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

STRYKER CORPORATION, CORIN GROUP, PLC, and CORIN USA LIMITED,

Defendants.

OPINION AND ORDER

This matter comes before the Court on defendants Corin Group, PLC and Corin USA Limited's Motion to Dismiss (Doc. #3) filed on January 18, 2018. Plaintiffs filed a Response in Opposition (Doc. #20) on March 5, 2018. For the reasons set forth below, the Motion is granted in part with leave to amend Counts III-V.

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 patient's body. On July 9, 2009, plaintiff Noel D. Romer underwent surgery to implant the Cormet Advanced Hip Resurfacing System (the "Cormet System") in his left hip. (Doc. #2, ¶ 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, 2016. (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. #2, ¶ 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 dangerous 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: negligence per se, manufacturing defects (Count I); negligence per se, improper quality control testing procedures (Count II); strict liability, failure to warn (Count III); strict liability, malfunction theory (Count IV); negligence (Count V). Plaintiff Holly Romer also brings a claim for loss of consortium (Count VI).

After removal, the Corin defendants [1] (hereinafter "defendants") moved to dismiss, arguing 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 argue that all of plaintiffs' claims must be dismissed because they are expressly preempted by, or are derivative of, the MDA pursuant to Riegel, and plaintiffs fail to properly allege any parallel state law claims.

II.

Under Federal Rule of Civil Procedure 8(a)(2), a Complaint must contain a "short and plain statement of the claim 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).

[1] Defendant Stryker Corporation has not yet been served.

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

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.

The MDA includes an express preemption provision (§ 360k) for Class III medical devices[2], 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 in addition to or different from federal regulations used to evaluate Class III medical devices that underwent the PMA process. 552 U.S. 312 (2008).

After Reigel, a plaintiff injured due to use of a Class III device approved through a PMA can escape preemption only if he

[2] The MDA provides for two types of preemption for certain state law claims relating to medical devices: express and implied. Defendants argue only express preemption.

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.

IV. Mr. Romer's Claims

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)

1. Sufficiency of Claims Under Florida Law

Mr. Romer bases his negligence per se claims on two possible theories of liability: manufacturing defect and improper quality control. In the Complaint, Mr. Romer sets forth 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. #2, ¶¶ 14-32.) Mr. Romer claims that the manufacturing defect was the result of defendants' failure to comply with the Approved Design Standards in the manufacturing process. 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.) Plaintiff then goes on to list seven manufacturing defects. (Id., ¶¶ 45(a)-(g).) Defendants argue that the Complaint contains nothing suggestive of an actual manufacturing defect, but includes only unsupported, conclusory allegations about the system that can be found on the internet.

"[I]n Florida, 'the violation of a statute may be utilized as evidence of negligence.'" Godelia, 881 F.3d at 1318 (quoting Fla. Dep't of Corr. v. Abril, 969 So. 2d 201, 2015 (Fla. 2007)). Under Florida law, "negligence per se is a violation of any other statute

which establishes a duty to take precautions to protect a particular class of persons from a particular injury or type of injury." deJesus v. Seaboard Coast Line R. Co., 281 So. 2d 198, 200 (Fla. 1973). Here, Mr. Romer alleges defendants violated the "statutory and regulatory standards of care, as embodied in the Approved Design Standards," which caused the defects that injured Mr. Romer. (Doc. #2, ¶ 54; ¶ 59.) Similar to the court's conclusion in Godelia, these allegations are sufficient to state a claim under Florida law for negligence per se related to a manufacturing defect.

Defendants also argue that the Complaint lacks any allegations plausibly suggesting that any of the purported manufacturing defects actually occurred in Mr. Romer's device. The Eleventh Circuit rejected a similar argument in Godelia. There, the court noted that it was error for the district court to determine that Mr. Godelia did not adequately plead causation because "[w]hile it may come to pass that Mr. Godelia has a difficult time proving that it was the violations of the MDA regulations that caused a defect in Mr. Godelia's LifeVest, the allegations in his complaint are sufficient to state a claim that is plausible on its face." 881 F.3d at 1318-19 (declining the invitation to apply a heightened pleading standard of causation to medical device claims). Similarly, here, it is plausible that defendants' failure to comply with the Approved Design Standards

and regulations set forth in the Complaint resulted in a defect that caused Mr. Romer's injury. Therefore, Mr. Romer's claims under Florida law for negligence per se are sufficiently pled.

2. Express Preemption

Defendants argue that Mr. Romer's negligence per se claims are expressly preempted because they allege no potential regulatory violation in support. The Court disagrees. Mr. Romer alleges that "[t]he Cormet System Mr. Romer received was not manufactured in strict compliance with the Approved Design Standards set forth above. The Approved Design Standards describe the only acceptable end result of the manufacturing process for the Cormet System, and the Cormet System Mr. Romer received does not match that end result." (Doc. #2, ¶ 45.) Plaintiff states that this violated the conditions of the FDA's approval and the general regulations applicable to Class III medical devices. (Id.) And under Count II, plaintiff states that defendants' "inadequate quality control and testing procedure violated 21 C.F.R. § 820.30, which requires Defendants to establish and maintain procedures to control the design of a Class III medical device and to appropriately test such a device to ensure that all design requirements are met." (Id., ¶ 59.) Thus, Mr. Romer has plausibly alleged a violation of a specific federal regulation, which caused Mr. Romer's injuries to escape preemption. See Mink, 860 F.3d at 1331 (noting that plaintiff alleged the federal

requirements that defendant violated, including the premarket approval specifications for the device). Therefore, the Court concludes that Counts I and II are cognizable common law causes of action under Florida law and are not preempted by federal law.

B. Strict Liability (Counts III, IV)

1. Sufficiency of Claims under Florida Law

Mr. Romer bases his strict liability claims on three possible theories of liability: failure to warn, manufacturing and design defects, and improper quality control testing.

"Florida law recognizes strict liability claims based on a manufacturing defect." Godelia, 881 F.3d at 1318 (citing West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976)). A product may also be defective by virtue of a design defect or an inadequate warning. Brown v. Glade and Grove Supply, Inc., 647 So. 2d 1033, 1035 (Fla. 4th DCA 1994). Under Florida law, a plaintiff "must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages." Godelia, 881 F.3d at 1318. To state a claim for failure to warn under Florida law, a plaintiff must allege that "the manufacturer or seller knew, or by the exercise of reasonable care should have known, of the potential danger in the use of the product, and, in the reasonable course of business, should have been able to foresee

the possible uses of the product as well as the potential damage or injury that might result from such use." Advance Chemical Co. v. Harter, 478 So. 2d 444, 447 (Fla. 3d DCA 1985).

Here, Mr. Romer alleges that the Cormet System "suffered from design defects including a latent propensity to effuse metallic contaminants into the human blood and tissue." (Doc. #2, ¶ 67.) Plaintiff further allege that defendants "inadequately warned or failed to warn purchasers of its products or potential users of its products within the general public and foreseeable users of its products, such as Plaintiff, of the defects in the subject Cormet System about which Defendants knew or should have known." (Doc. #2, ¶ 70.) Plaintiff also states that the Cormet System was unsafe for its intended purpose because of manufacturing defects (Id., ¶ 76). The Court finds that Mr. Romer has plausibly alleged strict liability claims recognized under Florida law.

2. Express Preemption

The Court agrees, however, that Mr. Romer fails to identify a federal regulatory violation in support of his strict liability claims. Although these counts "re-allege and adopt each of the General Allegations and incorporate them as if they were fully set forth herein," a review of the Complaint reveals no "General Allegations" section and the Court will not guess which section's allegations plaintiff is referring to in order to find a federal regulatory violation. Thus, the only allegations the Court finds

under the strict liability claims relate to a Florida common law duty to use due care in manufacturing medical devices, which is expressly preempted under Section 360k. The Court will allow plaintiff to amend the strict liability claims.

C. Negligence (Count V)

1. Sufficiency of Claims under Florida Law

Mr. Romer bases the negligence claim on two possible theories of recovery: manufacturing defect and failure to warn. Plaintiff alleges that the Cormet System was defective because of defendants' negligence and carelessness in connection with the design and manufacture of the Cormet System, causing a latent propensity to effuse metallic contaminants into the human blood and tissue. (Doc. #2, ¶¶ 87-88.) Plaintiff further alleges that defendants manufactured the Cormet System and placed it in commerce, the Cormet System was defective and nonconforming, and those defects caused Mr. Romer's injuries. This is sufficient. See Ford, 327 So. 2d at 202 (holding that manufacturers may be liable for a manufacturing defect that causes or enhances injury); Moorman v. American Safety Equipment, 594 So. 2d 795 (Fla. 4th DCA 1992).

Mr. Romer also alleges that defendants "negligently warned or failed to warn purchasers of its products or potential users of its products within the general public and foreseeable users of its products . . ." (Id., ¶ 89.) Florida law recognizes the common law duty of failure to warn as a basis for a negligence

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 manufactures may be negligent for failing to warn entities that sell their product).

2. Express Preemption

Much like the strict liability claims, the Court finds that Mr. Romer fails to identify a federal regulatory violation in support of the negligence claim; thus, the same reasoning for dismissal applies. The Court will allow plaintiff to amend.

D. Loss of Consortium

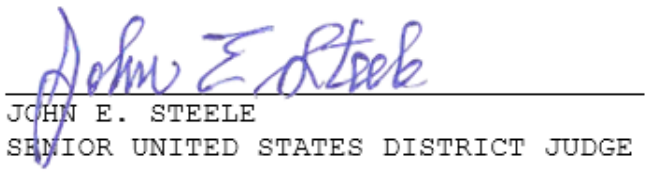
Holly Romer brings a claim for loss of consortium, which defendants argue must be dismissed as derivative of Mr. Romer's preempted claims. Because the Court has found that Counts I and II are properly pled and not expressly preempted, the loss of consortium claim may stand.

Accordingly, it is hereby

ORDERED AND ADJUDGED:

Corin Group, PLC and Corin USA Limited's Motion to Dismiss (Doc. #3) is **GRANTED in part and DENIED in part.** Counts III-V are **DISMISSED without prejudice** to filing an Amended Complaint within **FOURTEEN (14) DAYS** of this Opinion and Order; otherwise, the Motion is denied.

DONE and ORDERED at Fort Myers, Florida, this 27th day of March, 2018.



JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:
Counsel of Record