UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ELIZABETH WESTERFIELD and JERALD WESTERFIELD,

Plaintiffs,

v. **Case No: 8:19-cv-00146-T-02AEP**

CORIN GROUP, PLC; CORIN USA LIMITED; STRYKER SUSTAINABILITY SOLUTIONS, INC.; STRYKER SALES CORPORATION; STRYKER CORPORATION; and HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS,

Defendants.

ORDER

This matter comes before the Court following oral argument on Defendants' Fed. R. Civ. P. 12(b)(6) motions to dismiss Plaintiffs' complaint (Dkts. 5-6), Plaintiffs' response in opposition (Dkt. 15), and Defendants' replies (Dkts. 16-17). Upon consideration, the Court will grant the motions to dismiss but allow Plaintiffs leave to amend.

This case relates to injuries Plaintiff Elizabeth Westerfield allegedly suffered after being implanted with the Cormet System, a metal-on-metal hip resurfacing system. As reflected by the parties' briefing, this case raises issues of express and

implied preemption under the federal Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360k ("MDA"). Plaintiffs' complaint was originally filed in state court and does not appear to have had the benefit of the Eleventh Circuit's latest guidance on these fairly complex issues.

The Eleventh Circuit has recently weighed in on MDA preemption issues in *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), and *Godelia v. Doe 1*, 881 F.3d 1309 (11th Cir. 2018). As the Eleventh Circuit has explained, the MDA both expressly and impliedly preempts certain state law claims relating to Class III medical devices such as the Cormet System. *Godelia*, 881 F.3d at 1317. 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." *Id.* (quoting 21 U.S.C. § 360k(a)). 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." *Id.* (quoting 21 U.S.C. § 337(a)). The implied preemption provision bars "claims that merely attempt to enforce duties owed to the [Food and Drug Administration ("FDA")]," *id.*, including claims that a defendant failed to make required disclosures to the FDA, *Mink*, 860 F.3d at 1330. Taken together, the express and implied preemption provisions leave plaintiffs with a narrow gap to make medical device claims: "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)." *Id.* at 1327.

Under this standard, the Eleventh Circuit has disallowed claims based on a defendant's alleged failure to make required disclosures to the FDA because such claims are impliedly preempted by the MDA. *Id.* at 1330. It has, however, allowed manufacturing defect claims to proceed where the plaintiff alleges in a non-conclusory fashion that the device was manufactured in a way that violated the FDA's premarket approval specifications or other federal regulations. *Id.* at 1329-31; *Godelia*, 881 F.3d at 1317-21.

The Eleventh Circuit's new guidance was noted in this District in two recent cases. In *Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288 (M.D. Fla. 2018), the court found that a plaintiff's failure-to-report claims were impliedly preempted because she merely alleged that the defendant "failed to tell the FDA those things required by federal law." *Id.* at 1295-96, 1300 (internal quotation and citation omitted). It also found that the plaintiff's failure-to-warn claims were expressly preempted because they lacked an allegation that the defendant failed to make a warning required by the FDA or federal law. *Id.* The court denied a motion to dismiss the plaintiff's manufacturing defect claims, however, because those claims adequately alleged violations of federal law, including alleging that the device was

manufactured in a way that differed from the specifications set forth in the FDA's premarket approval order for the device. *Id.* at 1298-99. More recently, in *Romer v. Corin Group, PLC*, No. 2:18-cv-19-FtM-99MRM, 2018 WL 4281470, at *5-6 (M.D. Fla. Sept. 7, 2018), the court dismissed a design defect claim as expressly preempted because the plaintiffs made no allegation that the defendants altered the design of the device from the design approved by the FDA.

Under these standards, all of Ms. Westerfield's claims are due to be dismissed. Her husband's loss of consortium claim is also due to be dismissed because it is derivative of her claims. The Court will, however, allow Plaintiffs to file an amended complaint that incorporates the guidance set forth in *Mink, Godelia, Rowe,* and *Romer*. In formulating their amended complaint, Plaintiffs are advised to hew closely to the Eleventh Circuit's most recent teachings in *Mink* and *Godelia*.

Accordingly, Defendants' motions to dismiss (Dkts. 5-6) are granted. Plaintiffs complaint (Dkt. 1-3 at 2-79) is dismissed. Plaintiffs may file an amended complaint on or before May 7, 2019.

DONE and **ORDERED** in Tampa, Florida on March 15, 2019.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

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Counsel of Record