UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

NOEL D. ROMER and HOLLY ROMER,

Plaintiffs,

v.

Case No. 2:18-cv-19-FtM-99MRM

CORIN GROUP, PLC, and CORIN USA LIMITED,

Defendants.
_____/

OPINION AND ORDER

This matter comes before the Court on Defendants' Motion to Dismiss Plaintiff's First Amended Complaint (Doc. #44) filed on May 18, 2018. Plaintiffs filed a Response in Opposition (Doc. #49) on June 11, 2018, and defendants replied (Doc. #57). For the reasons set forth below, the Motion is granted with leave to amend.

I.

This is a products liability case in which plaintiffs allege that an artificial hip replacement designed, manufactured, and marketed by defendants was defective, causing metallic contaminants to release into the Noel Romer's body. On July 9, 2009, Mr. Romer underwent surgery to implant the Cormet® Advanced Hip Resurfacing System (the "Cormet® System") in his left hip. (Doc. #38, ¶ 34). After surgery, Mr. Romer experienced significant

pain during recovery and in the months that followed, as well as loosening of the hip. He also experienced high metal levels in his blood. (Id., ¶ 36-37). Due to these problems, Mr. Romer required another surgery on August 26, 2017. (Id., ¶ 38).

The Cormet® System is a Class III medical device that receives the highest level of federal oversight under the current premarket approval (PMA) process allowed under the Medical Device Amendments of 1976 (MDA) (Doc. #38, ¶ 14). As a Class III medical device, the Cormet® System requires premarket approval from the Food and Drug Administration (FDA) before it can be made commercially available. The FDA gave this approval for the Cormet® System on July 3, 2007, but set conditions, namely that the manufacture of each Cormet® System must adhere to "Approved Design Standards" in order to ensure the device is able to withstand the stresses of ordinary use without releasing levels of metal into the body.

On December 6, 2017, plaintiffs initiated this action in state court, seeking to recover damages from defendants based on five theories of products liability under Florida law and plaintiff Holly Romer also asserted a claim for loss of consortium (Doc. #2).

After removal, the Corin defendants (hereafter "defendants") moved to dismiss, arguing that the claims were not sufficiently pled and that the FDA device regulations preempt plaintiffs' state law claims, relying on Riegel v. Medtronic, Inc., 552 U.S. 312

(2008). Under Riegel, the MDA preempts state law requirements that are "in addition to, or different from" federal requirements for Class III medical devices that undergo the PMA process. Thus, defendants argued that all of plaintiffs' claims must be dismissed because they are expressly preempted by the MDA pursuant to Riegel, and plaintiffs failed to properly allege any parallel state law claims.

On March 27, 2018, this Court granted in part Corin's motion to dismiss with leave to amend, finding that plaintiffs' negligence per se, strict liability, and negligence claims were sufficiently pled, but allowed plaintiffs to amend the strict liability and negligence claims regarding preemption. (Doc. #24.)

Plaintiffs filed an Amended Complaint (Doc. #38) on April 20, 2018. Defendants again move to dismiss Counts I and II (negligence per se), and Counts III (strict liability) and Count V (negligence) to the extent these claims are based on theories of design defect, failure to warn, and failure to report adverse events to the FDA. Defendants argue both failure to state a claim and express/implied preemption. (Doc. #44.)

II.

Under Federal Rule of Civil Procedure 8(a)(2), a Complaint must contain a "short and plain statement of the claims showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This obligation "requires more than labels and conclusions, and a

formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citation omitted). To survive dismissal, the factual allegations must be "plausible" and "must be enough to raise a right to relief above the speculative level." Id. at 555. See also Edwards v. Prime, Inc., 602 F.3d 1276, 1291 (11th Cir. 2010). This requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citations omitted).

In deciding a Rule 12(b)(6) motion to dismiss, the Court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff, Erickson v. Pardus, 551 U.S. 89 (2007), but "[l]egal conclusions without adequate factual support are entitled to no assumption of truth." Mamani v. Berzain, 654 F.3d 1148, 1153 (11th Cir. 2011) (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. "Factual allegations that are merely consistent with a defendant's liability fall short of being facially plausible." Chaparro v. Carnival Corp., 693 F.3d 1333, 1337 (11th Cir. 2012) (internal citations omitted). Thus, the Court engages in a two-step approach: "When there are well-pleaded factual allegations, a court should assume their veracity and then

determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

III. Federal Preemption Law

As discussed in this Court's previous Opinion and Order, the Eleventh Circuit has recently provided guidance on Federal Preemption Law in the context of the MDA. See Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017). (discussing metal-on-metal hip replacements such as the one at issue here); Godelia v. Zoll Services, Inc., 881 F.3d 1309 (11th Cir. 2018). The MDA established the federal regulatory regime for medical devices. 21 U.S.C. § 360c et seq. "Any company wanting to sell a metal-on-metal hip replacement system is required to undergo the FDA's 'premarket approval process.'" Mink, 860 F.3d at 1325 (citing 21 C.F.R. § 814.1). This is a rigorous process that evaluates a medical device's safety and effectiveness. Id.

A. Express Preemption

The MDA provides for two types of preemption for certain state law claims relating to medical devices: express and implied. Defendants argue both apply here.

The MDA includes an express preemption provision (§ 360k) for Class III medical devices, which protect manufacturers from civil liability to the extent that they comply with federal law. Section 360k states: "no State...may establish...any requirement which is (1) different from, or in addition to, any requirement applicable

under this chapter to the device, and (2) which relates to the safety and effectiveness of the device..." 21 U.S.C. § 360k(a). In Riegel, the Supreme Court held that the MDA preempted state law products liability restrictions, including common law requirements, which were used in addition to or different from federal regulations used to evaluate Class III medical devices that underwent the PMA process. 552 U.S. 312.

After Riegel, a plaintiff injured due to use of a Class III device approved through a PMA can escape preemption only if he asserts a "parallel" state law claim. Mink, 860 F.3d at 1326. In Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300-01 (11th Cir. 2011), the Eleventh Circuit found that plaintiffs cannot effectively state a "parallel claim" absent allegations that the defendant violated a "particular federal specification." Id. (noting that recitation of "magic words" is insufficient and parallel claims must be "specifically stated in the initial pleadings"). Thus, the Wolicki-Gables panel concluded that the claims asserted by plaintiff were expressly preempted because nothing "specifically stated in the initial pleadings" what parallel federal requirements had been violated in addition to common law requirements. Id. at 1301. Therefore, a plaintiff has to sue for conduct that violates a federal requirement in order to avoid express preemption.

Additionally, the parallel claim must arise from an actual state-law requirement and cannot exist "solely by virtue of the FDCA ... requirements." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001). This is so because, in addition to express preemption articulated under § 360k(a), the FDCA includes an implicit preemption provision requiring that any action "for the enforcement, or to restrain violations" of the FDCA be brought "by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the [FDA] to take action," there is no private right of action under the FDCA. Buckman, 531 U.S. at 349.

B. Implied Preemption

The implied preemption provision of the MDA 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). The Supreme Court has interpreted this implied preemption provision to bar claims that merely attempt to enforce duties owed to the FDA, so-called "fraud-on-the-FDA claims." Buckman, 531 U.S. at 348.

Taken together, "these two types of preemption leave a 'narrow gap' through which plaintiffs making medical device claims must proceed." Godelia, 881 F.3d at 1317.

> 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). Put differently, a plaintiff may proceed on her claim 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. (internal citations omitted).

IV.

As set forth in Mink and Godelia, because preemption is derived from the Supremacy Clause, a court must first evaluate whether each claim is viable under state law, and only then will the court consider whether it is expressly preempted. See Mink, 860 F.3d at 1327-28; Godelia, 881 F.3d at 1317 (citing U.S. Const. Art. VI. cl. 2).

A. Negligence Per Se (Counts I, II)

Mr. Romer bases his negligence per se claims on two possible theories of liability: manufacturing defect and improper quality control. Plaintiff seeks to recover under a negligence per se theory, asserting that defendants should be presumed negligent because they purportedly failed to comply with the "Approved Design Standards for the Cormet System," which are the manufacturing standards imposed by the FDA as conditions of approval of the system. (Doc. #38.) Plaintiff also states: "the device Mr. Romer received violates the conditions of the FDA's approval and the general regulations applicable to Class III medical devices. Specifically, Mr. Romer's Cormet System suffers from one or more

of the following manufacturing defects: . . ." (Id., ¶ 45.) Plaintiffs then goes on to list seven manufacturing defects. (Id., ¶¶ 45(a)-(g).) Plaintiffs allege under Count II that defendants' hip simulator tests were unrealistic and thus failed to identify a Cormet® that complied with the Approved Design Standards, thus violating 21 C.F.R. §§ 820.30, 820.90. (Id., ¶¶ 59-60.)

Defendants argue that the negligence per se claims fail as a matter of law because Florida law does not recognize a claim for negligence per se based on an alleged violation of the Food, Drug and Cosmetic Act ("FDCA"), or the FDA's implementing regulations.[1]

Under Florida law, the violation of a federal regulation does not create civil liability based upon a theory of negligence per se in the absence of evidence "of a legislative intent to create a private cause of action." Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999). Where a statute or regulation does not expressly provide for a civil cause of action, the Court must look to the legislative intent of the statute to determine whether the legislative body enacting the law "intended to create the private remedy asserted." Murthy v. N. Sinha Corp., 644 So. 2d 983, 985 (Fla. 1994). "In general, a statute that does not purport to establish civil liability but

[1] The Court's previous Opinion and Order did not reach the question presented by the Amended Complaint – whether Florida law prohibits negligence per se claims where the alleged statutory violation is of the FDCA.

merely makes provision to secure the safety or welfare of the public ... will not be construed as establishing a civil liability." Moyant v. Beattie, 561 So. 2d 1319, 1320 (Fla. 4th DCA 1990).

The stated purpose of the FDCA is to ensure that medical devices are safe, effective, and compliant with the FDCA by requiring manufacturers of certain types of medical devices to meet a minimum quality standard in the design, manufacture, packaging, labeling, and storage of their products. 21 C.F.R. § 820.1. Numerous courts have recognized that neither the regulation nor the FDCA expressly create civil liability for noncompliance, strongly suggesting a legislative intent not to create a private cause of action. See, e.g., Blinn, 55 F. Supp. 2d at 1361 (language of FDCA strongly suggests legislative intent not to create private remedy for statutory violation); Pantages v. Cardinal Health 200, Inc., No. 5:08-cv-116-Oc-10GRJ, 2009 WL 2244539, *2-3 (M.D. Fla. July 24, 2009) (finding that plaintiff's negligence per se claim failed to state a claim for which relief can be granted because Florida law does not recognize a claim based upon a theory of negligence per se for an alleged violation of the FDCA); Lacognata v. Hospira, Inc., No. 8:12-cv-822-T-30TGW, 2012 WL 6962884, *2 (M.D. Fla. July 2, 2012), aff'd, 521 App'x 866 (11th Cir. 2013) ("Florida law does not recognize a claim based upon a theory of

negligence per se for an alleged violation of this particular [FDA] regulation.").

Here, plaintiffs allege that defendants are regulated by the FDCA and federal regulations promulgated by the FDCA, that Mr. Romer is a member of the class that the regulations were designed to protect, and that he was injured due to violations of the regulations. (Doc. #38, ¶¶ 40, 43-45, 59-60.) The Court concludes that the negligence per se claims fail to state a cause of action for which relief can be granted because Florida law does not recognize a claim based upon a theory of negligence per se for an alleged violation of the FDCA, or the FDA's implementing regulations.

B. Strict Liability and Negligence Claims (Counts III, V)

Florida tort law provides that the manufacturer of a defective product may be subject to liability under two theories: negligence and strict liability.[2] In order to prevail under either theory, the plaintiff must establish that the product was defective or unreasonably dangerous. Colville v. Pharmacia & Upjohn Co. LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citing Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003)). Under

[2] In its previous Opinion and Order the Court did not reach defendants' argument that a design defect theory of liability is expressly preempted, only finding that the Complaint failed to identify any purported federal regulatory violation. (Doc. #24.)

Florida law, "a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning." Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999) (quoting Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170 (Fla. 4th DCA 1998)). In this case, plaintiffs assert all three defects, but defendants only move to dismiss the strict liability and negligence claims to the extent they are based on theories of design defect, failure to warn, and failure to report adverse events to the FDA.[3]

1. Design Defect

Under Counts III and V, plaintiffs allege that the Cormet® System "suffered from design defects including a latent propensity to effuse metallic contaminants," and that "safer alternative designs existed that would have prevented or significantly reduced the risk of the accident alleged in this case." (Doc. #39, ¶¶ 67-68.) Defendants argue these claims are expressly preempted. Plaintiffs respond that they allege defendants violated Good Manufacturing Practices, as well as various federal regulations and failure to comply with the Approved Design Standards, which are parallel claims that survive preemption.

[3] Defendants state that they will address the deficiencies related to manufacturing defect at the summary judgment stage. (Doc. #44, n.1.)

Under Florida law, a strict product liability action based upon design defect requires the plaintiff to prove: (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury. McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002). Florida courts apply the following two-pronged test to determine whether a plaintiff has established a defective design:

> First, a product may be found defective in design if the plaintiff establishes that the product failed to perform as safely as an ordinary customer would expect when used in an intended or reasonably foreseeable manner. . . Second, a product may alternatively be found defective in design if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design.

See Pinchinat v. Graco Children's Prods., 390 F. Supp. 2d 1141, 1148 (M.D. Fla. 2005). To prevail on a products liability claim sounding in negligence, a plaintiff must establish: (1) a duty or obligation recognized by the law requiring the defendant to protect others from unreasonable risks; (2) a breach of that duty; (3) a reasonably close casual connection between the conduct and the resulting injury; and (4) actual loss or damages. Williams v. Davis, 974 So. 2d 1052, 1056 (Fla. 2007) (citing Clay Elec. Coop., Inc. v. Johnson, 873 So. 2d 1182, 1185 (Fla. 2003)).

The FDA regulates the design of Class III medical devices. See 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814. Under Florida law, "a product is defective because of a design defect if it is in a condition unreasonably dangerous to [the user] [a person in the vicinity of the product] and the product is expected to and does reach the user without substantial change affecting that condition." A product is unreasonably dangerous because of its design if "the product fails to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, or the risk of danger in the design outweighs the benefits." See Florida Standard Jury Instruction 403.7.

Here, a fact-finder considering a strict liability or negligence claim could find liability if a design defect rendered the subject medical devices unreasonably dangerous, even if defendants complied with all FDA regulations. Plaintiffs argue that the design defect claim is based on defendants' alleged failure to comply with federal laws after the FDA already approved the design of the Cormet® device; however, plaintiffs makes no allegation that Corin somehow altered the design of the device from the design approved by the FDA during the rigorous PMA process. Accordingly, the Court finds that the design defect claim is expressly preempted. See Riegel, 552 U.S. at. 316 (when state tort law claims would impose requirements that are "different from,

or in addition to" those imposed by the FDA, those claims are expressly preempted). Brown v. DePuy Orthopaedics, Inc., 978 F. Supp. 2d 1266, 1271 (M.D. Fla. 2013).

To the extent plaintiffs are asserting parallel claims, they acknowledge in their brief that a valid parallel claim cannot challenge the rigorous PMA process itself or the requirements imposed by the FDA pursuant to that process. (Doc. #49, p. 6.) However, plaintiffs' design defect claim does just that.

2. Failure to Warn and Reporting Violations

Plaintiffs allege that defendants inadequately or negligently failed to warn purchasers, users, and the general public of known or knowable defects in the Cormet®, and that defendants failed to report adverse events of injuries similar to Mr. Romer's to the FDA.[4] (Doc. #38, ¶¶ 52, 70-71, 73, 97, 102). Defendants argue that plaintiffs' warning claims are expressly preempted because they attack the FDA's approval of the Cormet®'s warnings, seeking to second guess the FDA's determination that the Cormet® warning language is adequate and would force Corin to meet an additional standard beyond what the FDA requires. Defendants further argue that the reporting violations claims are impliedly preempted.

[4] Florida law recognizes plaintiffs' "failure to report adverse events" theory as "negligent failure to warn." Mink, 860 F.3d at 1329.

Florida law recognizes the common law duty of failure to warn as a basis for negligence and strict liability claim. See Aubin v. Union Carbide Corp., 177 So. 3d 489, 514 (Fla. 2015); High v. Westinghouse Elec. Corp., 610 So. 2d 1259, 1262-63 (Fla. 1992) (recognizing manufacturers may be negligent for failing to warn entities that sell their product); Pinchinat, 390 F. Supp. 2d 1141 (quoting Ferayorni, 711 So. 2d at 1172).

As discussed above, the MDA "expressly pre-empts only state requirements different from, or in addition to, any requirement applicable ... to the device under federal law." See Wolicki–Gables, 634 F.3d at 1300. Under Riegel's express preemption regime, the question here is whether plaintiffs' claims would impose state law requirements that are different from, or in addition to, those under the federal regime. The Riegel Court held that PMA necessarily imposes device-specific "requirements" under the MDA. 552 U.S. at 322–23. "The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A)." Id. at 318. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing

processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319 (citing § 360e(d)(6)(A)(i)).

Here, plaintiffs claim that defendants breached a duty owed to purchasers, users, and the general public to provide adequate warning of the dangers of the product, which plaintiffs argue are parallel to their duty to comply with PMA federal reporting requirements. (Doc. #49, p. 7.) However, such a claim imposes requirements that are different from, or in addition to, the federal requirements under the MDA that defendants are required to adhere to in the Cormet® System's labeling. In a recent and similar case, the Court found that because a plaintiff did not allege that defendant failed to give the warning required by the FDA and federal requirements, plaintiff was attempting to hold defendant to a state law requirement that was different or in addition to what federal law requires. Rowe v. Mentor Worldwide, LLC, 297 F. Supp. 2d 1288, 1295 (M.D. Fla. 2018) (citing Mink, 860 F.3d at 1235 (quoting 21 U.S.C. § 360k(a)). Thus, the Court finds that the failure to warn claim is expressly preempted.

To the extent that plaintiffs' failure to warn claim is premised on defendants' failure to comply with FDA reporting requirements, defendants argue that the claim is impliedly preempted because plaintiffs' claim is simply an attempt to recast a claim for violation of the FDCA as a state law negligence claim. Plaintiffs claim that defendants failed to report adverse events

to the FDA in contravention of the FDA's Manufacturing Reporting Requirements.[5] (Doc. #38, ¶¶ 73, 97). Under Florida law, the duty to warn requires a manufacturer to adequately warn consumers of "a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1347 (M.D. Fla. 2003) (citing Ferayorni, 711 So. 2d at 1172, rev'd on other grounds, 822 So. 2d 502 (Fla. 2002)). Although the MDA requires manufacturers to report adverse events associated with a medical device to the FDA, plaintiffs have not identified a duty under Florida law that requires manufacturers to warn an agency such as the FDA of potential dangers associated with a medical device.

Because plaintiffs' failure to warn claim is premised upon an FDA-reporting requirement that is not paralleled by a Florida law duty, plaintiffs' claim is impliedly preempted. See Byrnes v. Small, 60 F. Supp. 3d 1289, 1297 (M.D. Fla. 2015) (finding the

[5] After a device is approved through the PMA process, a manufacturer must make Medical Device Reporting ("MDR") submissions to the FDA. 21 C.F.R. § 803.50(a). Specifically, the regulations require a manufacturer to report to the FDA within thirty days "information ... that reasonably suggests that a device ... (1) [m]ay have caused or contributed to a death or serious injury or (2) [h]as malfunctioned and this device or a similar device ... would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Id.; see also § 360i(a)(1) (requiring the adoption of regulations that direct a manufacturer to report information regarding the dangers associated with a device).

plaintiffs' claim for failure to warn impliedly preempted because the plaintiffs did not identify a parallel duty under Florida law to provide adequate warnings to the FDA). Traditional state-law tort claims survive implied preemption so long as they do not seek to privately enforce a duty owed to the FDA. Buckman, 531 U.S. at 348. Since Florida does not provide a duty to file such reports with the FDA, plaintiffs' claim is merely an "attempt to recast a claim for violation of the FDCA as a state-law negligence claim" and is impliedly preempted. McClelland v. Medtronic, Inc., 944 F. Supp. 2d 1193, 1200–01 (M.D. Fla. 2013).

V.

After the Court dismissed the initial Complaint, the Court granted plaintiffs leave to file an Amended Complaint; however, in its previous Opinion and Order the Court did not address many of the issues that the Amended Complaint raised. Therefore, because a party generally should be given at least one opportunity to amend before the court dismisses a complaint with prejudice, Bryan v. Dupree, 252 F.3d 1161, 1163 (11th Cir. 2001), and because plaintiffs request leave to amend their complaint "once more" (Doc. #49, p. 10), the Court will allow plaintiffs a final opportunity to file a Second Amended Complaint setting forth claims.

Accordingly, it is hereby

ORDERED:

1. Defendants' Motion to Dismiss (Doc. #44) is **GRANTED.**

Counts I and II and Counts III and V to the extent these claims are based on theories of design defect, failure to warn, and failure to report adverse events to the FDA, are **DISMISSED without prejudice** to filing a Second Amended Complaint within **fourteen (14) days** of this Opinion and Order.

2. If no Second Amended Complaint is filed, this case will proceed on the manufacturing defect claims, as well as Counts IV and VI.

DONE and ORDERED at Fort Myers, Florida, this 7th day of September, 2018.

JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:
Counsel of Record