UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

REGINA BARNES, AS NEXT FRIEND OF TIANA GIBSON, AN INCAPACITATED ADULT, Plaintiff, v. MEDTRONIC, INC., et al., Defendants.	CIVIL ACTION NO. 1:20-CV-04310-JPB

ORDER

This matter is before the Court on Medtronic, Inc., Medtronic USA, Inc., Medtronic Logistics, LLC, and Medtronic Puerto Rico Operations, Co.'s (collectively, "Defendants") Motion to Dismiss Plaintiff's Amended Complaint [Doc. 17]. This Court finds as follows:

BACKGROUND AND FACTUAL ALLEGATIONS

This is a products liability action involving a SynchroMed II Programmable Implantable Infusion Pump System ("SynchroMed Device"), a Class III medical device manufactured by Defendants. [Doc. 14, pp.1-2]. Like its name suggests, the SynchroMed Device is a programmable drug infusion system that is implanted in the body to deliver medication into the intrathecal space (spinal canal) of the

patient. Id. at 4-5. In 1988, the Food and Drug Administration ("FDA") approved the SynchroMed Device through the Premarket Approval ("PMA") process. Id. at 5.

Tiana Gibson ("Plaintiff")[1] was in a car accident in 2011 and as a result, suffers from spasticity of the bilateral upper extremities, lower extremity weakness and seizure disorder. Id. To reduce both the muscle spasticity associated with her condition and her need to take oral medications, Plaintiff elected to have a SynchroMed Device implanted to deliver baclofen, a muscle relaxer, into the intrathecal space of her spine. Id. at 7. Plaintiff has had at least three SynchroMed Devices implanted since 2011.[2] Plaintiff's third SynchroMed Device is the only product at issue in this suit. Id.

On January 16, 2018, Plaintiff underwent surgery and had her third SynchroMed Device implanted. Id. For several months thereafter, Plaintiff experienced vomiting in between her doctor's visits. Id. At the end of October 2018, Plaintiff suffered six seizures in a handful of days. Id. Then, from October 2018 to December 2018, Plaintiff's muscle spasticity significantly worsened, and

[1] Because Plaintiff is incapacitated, Regina Barnes brought this action on Plaintiff's behalf.

[2] The first device was implanted in 2011 and removed in 2017. [Doc. 14, p. 7]. In 2017, the second device was implanted. Id. That device, however, eroded through Plaintiff's skin and needed to be replaced, resulting in the implantation of a third device. Id.

Plaintiff experienced dramatic changes in mood. Id. at 8. Based on these symptoms, in December 2018, Plaintiff's physicians determined that the SynchroMed Device had malfunctioned and failed. Id. The device was thereafter removed and replaced on January 2, 2019. Id.

Contending that the device was defective and that she was injured as a result, Plaintiff filed this action against Defendants on October 20, 2020. [Doc. 1]. On February 5, 2021, Plaintiff filed her Amended Complaint asserting the following causes of action: (1) Strict Liability Manufacturing Defect; (2) Negligent Manufacturing Defect; (3) Breach of Implied Warranty of Merchantability; (4) Negligence Per Se; (5) Breach of Express Warranty; (6) Punitive Damages; and (7) Attorney's Fees and Expenses of Litigation. [Doc. 14]. Shortly thereafter, on February 19, 2021, Defendants filed the instant Motion to Dismiss Plaintiff's Amended Complaint. [Doc. 17]. The motion is now ripe for review.

LEGAL STANDARD

In evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court "accept[s] the allegations in the complaint as true and construe[es] them in the light most favorable to the plaintiff." Traylor v. P'ship Title Co., LLC, 491 F. App'x 988, 989 (11th Cir. 2012). Federal Rule of Civil

Procedure 8(a)(2) provides that a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Although detailed factual allegations are not necessarily required, the pleading must contain more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Importantly, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (citation omitted). At bottom, the complaint must contain more than "an unadorned, the-defendant-unlawfully-harmed-me accusation" (id.) and must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Traylor, 491 F. App'x at 990 (quoting Iqbal, 556 U.S. at 678).

ANALYSIS

In their Motion to Dismiss, Defendants assert that Plaintiff's claims are preempted by federal law. Defendants also assert that Plaintiff's claims are inadequately pled. Because preemption is a principle derived from the Supremacy Clause of the United States Constitution, this Court "must first analyze whether each claim can stand under state law, and only then decide the preemption questions where necessary." Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1328 (11th Cir. 2017).

1. Plaintiff's Claims

As explained in the rule immediately above, before this Court can analyze whether Plaintiff's claims are preempted, the Court must first determine whether Plaintiff's claims are properly pled. Each claim will be addressed in turn.

a. Strict Liability Manufacturing Defect

In Count 1, Plaintiff asserts a claim for strict liability manufacturing defect. Georgia statutes provide for strict liability for defective products. Specifically, O.C.G.A. § 51-1-11(b)(1) states that a manufacturer of personal property sold as new is liable in tort to "any natural person who may use, consume, or reasonably be affected by the property" and who suffers an injury to her person or property "because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained." Thus, to state a claim for strict liability manufacturing defect, the plaintiff must allege that "(1) the defendant was the manufacturer of the product; (2) the product, when sold, was not merchantable and reasonably suited to the use intended, and (3) the product's defective condition proximately caused plaintiff's injury." Sharp v. St. Jude Med., S.C., Inc., 838 F. App'x 462, 466 (11th Cir. 2020) (quoting Brazil v. Janssen Rsch. & Dev. LLC, 196 F. Supp. 3d 1351, 1357 (N.D. Ga. 2016)). A plaintiff can show that a product

was "not merchantable" through any of three variations of product defects: manufacturing defects, design defects or marketing/packaging defects. Id.

As already stated, Plaintiff asserts a manufacturing defect. Where a manufacturing defect is asserted, a plaintiff must "allege the existence of a specific manufacturing defect that proximately caused the harm." Id. (quoting Brazil, 196 F. Supp. 3d. at 1358). Manufacturing defects will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specification established for the creation of the product. At bottom, a plaintiff only needs to allege a deviation that was the proximate cause of an injury. Id.

In the present case, Plaintiff sufficiently states a claim for strict liability manufacturing defect. Plaintiff's Amended Complaint alleges that: (1) her SynchroMed Device, which was manufactured by Defendants, was not reasonably suited for its intended use due to manufacturing defects; and (2) those defects were the proximate cause of her injury. Specifically, Plaintiff alleges that defects in the manufacture of the SynchroMed Device caused a motor stall, resulting in baclofen withdrawal symptoms and necessitating an invasive removal surgery. In her allegations, Plaintiff asserts that Defendant violated numerous federal statutes and regulations that are designed to prevent the manufacture and distribution of adulterated products, including: 21 C.F.R. §§ 820.30(c), 820.30(g), 820.70(a),

820.75(a), 820.100(a), 820.100(a)(2), 820.100(a)(3) 820.100(a)(5), 820.824, 820.198(a), 820.198(a)(3) and 820.198(c). Moreover, Plaintiff identifies an August 9, 2017 recall which was initiated to address motor stall issues. These are sufficient facts to allow this Court to reasonably infer that Defendants' violations of federal regulations caused Plaintiff's device to fail. Ultimately, this Court finds that the allegations provide sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. Therefore, under Georgia law, Plaintiff has properly pled this claim. See Cooksey v. Medtronic, Inc., No. 1:20-CV-00805, 2020 WL 10090793, at *3 (N.D. Ga. Dec. 16, 2020) (determining that similar allegations involving the same device stated a claim for strict liability manufacturing defect); Green v. Medtronic, Inc., No. 1:19-CV-3242, 2020 WL 4577713, at *3 (N.D. Ga. May 1, 2020) (same).

b. Negligent Manufacturing Defect

In Count II, Plaintiff asserts a claim for negligent manufacturing defect. This claim is recognized under Georgia law. Sharp, 838 F. App'x at 466. A plaintiff must allege the following to state a claim for negligent manufacturing: "(1) a legal duty to conform to a standard of conduct for the protection of others against an unreasonable risk of harm; (2) breach of that standard; (3) causation; and (4) some loss or damage as a result of the alleged breach of the legal duty." Id.

Ultimately, to avoid liability for negligent manufacturing, a manufacturer must exercise reasonable care in manufacturing its products so that the products are reasonably safe for intended or foreseeable uses. Id.

After reviewing Plaintiff's Amended Complaint, this Court finds that Plaintiff's allegations are sufficient to establish a negligent manufacturing claim. Specifically, Plaintiff asserts that Defendants had a duty to individuals, including Plaintiff, to use reasonable care in manufacturing the SynchroMed Device and Defendants breached that duty when they failed to comply with federal regulations. Like Plaintiff's strict liability manufacturing defect claim, Plaintiff alleges that the breach of the duty led to the injury. Because Plaintiff's factual allegations in this claim nearly mirror those present in the strict liability claim, and Plaintiff sufficiently alleges Defendants breached their duty, Plaintiff presents a negligent manufacturing defect claim under Georgia law. See Cooksey, 2020 WL 10090793, at *4; Green, 2020 WL 4577713, at *3.

c. Breach of Implied Warranty of Merchantability

In Georgia, a warranty of merchantability is implied in any sale of goods or contract for the sale of goods. O.C.G.A. § 11-2-314. To plead a claim for breach of the implied warranty, a plaintiff must show four elements: "(1) that the goods were subject to the warranty; (2) that the goods were defective; (3) that the injury

was caused by the defective goods; and (4) that damages were incurred as a result." Whitaker v. Excel Indus., 512 F. Supp. 3d 1375, 1381 (S.D. Ga. 2021) (quoting Mitchell v. BBB Servs. Co., 582 S.E.2d 470, 471-72 (Ga. Ct. App. 2003)). In addition to these elements, a plaintiff must also show contractual privity with the manufacturer. See Gill v. Blue Bird Body Co., 147 F. App'x 807, 809-10 (11th Cir. 2005) (recognizing that Georgia courts have "repeatedly held" that where a plaintiff lacks contractual privity with a manufacturer, she cannot bring an implied warranty claim against the manufacturer).

In this case, Plaintiff alleges that Defendants breached their implied warranty of merchantability under Georgia law by committing the same regulatory violations that underlie her manufacturing defect claims. Plaintiff also alleges the existence of a warranty. Normally, no implied warranty of merchantability exists between a manufacturer and a remote consumer because no privity of contract exists between them. However, privity of contract can exist between a buyer and a manufacturer if the manufacturer extends an express warranty to the buyer. See Cooksey v. Medtronic, Inc., 1:20-CV-00805, 2021 WL 2481894, at * 4 (N.D. Ga. June 1, 2021). In this case, Plaintiff alleges that Defendants extended an express warranty to her, thereby establishing the necessary privity for Plaintiff to bring a

breach of implied warranty of merchantability claim. As such, this Court finds that Plaintiff has sufficiently stated a claim.

d. Negligence Per Se

In Count 4 of the Amended Complaint, Plaintiff asserts a claim for negligence per se. Under Georgia law, negligence per se can arise when a defendant violates a statute or ordinance. Hubbard v. Dep't of Transp., 568 S.E.2d 559, 566-67 (Ga. Ct. App. 2002). To assert a claim for negligence per se, the plaintiff must point to a statute, ordinance or regulation that imposes a legal duty. Comerinsky v. Augusta Coating & Mfg. LLC, 418 F. Supp. 3d 1252, 1264 (S.D. Ga. 2019). Moreover, the plaintiff must fall into the class of persons the statute was intended to protect and suffer the harm the statute was intended to guard against. Id.

Plaintiff bases her negligence per se claim upon Defendants' alleged violations of the Georgia Food, Drug, and Cosmetics Act, a penal statute that does not provide a civil remedy. "As a general rule, claims for negligence per se under Georgia law fail 'if the statute or regulation establishing the claimed legal duty does not provide a cause of action for damages for its violation.'" Green, 2020 WL 4577713, at *4 (quoting Scoggins v. Floyd v. Healthcare Mgmt. Inc., No. 4:14-CV-00274, 2016 WL 11544774, at *41 (N.D. Ga. June 10, 2016)). Because

Plaintiff only points to violations of statutes that are penal in nature, Plaintiff has failed to state a claim for negligence per se. See id.

e. Breach of Express Warranty

Moving to Count 5, Plaintiff asserts a claim for breach of express warranty. Under Georgia's version of the Uniform Commercial Code, an express warranty is:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

O.C.G.A. § 11-2-313. Importantly, Georgia law imposes two conditions before a breach of express warranty can exist: (1) notice of the defect; and (2) a reasonable opportunity to repair the defect. Knight v. Am. Suzuki Motor Corp., 612 S.E.2d 546, 549 (Ga. Ct. App. 2005).

In her allegations, Plaintiff contends that Defendants provided a limited written warranty. That limited warranty states that if the SynchroMed Device "fail[s] to function within normal tolerances due to a defect in materials or workmanship within . . . two (2) years commencing with the date of implantation,"

or if Plaintiff's SynchroMed catheter or accessories "fail to function within normal tolerances due to a defect in materials or workmanship within . . . one (1) year commencing with the date of implantation," then "Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Component equal to the Purchase Price, . . . or (b) provide a functionally comparable replacement Component at no charge." [Doc. 14, p. 52]. The limited warranty expressly states that "MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE COMPONENTS TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT OR OTHERWISE." [Doc. 14-17]. Plaintiff argues that Defendants breached the warranty when the SynchroMed Device failed fewer than one year after it was implanted, and Defendant has neither refunded nor replaced the SynchroMed Device free of charge.

In this case, Plaintiff has not sufficiently alleged that she complied with Georgia law before asserting her express warranty claim. Specifically, Plaintiff's allegations do not show that she gave Defendants notice of the defect or a reasonable opportunity to repair the defect. In fact, Plaintiff presents no

allegations that she ever communicated with Defendant prior to the initiation of the lawsuit. She also has not argued that these requirements should be excused in any way. Under the facts as alleged, Plaintiff has not stated a claim for breach of express warranty. See Cooksey, 2020 WL 10090793, at *6 (dismissing the breach of express warranty claim because plaintiff failed to comply with the conditions precedent identified under Georgia law).

2. Federal Preemption

This Court will begin its discussion of federal preemption law by providing a brief overview of the law governing medical devices. The Medical Device Amendments of 1976 ("MDA") gave the FDA regulatory authority over medical devices. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1325 (11th Cir. 2017). Class III devices, like the SynchroMed Device, which are deemed the highest risk, are required to go through an extensive premarket approval process. Id. The premarket approval process is rigorous and once a device has been approved, a manufacturer may not make any change to the device that could affect its safety or effectiveness unless that change gets additional approval from the FDA. Id.

The MDA contains two provisions that are relevant here: the express preemption provision and the implied preemption provision. The express preemption provision bars any claim based on a state law requirement, "which is

different from, or in addition to, any requirement" under the MDA that "relates to the safety or effectiveness of the device" or any other MDA requirement. 21 U.S.C. § 360(k)(1). The implied preemption provision states that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Implied preemption "prohibits state-law claims that seek to privately enforce duties owed to the FDA." Mink, 860 F.3d at 1327.

"Taken together, these two types of preemption leave a 'narrow gap' through which plaintiffs making medical device claims must proceed." Godelia v. Doe 1, 881 F.3d 1309, 1317 (11th Cir. 2018). "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." Mink, 860 F.3d at 1327. Stated another way, a plaintiff can proceed so long as she claims the "breach of a well-recognized duty owed to her under state law" and so "long as she can show that she was harmed by a violation of applicable federal law." Id. (quoting Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010)).

In analyzing whether Plaintiff's surviving claims (strict liability manufacturing defect, negligent manufacturing defect and breach of implied

warranty of merchantability) are preempted, it is important to recognize that the Supreme Court of the United States has made clear that the preemption provisions were not intended to "have the perverse effect of granting complete immunity from [tort] liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use." Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996) (quotation omitted).

The manufacturing defect claims (including both strict liability and negligence) will be analyzed together because the preemption analysis for both is nearly identical. See Mink, 860 F.3d at 1331 ("Our analysis on this [strict liability manufacturing defect claim is nearly the same as the . . . negligence claims premised on this same theory."). In these claims, Plaintiff contends that the manufacturing defect was the direct result of Defendants' failure to comply with federal regulations. In her pleadings, Plaintiff identifies multiple violations of federal statutes and Current Good Manufacturing Practices ("CGMP") intended to prevent the manufacture and distribution of adulterated products. She also cites numerous FDA inspections that showed violations of federal law. Plaintiff contends that these violations resulted in defects, specifically motor stall, that caused her injury.

Defendants argue that Plaintiff's allegations do not show a causal nexus between the violations of federal laws and the defect that caused the injury. This Court recognizes that Plaintiff "cannot simply incant the magic words" that Defendant violated federal regulations and survive dismissal. Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011). But here, Plaintiff has done more than incant magic words. As stated immediately above, she identifies multiple inspections revealing violations of federal regulations, identifies the particular regulations violated and references warning letters and recalls. Ultimately, this Court finds that Plaintiff has met her burden to plead specific violations of federal regulations. See Godelia, 881 F.3d at 1319 (recognizing that without discovery, the plaintiff would not likely have an opportunity to access documents describing all the regulatory requirements). Although Defendants argue that Plaintiff's allegations fail to show a causal link, Plaintiff's allegations are adequate and "[n]o more is required at the motion to dismiss stage." Green, 2020 WL 4577713, at *3 (declining to accept the defendants' invitation to apply a heightened pleading standard).

In sum, the Court finds that Plaintiff's manufacturing defect claims are violations of state common law and a parallel federal requirement. Plaintiff's claims are premised on the duty to use due care in manufacturing devices and this

duty runs parallel to the federal requirements that the devices be manufactured according to approved specifications. Cooksey, 2020 WL 10090793, at *9. Thus, these claims are not expressly preempted.

The claims are also sufficient to avoid implied preemption. Here, Plaintiff's claims do not require this Court to find Defendants liable based solely on a failure to report to the FDA. Instead, Plaintiff asserts claims based on a manufacturing defect and the duty enforced is the traditional state tort duty of a manufacturer to use due care. See Mink, 860 F.3d at 1331. Because the claims are not based on "fraud-on-the-FDA," they are not impliedly preempted.

As to the breach of implied warranty of merchantability claim, it is also not expressly or impliedly preempted. "[A]n implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty." Green, 2020 WL 4577713, at *5 (quoting Bass v. Stryker Corp., 669 F.3d 501, 517 (5th Cir. 2012)). Plaintiff alleges in her Amended Complaint that Defendants breached their implied warranty of merchantability under Georgia law by committing the same federal violations and CGMP violations that underlie Plaintiff's products liability claims. For the same reasons that those claims are not

preempted, the breach of implied warranty of merchantability claim is likewise not preempted.

In sum, this Court finds that Plaintiff's allegations sufficiently state a claim for strict liability manufacturing defect, negligent manufacturing defect and breach of implied warranty of merchantability. This Court also finds that the claims are sufficiently pled to avoid express and implied preemption. The remaining claims are subject to dismissal.

CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss Plaintiff's Amended Complaint [Doc. 17] is **GRANTED IN PART AND DENIED IN PART**. The parties are **DIRECTED** to submit their Joint Preliminary Report and Discovery Plan no later than fourteen days from the date of this Order.

SO ORDERED this 24th day of August, 2021.

J. P. BOULEE
United States District Judge