UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

DONALD WOMACK and
LYNNE WOMACK,

Plaintiffs,

v. Case No: 8:19-cv-698-30SPF

NEVRO CORP.,

Defendant.

ORDER

THIS CAUSE comes before the Court upon Defendant Nevro Corp.'s Rule 12(b)(6) Motion to Dismiss Plaintiffs' Amended Complaint (Dkt. 17), Plaintiffs' Response in Opposition (Dkt. 19), and the Parties' respective Replies (Dkts. 31, 36). The Court, having reviewed these filings, and being otherwise advised in the premises, concludes that Defendant's motion should be granted because Plaintiffs have failed to plead parallel product liability claims. Further, Plaintiffs' misleading advertising claim does not meet Rule 9's pleading standard. The Court will permit Plaintiffs a final opportunity to amend their complaint to remedy these deficiencies.

BACKGROUND

This product liability action concerns Defendant Nevro Corp.'s Senza SCS System ("Senza"), a surgically implanted spinal cord stimulator indicated for the management of chronic and intractable pain. The Senza is a "Class III" medical device cleared for commercial distribution by the U.S. Food and Drug Administration ("FDA") through the rigorous premarket approval process. In their amended complaint, Plaintiffs assert five causes of action based on the Senza's manufacturing and labeling.

Specifically, Plaintiff Donald Womack received a Senza implant in September 2017. Soon thereafter, Womack reported to Megan Poole, Nevro's representative, that the Senza implant felt extremely hot. Poole informed Womack that the heat he sensed would stop after the device had finished charging. Womack alleges that "this never happened." (Dkt. 14 at ¶33). Subsequently, Womack suffered personal injuries related to the Senza implant.

On March 12, 2019, Plaintiffs filed their original complaint alleging that design, manufacturing, and labeling defects in the Senza caused Womack to suffer personal injuries. On April 1, 2019, Nevro moved to dismiss these claims, primarily on the grounds that Section 360k(a) of the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360 et seq., to the federal Food, Drug, and Cosmetic Act ("FDCA") preempted them.

Rather than file a response to Nevro's motion, Plaintiffs elected to file an amended complaint, which is the operative pleading. The amended complaint alleges claims for negligence, strict products liability, failure to warn, misleading advertising pursuant to Fla. Stat. § 817.41, and loss of consortium. Nevro moves to dismiss all claims for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

MOTION TO DISMISS STANDARD

Rule 12(b)(6) allows a complaint to be dismissed for failure to state a claim on which relief can be granted. When reviewing a motion to dismiss, courts must limit their consideration to the well-pleaded allegations, documents central to or referred to in the complaint, and matters judicially noticed. *See La Grasta v. First Union Securities, Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (internal citations omitted); *Day v. Taylor*, 400 F.3d

1272, 1276 (11th Cir. 2005). Furthermore, they must accept all factual allegations contained in the complaint as true, and view the facts in a light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 93–94 (2007).

Legal conclusions, though, "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 664 (2009). In fact, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003). To survive a motion to dismiss, a complaint must instead contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (internal quotation marks and citations omitted). This plausibility standard is met when the plaintiff pleads enough factual content to allow the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (internal citations omitted).

DISCUSSION

The crux of Nevro's motion to dismiss is that the product liability claims are preempted. The Court agrees based on the current allegations.

As this Court has done previously—*see Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1294–95 (M.D. Fla. 2018), and *Ramkelawan v. Globus Med. Inc.*, No. 5:18-CV-100-OC-30PRL, 2018 WL 8368675, at *2–3 (M.D. Fla. Aug. 8, 2018)—the Court begins by presenting this short primer on federal preemption law under the MDA from a recent Eleventh Circuit opinion:

> The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, give the FDA regulatory authority over medical devices. [*Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1325 (11th Cir. 2017)]. Class III devices . . ., which are deemed the highest risk, are required to go through an extensive premarket approval process. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18, 128 S.Ct. 999, 1003–04, 169 L.Ed.2d 892 (2008). 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.* at 319, 128 S.Ct. at 1005.
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> The MDA provides for two types of preemption of certain state law claims relating to medical devices: express and implied. 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. § 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.* § 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 Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S.Ct. 1012, 1017, 148 L.Ed.2d 854 (2001).
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> Taken together, these two types of preemption leave a "narrow gap" through which plaintiffs making medical device claims must proceed. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "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. 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.* (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

Godelia v. Doe 1, 881 F.3d 1309, 1317 (11th Cir. 2018).

In *Rowe*, this Court observed that to sufficiently plead a parallel claim after *Mink* and *Godelia*, a plaintiff is not required to allege a violation of a device-specific regulation. 297 F. Supp. 3d at 1298-1300. This Court underscored, though, that a plaintiff still must identify some pertinent federal regulation, a violation of that specific

regulation, and sufficient facts to substantiate the allegation, including a causal link to the alleged injury. *Id.*

Here, as Nevro points out in its motion, the amended complaint is silent as to any applicable federal regulation that was violated. In Count I, Plaintiffs allege that Florida law imposes a duty on Nevro "to exercise all reasonable care when producing, manufacturing, distributing, and selling" the Senza. (Dkt. 14 at ¶68). Plaintiffs then aver that Nevro breached this duty of care "when it produced the [Senza] in a manner that did not comply with the design specifications approved by the FDA." *Id.* at ¶71. This is all the negligence claim states.

Similarly, with respect to their strict liability claim, Plaintiffs broadly allege that the Senza was unreasonably dangerous because it was "produced, manufactured, and distributed in a manner that violated federal law and the FDA's design specifications for the [Senza]." *Id.* at ¶¶85-86. Lacking from the allegations is any particular regulation or design specification that was violated. There are also no facts describing how any alleged manufacturing violations rendered the device unreasonably dangerous. The closest Plaintiffs come to alleging any kind of defect is in paragraph 59 of their amended complaint, where they state that the Senza is "merely the latest type of implantable medical device to contains [sic] an internal battery. As such, a key consideration of the actual FDA-approved design and manufacturing process is whether the battery contained within the device is designed in a manner which prevents it from heating to a temperature which can burn any surrounding tissue, or designed so that the materials surrounding the battery effectively insulates[sic] any heat generated by the battery from being transmitted

to the surrounding tissue." (Dkt. 14). These allegations are too speculative to survive preemption.

As Nevro aptly states in its motion: "In short, Plaintiffs[sic] negligence and strict liability claims allege only that: (i) federal law imposed some unspecified requirements on Nevro; (ii) Nevro failed to satisfy some unspecified requirement(s) in some unspecified way; and (iii) Plaintiff was somehow injured as a result." (Dkt. 17 at 13-14). For these reasons, the claims must be dismissed.

In their reply, Plaintiffs appear to concede that the product liability claims are preempted as they are currently pled. Plaintiffs state that they may have "spawned a defective pleading." (Dkt. 36 at 3). And that Plaintiffs should have invoked 21 C.F.R. § 814.80 "as an applicable and specific federal regulation." *Id.* It seems that Plaintiffs seek to amend their complaint to "now argue that had [Nevro] complied with 21 C.F.R. § 814.80, their May 8, 2015 PMA order, as well as the still undisclosed design and manufacturing specifications specific to [Nevro's] Class III medical device, a defective device would likely never have been implanted" in Womack. *Id.* Under these circumstances, the Court will grant Plaintiffs a final opportunity to file an amended complaint.

Plaintiffs appear to also concede that the failure to warn claim is preempted because Plaintiffs do not allege that the warnings provided deviated from those warnings the FDA approved in the rigourous PMA process. *See Rowe*, 297 F. Supp. 3d at 1295 ("[Plaintiff] does not allege that [defendant] failed to give the warning required by the FDA and federal requirements. So [plaintiff] is attempting to hold defendant to a state-

law requirement that is different or in addition to what federal law requires. So [Plaintiff] cannot pursue . . .this theory of liability."). Accordingly, this claim will also be dismissed with leave to amend.

Finally, the Court will not discuss the misleading advertisement claim in any detail because Nevro's motion aptly presents the arguments with respect to this claim, i.e., that the claim fails to provide the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure, and Plaintiffs do not adequately address the merits of this claim in their filings. So this claim will also be dismissed. The Court emphasizes that if Plaintiffs choose to amend this claim, they shall be mindful of their duty to plead in good faith as delineated in Rule 11 of the Federal Rules of Civil Procedure.

Accordingly, it is ORDERED AND ADJUDGED that:

1. Defendant Nevro Corp.'s Rule 12(b)(6) Motion to Dismiss Plaintiffs' Amended Complaint (Dkt. 17) is granted.
2. Plaintiffs shall have fourteen (14) days from the date of this Order to file an amended complaint. This will be Plaintiffs' final opportunity to amend their complaint. Failure to file an amended complaint by this deadline will result in the dismissal of this action with prejudice.

DONE and **ORDERED** in Tampa, Florida on June 21, 2019.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies provided to:
Counsel/Parties of record