UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

JEANNE SCIANNEAUX	CIVIL ACTION
VERSUS	NO: 13-684
ST. JUDE MEDICAL S.C., INC., AND ABC INSURANCE CO.	SECTION: R(5)

ORDER AND REASONS

Defendant, St. Jude Medical S.C., Inc. ("St. Jude"), filed a motion to dismiss plaintiff's complaint. Plaintiff Jeanne Scianneaux opposes the motion.[1] For the following reasons, the Court GRANTS defendant's motion.

I. BACKGROUND

Plaintiff alleges that she was injured by medical devices that were manufactured and sold by defendant St. Jude. Specifically, plaintiff alleges that she had a defibrillator implanted in her chest and the leads connecting the device to her heart failed. Because the leads failed, she says she needed another surgery, which caused a debilitating stroke. The defendant moves to dismiss and argues that plaintiff has failed to state a claim for relief under *Twombly*.

[1] R. Doc. 36.

A. Plaintiff's Specific Allegations

Plaintiff alleges that on or about May 27, 2010, a cardiologist surgically implanted in her chest a "Medtronic Defibrillator, which was manufactured and sold into the medical field by St. Jude."[2] She alleges that "[a]t that time Defendant had purposely withheld information that the leads were failing and defective from the nations [*sic*] physicians."[3] The complaint alleges that the Medtronic Defibrillator was recalled by the FDA because "the leads on the device could result in the device failing to deliver a shock or conversely shocking the patient unnecessarily."[4] Plaintiff also alleges that "St. Jude admitted to the FDA . . . that defects and flaws with the leads on the Medtronic Defibrillator, were more prevalent than had been previously revealed by St. Jude."[5] She alleges that "the FDA classified the leads recall as a Class I recall, the most serious type of recall and ordered St. Jude to conduct post market studies."[6] The complaint alleges that "St. Jude knew, before her implant on May 27, 2010, that the device and the leads were so

[2] R. Doc. 35 at 3.

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.* at 4.

defective, as to be life threatening."[7] Plaintiff alleges that St. Jude knew of the defects in 2009, before discontinuing the product in 2010, and "fraudulently failed to disclose the life threatening defects with intent to cover up, mislead[, and] continue to sell the defective device."[8] Plaintiff alleges that the leads failed and she underwent surgery "in order to survive."[9] She alleges that she needed a new defibrillator, and that the necessary surgical procedure caused her to suffer a stroke.[10]

In her Amended Complaint, plaintiff added allegations that St. Jude (1) failed to comply with FDA-approved specifications for the device; (2) failed to manufacture the device in compliance with FDA specifications; and (3) deviated from FDA requirements in connection with the sale of the device.[11]

Based on these events, the complaint avers that St. Jude is liable to plaintiff based on theories of negligence, breach of warranty, strict liability, and fraud. Plaintiff seeks compensatory and punitive damages. St. Jude moves to dismiss

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[7] *Id.*

[8] *Id.*

[9] *Id.* at 5.

[10] *Id.*

[11] *Id.* at 6-7.

plaintiff's claims pursuant to Federal Rule of Civil Procedure 12(b)(6).[12]

II. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)(quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the plaintiff pleads facts that allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* A court must accept all well-pleaded facts as true, viewing them in th elight most favorable to the plaintiff. *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 816 (5th Cir. 2012) (quoting *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007)). But a court is not bound to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678.

A legally sufficient complaint must establish more than a "sheer possibility" that the plaintiff's claim is true. *Id.* It need not contain detailed factual allegations, but it must go beyond labels, legal conclusions, or formulaic recitations of the elements of a cause of action. *Id.* (citing *Twombly,* 550 U.S. at 555). In other words, the face of the complaint must contain

[12] R. Doc. 9.

enough factual matter to raise a reasonable expectation that discovery will reveal evidence of each element of the plaintiff's claim. *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009). If there are insufficient factual allegations to raise a right to relief above the speculative level, *Twombly*, 550 U.S. at 555, or if it is apparent from the face of the complaint that there is an insuperable bar to relief, see *Jones v. Bock*, 549 U.S. 199, 215 (2007); *Carbe v. Lappin*, 492 F.3d 325, 328 & n.9 (5th Cir. 2007), the claim must be dismissed.

III. Discussion

The Louisiana Products Liability Act ("LPLA") provides the exclusive remedy against a manufacturer for damages caused by its product. La. Rev. Stat. Ann. § 9:2800.52. A plaintiff may not recover under any theory of liability that is not set forth in the LPLA. *Id.*; *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261-62 (5th Cir. 2002). The statute provides that a manufacturer "shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. Rev. Stat. Ann. § 9:2800.54(A).

A product is unreasonably dangerous for the purposes of the statute "if and only if" it is unreasonably dangerous: (1) in construction or composition, (2) in design, (3) because of

inadequate warning, or (4) because of nonconformity to an express warranty. *Id.* at § 2800.54(B)(1–4). Thus, the LPLA limits the plaintiff to four theories of recovery: manufacturing defect, design defect, inadequate labeling, and breach of express warranty.

"While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer." *Jefferson v. Lead Indus. Ass'n, Inc.*, 930 F. Supp. 241, 245 (E.D. La. 1996) *aff'd,* 106 F.3d 1245 (5th Cir. 1997) (citing *Automatique New Orleans, Inc. v. U–Select–It, Inc.,* 1995 WL 491151 at *3 n.2 (E.D. La. Aug. 15, 1995) (no independent negligence claim); *Hopkins v. NCR Corp.,* 1994 WL 757510 at *1–2 (M.D. La. Nov. 17, 1994) (strict liability under article 2317 not cognizable theory against manufacturer); J. Kennedy, *A Primer on the Louisiana Products Liability Act,* 49 La. L. Rev. 565, 589-90 (1989)). Similarly, breach of implied warranty is unavailable as a theory of recovery for personal injury. *Id.*

Plaintiff does not allege a violation of the LPLA. Instead, she seeks relief based on general theories of breach of express and implied warranties, strict liability, fraud, and

negligence.[13] Indeed, the only statutory provisions cited by the plaintiff in her Amended Complaint are Articles 2315 and 2316 of the Louisiana Civil Code,[14] which serve as the basis for a general negligence claim. As discussed above, however, such freestanding theories of recovery are unavailable when the cause of action sounds in product liability. As a result, plaintiff's claims fail as a matter of law to the extent that they seek relief outside the scope of the LPLA.

Insofar as the allegations that St. Jude breached a warranty and sold "a defective and dangerous product"[15] may be construed as setting forth a claim under the LPLA, plaintiff's conclusory allegations that St. Jude violated FDA regulations are insufficient to establish a parallel cause of action and are thus preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act (the "FFDCA"). Even if the complaint did allege a violation of FDA regulations with sufficient particularity to avoid preemption, plaintiff fails under *Twombly* to establish a plausible LPLA claim.

A. Preemption

[13] R. Doc. 35 at 5-7.

[14] *Id.* at 7.

[15] R. Doc. 35 at 6.

St. Jude concedes that it manufactured Riata leads, which are used in implantable defibrillators.[16] The Riata lead is a Class III device under the FFDCA and is subject to the FDA's pre-market approval process. The Court has taken judicial notice of the FDA's website, which indicates that the Riata lead underwent the FDA's pre-market approval process under the FFDCA.[17] The MDA expressly preempts state law claims against manufacturers when the effect is to establish “safety or effectiveness” standards that are “different from, or in addition to” the requirements for pre-market approved products under the FFDCA. 21 U.S.C. § 360k. However, “parallel” state actions — state law claims that are premised on violations of FDA regulations — are permitted. *Id.*; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

Plaintiff therefore may bring suit under the LPLA only if she can show that it was a violation of FDA regulations that rendered the Riata leads "unreasonably dangerous." *See Riegel*, 552 U.S. at 330. Moreover, the allegations that St. Jude violated FDA regulations must satisfy the pleading requirements of *Twombly*. *See Bass v. Stryker Corp.*, 669 F.3d 501, 509-10 (5th Cir. 2012) (affirming the conclusion that "to plead a parallel claim successfully, a plaintiff's allegations that the

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[16] *Id.* at 6-7.

[17] FDA database of premarket approvals, accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

manufacturer violated FDA regulations must meet the *Twombly* plausibility standard," and applying that standard to plaintiff's claim). Though a formal finding of a violation by the FDA is not required, *id.* at 509 (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d. 762, 772 (5th Cir. 2011)), the plaintiff must at least "specif[y] with particularity what went wrong in the manufacturing process and cite[] the relevant FDA manufacturing standards [the defendant] allegedly violated." *Id.* at 510 (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)).

Here, plaintiff has alleged only that St. Jude "deviated from FDA requirements" and "failed to comply with the FDA approved specifications for the device."[18] She does not identify which FDA regulations were violated or explain how the design, manufacture, or sale of the device deviated from FDA requirements. *Cf. id.* (holding that the plaintiff had adequately pleaded his parallel claims by identifying the regulations that were allegedly violated, providing a letter in which the FDA had warned the defendant of violations of particular regulations, showing that the defendant had issued a voluntary recall of the allegedly defective product, and pleading a causal connection between the violations and the harm suffered). The plaintiff has alleged that the leads were the subject of a Class I recall by

[18] R. Doc. 35 at 5-6.

the FD, and that the recall was the result of St. Jude's failure to comply with FDA regulations. As St. Jude points out in its reply brief,[19] however, evidence of a recall alone does not show that the defendant failed to obtain pre-market approval or that it violated any FDA regulations. A bare assertion of the existence of a recall does no more to identify the regulations allegedly violated than do the conclusory allegations that St. Jude "deviated from" or "failed to comply with" FDA regulations. Such "formulaic recitations of the elements of a cause of action," *Twombly*, 550 U.S. at 555, are insufficient to transform plaintiff's otherwise preempted claim into a parallel cause of action.

B. Failure to Plead the Elements of an LPLA Claim

Even if the complaint did allege a violation of FDA regulations with sufficient particularity to avoid preemption, plaintiff fails under *Twombly* to establish a plausible LPLA claim. As discussed above, in addition to pleading a violation of FDA regulations, a plaintiff must plead facts in support of each element of a claim under the LPLA, including "(1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that the characteristic made the product unreasonably dangerous in one of the four ways provided in the

[19] R. Doc. 42 at 6.

statute; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Jefferson*, 930 F. Supp. at 245 (citing La. Rev. Stat. Ann. § 9:2800.54).

The complaint is light on factual allegations and heavy on conclusory statements. Although the complaint alleges that "the leads failed," it does not provide factual allegations regarding the type of lead at issue, or that St. Jude manufactured them. Further, plaintiff does not identify how the leads failed or how her injury was caused by defective leads. She also asserts a claim under warranty and implied warranty, but fails to identify what warranty was breached and how. Plaintiff's complaint contains insufficient factual allegations to raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 555.

In *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011), the plaintiff alleged that an artificial hip implant contained defects "in violation of the manufacturing processes and design approved by the FDA." *Id.* at 782. The plaintiff invoked the doctrine of *res ipsa loquitur* to conclude that his injuries were caused by the manufacturing defect contained in the hip prosthesis. *Id.* The court found the complaint "impermissibly conclusory and vague." *Id.* The complaint did "not specify the manufacturing defect; nor [did] it specify a causal connection between the failure of the specific manufacturing process and the

specific defect in the process that caused the personal injury." *Id.* The court also noted the complaint's failure to "tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." *Id.* The court concluded that the plaintiff could not rely on *res ipsa loquitur* to make out his claim. *Id.* (citing *Iqbal*, 556 U.S. at 678).

As in *Funk*, plaintiff's complaint lacks the necessary factual allegations to make out a claim against defendant. Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed -me accusation." *Gulf Coast Hotel-Motel Ass'n v. Miss. Gulf Coast Golf Course Ass'n*, 658 F.3d 500, 504 (5th Cir. 2011) (citing *Iqbal*, 556 U.S. at 678). Because plaintiff has already been given one opportunity to amend and continues to provide nothing more than conclusory allegations, the complaint must be dismissed with prejudice.

III. Conclusion

For the foregoing reasons, the defendant's motion to dismiss is GRANTED.

New Orleans, Louisiana, this 19th **day of August, 2013.**

Sarah Vance

SARAH S. VANCE
UNITED STATES DISTRICT JUDGE