 79, 81). To the extent that plaintiff seeks recovery in strict liability for design defects, her Fifth Cause of Action is not cognizable under California law and must be dismissed.

For the reasons discussed above, the plaintiff's Second Cause of Action ("Design Defect"), which appears to be based in strict liability is DISMISSED, with leave to amend. The plaintiff may amend her complaint to assert a design defect claim sounding in negligence. To the extent that plaintiff's Fifth Cause of Action ("Strict Liability) seeks recovery for a design defect, the claim is DISMISSED. However, plaintiff may pursue her strict liability claim on the basis of alleged defects in Mirena's warning.

6. Sixth ("Implied Warranty") and Seventh ("Express Warranty") Causes of Action

Bayer contends that plaintiff fails to state plausible claims for breach of implied warranty (Sixth Cause of Action) and breach of express warranty (Seventh Cause of Action) because she does not plead privity of contract with Bayer.

As to implied warranty, Bayer is correct. Under California law, privity between the patient and the manufacturer of a pharmaceutical product is a necessary component of breach of implied warranty claims. *See Evraets v. Intermedics Intraocular, Inc.* 29 Cal. App. 4th 779 (Cal. App. Ct. 1994). Further, California courts have held that, in the context of prescription pharmaceuticals, the transaction is between the manufacturer and the physician, not the patient. Therefore, the plaintiff cannot maintain a claim for breach of implied warranty. *See Evraets v. Intermedics Intraocular, Inc*.29 Cal.App.4th 779, 34 Cal.Rptr.2d 852 (1994).

To plead a cause of action for breach of express warranty, one must allege the exact terms of the warranty, plaintiff's reasonable reliance thereon, and a breach which proximately caused plaintiff injury. *Williams v. Beechnut Nutrition Corp*., 185 Cal. App. 3d 135, 142, 229 Cal. Rptr. 605 (Cal. 1986). Generally, privity of contract is a required element of an express breach of warranty claim. *See Fieldstone Co. v. Briggs Plumbing Products, Inc.,* 54 Cal. App. 4th 357, n. 10 (Cal. Ct. App. 1997). *See also Blanco v. Baxter Healthcare Corp.,* 70 Cal. Rptr. 3d 566,

582 (Cal. Ct. App. 2008) (privity is requisite element in breach of either implied or express warranty claims). However, it appears privity is no longer an absolute requirement in express warranty cases. *See Fieldstone Co.,* 54 Cal. App. 4th 357 n.10. Under California law, "there is an exception where plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials." *Id.*[2] *See also Evraets v. Intermedics Intraocular, Inc.* 29 Cal. App. 4th 779, 789 (1994) (stating that California case law has generally abolished the requirement of privity for express warranty claims).[3] The Court also notes that California courts have recognized an exception to the privity requirement in cases involving both foodstuffs and drugs. *See Gottsdanker v. Cutter Laboratories,* 182 Cal. App. 2d 602, 606-607 (Cal. App. Ct. 1960)(discussing emergence of exception in food cases and extending to a vaccine).

Considering the above, the Court concludes there is sufficient authority to allow a breach of express warranty claim to proceed – even in the absence of privity. That said, the plaintiff's conclusory allegations do not sufficiently state a claim for express warranty under California law. Further, the Court notes that reliance appears to be a requisite element of a claim for express warranty (particularly

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[2] This Court has previously held, under circumstances similar to the instant case, that privity is not required for express warranty claims under California law. *In re Pradaxa (Dabigatran Etexilate) Products Liability Litigation* 2014 WL 114480, *6 (S.D. Ill. 2014) (Herndon, C.J.).

[3] The Court also notes there are at least two California Supreme Court decisions, both involving written warranties similar to advertisements and labels that were seen and relied on by plaintiffs, holding that privity was not a requisite element of plaintiff's express warranty claims. *See Seely v. White Motor Co.*, 63 Cal. 2d 9, 14 (Cal. 1965) ("Since there was an express **warranty** to plaintiff in the purchase order, no **privity** of contract was required"); *Hauter v. Zogarts,* 14 Cal. 3d 104, 115 n.8 (Cal. 1975) (although privity remains a requirement for implied warranty claims, it is not required for an action based upon an express warranty).

where privity is absent). The current complaint does not adequately allege reliance.

For the reasons discussed above, plaintiff's Sixth Cause of Action ("Implied Warranty") is DISMISSED WITH PREJUDICE. Plaintiff's Seventh Cause of Action ("Express Warranty") is DISMISSED with leave to amend.

IV. Conclusion

For the reasons stated herein, the Court **GRANTS IN PART AND DENIES IN PART** Bayer's motion to dismiss (Doc. 9).

IT IS SO ORDERED.

Signed this 26th day of September, 2014.

Chief Judge
United States District Court