UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LORI BYRNES and MATTHEW BYRNES,

Plaintiffs,

v. Case No: 8:14-cv-1726-T-36MAP

JOHN SMALL, MUSCULOSKELETAL INSTITUTE CHARTERED, MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants.
_____/

ORDER

This cause comes before the Court upon the Motion to Dismiss filed by Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") (Doc. 32). Plaintiffs Lori Byrnes and Matthew Byrnes (collectively, "Plaintiffs") responded in opposition to the Motion (Doc. 36). Medtronic replied in further support of its Motion (Doc. 39). On November 20, 2014, the Court held oral argument on the Motion. Doc. 57. Both sides submitted a number of supplemental authorities (Docs. 43, 46-51, 53, 61-62, 64-65, 71). The Court, having considered the parties' submissions and the oral argument, and being fully advised in the premises, will now GRANT the Motion to Dismiss.

I. STATEMENT OF FACTS[1]

[1] The following statement of facts is derived from the Complaint (Doc. 2), the allegations of which the Court must accept as true in ruling on a motion to dismiss. *See Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992); *Quality Foods de Centro Am., S.A. v. Latin Am. Agribusiness Dev. Corp. S.A.*, 711 F. 2d 989, 994 (11th Cir. 1983).

This action arises over the injuries allegedly caused to Lori Byrnes by the bone graft device Infuse, which was implanted in Ms. Byrnes in an off-label manner during a spinal fusion surgery. The Complaint alleges as follows: Spinal fusion surgeries are performed to treat a number of conditions, such as spinal deformities and back pain. Doc. 2 ("Compl.") ¶ 50. The goal of a spinal fusion surgery is to obtain a solid fusion of the vertebrae. *Id.* ¶ 51. Traditionally, in performing a spinal fusion surgery, a surgeon places a graft consisting of the patient's own bone or a cadaver bone in a spacer cage within the disc space between the vertebrae. *Id.* However, newer options using bio-engineered and bio-manufactured bone growth products have been developed, and are more appealing to surgeons because they obviate the need to harvest bone. *Id.* ¶ 54.

Infuse is a bio-engineered bone graft device that was designed, manufactured, and marketed by Medtronic for use in spinal fusion surgeries. *Id.* ¶ 2. It consists of three parts: (1) a metallic spinal fusion cage (the "LT-Cage"); (2) the bone graft substitute; and (3) a sponge-like carrier or scaffold for the bone graft substitute that is placed inside the fusion cage. *Id.* ¶ 56. The fusion cage serves to maintain spacing and temporarily stabilize the diseased region of the spine. *Id.* ¶ 57. The bone graft component serves to form the bone that will permanently stabilize the treated portion of the spine. *Id.* The sponge serves to bind the bone graft substitute, and resorbs over time. *Id.* ¶ 58. As the sponge dissolves, the bone graft substitute stimulates the production of new bone. *Id.*

Infuse is a Class III medical device. *Id.* ¶ 65. Accordingly, before Medtronic could market Infuse, it was required to submit a Premarket Approval Application ("PMA") for approval by the U.S. Food and Drug Administration ("FDA"). *Id.* ¶ 65. As presented in the PMA, Infuse consists of both the LT-Cage and the bone graft component. *Id.* ¶ 71. In July 2002, the FDA approved Infuse for a certain spinal fusion procedure, *id.* ¶ 63, specifically, the anterior lumbar interbody

fusion procedure, which involves a single-level fusion and is performed by approaching the spine from the front through an incision in the abdomen, *id.* ¶ 72. The approved label indicates that Infuse's components must be used as a system, and that the bone graft component must not be used without the LT-Cage. *Id.* ¶ 74.

Infuse has never been approved by the FDA for use in any other parts of the body or any other type of procedure (other than two non-spinal uses), *id.* ¶ 76, due to the number of adverse events resulting from the use of the bone graft substitute in off-label applications, *id.* ¶ 80. For example, in a trial examining the application of the bone graft substitute to posterior lumbar interbody fixation, a number of patients developed uncontrolled bone growth. *Id.* Further, the FDA admonished Medtronic to guard against the off-label use of Infuse. *Id.* ¶¶ 84-86.

Despite being aware of the FDA's concerns regarding the off-label use of Infuse, Medtronic nevertheless sold the LT-Cage and the bone graft component separately. *Id.* ¶ 75. Moreover, not only did Medtronic intentionally conceal from the general public the dangers of the off-label use of Infuse, *id.* ¶¶ 114-15, it actively promoted the off-label use of Infuse through its sales representatives and spine surgeon consultants, *id.* ¶ 132-38.

In October 2006, Dr. John Small performed a surgery on Ms. Byrnes using Infuse in an off-label manner. *Id.* ¶ 248. Specifically, Dr. Small implanted Infuse by means of a posterior approach lumbar fusion, and did not use the requisite LT-Cage. *Id.* Ms. Byrne subsequently suffered and reported increasingly severe pain. *Id.* ¶ 250. Imaging studies ultimately revealed that Ms. Byrnes had developed uncontrolled bone growth and nerve compression near where Infuse had been implanted. *Id.* ¶¶ 251.

In the Complaint, Ms. Byrnes asserts, *inter alia*, that Medtronic is liable for: (1) fraudulent misrepresentation and fraud in the inducement (First Cause of Action) (2) strict products liability

– failure to warn (Second Cause of Action); (3) strict products liability – design defect (Third Cause of Action); (4) strict products liability – misrepresentation (Fourth Cause of Action); (5) products liability – negligence (Fifth Cause of Action); and breach of express warranty (Sixth Cause of Action). *Id.* ¶¶ 264-348. Ms. Byrnes' husband, Matthew Byrnes, also asserts against Medtronic a claim for loss of consortium (Ninth Cause of Action). *Id.* ¶¶ 378-79.

Medtronic now moves to dismiss the Causes of Action asserted against it, arguing that they are preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Specifically, Medtronic argues that all of Ms. Byrnes' claims, with the possible exception of those alleging affirmative fraud, are either expressly preempted by the Medical Device Amendments to the FDCA ("MDA"), or impliedly preempted by 21 U.S.C. § 337(a). Medtronic also argues that, to the extent Ms. Byrnes' claims are premised on affirmative fraud, they must be dismissed because they have not been pleaded with requisite particularity. Medtronic finally argues that Mr. Byrnes' loss of consortium claim, as well as Plaintiffs' request for punitive damages, must fail because all of Ms. Byrnes' claims fail.

II. LEGAL STANDARD

To survive a motion to dismiss, a pleading must include a "short and plain statement of the claim showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). Labels, conclusions and formulaic recitations of the elements of a cause of action are not sufficient. *Id*. (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Furthermore, mere naked assertions are not sufficient. *Id*. A complaint must contain sufficient factual matter, which, if accepted as true, would "state a claim to relief that is plausible on its face." *Id*. (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

defendant is liable for the misconduct alleged." *Id*. (citation omitted). The court, however, is not bound to accept as true a legal conclusion stated as a "factual allegation" in the complaint. *Id*.

III. DISCUSSION

A. Statutory Framework of the Medical Device Amendments

The regulation of medical devices entering the market is governed by the FDCA, which provides that the enforcement of violations "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In 1976, Congress passed the MDA, which amended the FDCA and imposed a regime of detailed federal oversight. *See* 21 U.S.C. § 360c *et seq*. The new regulatory regime separated medical devices into three classes based on the risks they pose to the public. *Id.*; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *United States v. Endotec, Inc.*, 563 F.3d 1187, 1189-90 (11th Cir. 2009). Class I devices are those that present no unreasonable risk of illness or injury and are subject only to "general controls," such as labeling requirements. *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices possess a greater potential for danger and thus warrant "special controls" such as performance standards and postmarket surveillance measures. *Id.* at 316-17 (citing 21 U.S.C. § 360c(a)(1)(B)). The strictest regulation, Class III, is reserved for devices for which a less stringent classification could not provide reasonable assurance of safety and effectiveness. *Id.* at 317 (citing 21 U.S.C. § 360c(a)(1)(C)).

1. Premarket Approval

All Class III devices, such as the Infuse product, must undergo the "rigorous" PMA process administered by the FDA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The PMA process begins with the manufacturer submitting a multi-volume application, detailing a variety of information including the safety and efficacy of the device. *Riegel*, 552 U.S. at 317-18 (citing 21 U.S.C. § 360e(c)(1)). After the FDA completes its review, PMA approval is granted only if there

is a "reasonable assurance" of the device's "safety and effectiveness." *Id.* at 318 (citing 21 U.S.C. § 360e(d)). The FDA may also condition approval on adherence to performance standards, restrictions upon sale or distribution, or other compliance requirements. *Id.* at 319 (citing 21 C.F.R. §§ 861.1(b)(3), 814.82).

Even after PMA approval is granted, manufacturers are forbidden to make changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness, without FDA permission. *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If a manufacturer wishes to make such a change to a device, it must submit an application for supplemental PMA, which is evaluated under identical criteria as the initial application. *Id.* (citing 21 U.S.C. § 360e(d)(6)). Moreover, after PMA, manufacturers are subject to reporting requirements. *Id.* (citing 21 U.S.C. § 360i). These include the obligation to inform the FDA of new clinical investigations or scientific studies, 21 C.F.R. § 814.84(b)(2), and to report incidents where the device may have caused or contributed to death or serious injury, 21 C.F.R. § 803.50(a). *Riegel*, 552 U.S. at 319.

2. Preemption under the FDCA Framework

Prior to the statutory enactment of the MDA, the introduction of new medical devices was left largely for the states to supervise as they saw fit. *Riegel*, 552 U.S. at 315. However, the MDA "swept back some state obligations and imposed a regime of detailed federal oversight." *Id.* at 316. The MDA's express preemption provision provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). In *Riegel*, the Supreme Court suggested that the MDA's preemption of certain state obligations in favor of more detailed federal oversight was justified because of the harm that would be caused by stifling innovation in medical devices if "juries were allowed to apply the tort law of 50 States to all innovations." 552 U.S. at 326. The Supreme Court also noted that "State tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Id.* at 325.

Accordingly, "[t]he MDA expressly pre-empts [] state requirements different from, or in addition to, any requirement applicable . . . to the device under federal law." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *Riegel*, 552 U.S. at 321). However, because § 360k(a) only preempts state requirements to the extent that they are "different from, or in addition to the requirements imposed by federal law," state law claims premised on violations of FDA regulations that "parallel," rather than add to federal requirements are not preempted. *Id.* at 1300 (quoting *Riegel*, 552 U.S. at 330). In *Wolicki-Gables*, the Eleventh Circuit explained the parallel claim principle as follows:

> "In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are 'genuinely equivalent.' State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law."

634 F.3d at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

In *Riegel*, the Supreme Court established a two-prong test for determining whether a state claim is expressly preempted by the MDA: (1) determine whether the federal government has established requirements applicable to the medical device; and (2) if so, determine whether the

state law claims are based upon requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness. 552 U.S. at 321-22.

In addition to express preemption under the MDA, the FDCA also impliedly preempts suits by private litigants "for noncompliance with the medical device provisions." *See Buckman*, 531 U.S. at 349 n.4. That is because 21 U.S.C. § 337(a) states that all actions to enforce FDA requirements "shall be by and in the name of the United States." The Eighth Circuit has explained the interaction between *Riegel* and *Buckman* as follows:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (internal citations and quotations omitted); *see also In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) ("[W]hen Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted[.]").

B. Application of Preemption Analysis

Infuse was approved through the PMA process. Compl. ¶ 65. Therefore, for purposes of evaluating express preemption, the first prong of the *Riegel* test is automatically satisfied. *See Riegel*, 552 U.S. at 322-23 ("[p]remarket approval . . . imposes 'requirements' under the MDA' that are 'specific to individual devices'"); *Wolicki-Gables*, 634 F.3d at 1301. Citing *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), Plaintiffs argue that the PMA process does not result in device-specific federal requirements. *See* Doc. 36 at 27-28. That argument is without merit—to the extent *Goodlin* is inconsistent with *Riegel*, it has been abrogated. *See Yost v. Striker*

Corp., Case No. 09-cv-28, 2010 WL 1141586, at *1 n.1 (M.D. Fla. Mar. 23, 2010). Accordingly, the question remaining is whether any of the claims would impose state law requirements that are different from, or in addition to, those under the federal regime. Further, for any of the claims that the Court finds not expressly preempted, the Court must also evaluate whether they are impliedly preempted by determining whether they are cognizable only by virtue of the provisions of the FDCA, or whether they state a claim under state law even in the absence of the FDCA.

C. Claim-by-Claim Analysis

1. Fraudulent Misrepresentation and Fraud in the Inducement (First Cause of Action)

Medtronic argues that the First Cause of Action is expressly and impliedly preempted to the extent that it is premised on any failure-to-warn theory. The Court agrees. *First*, to the extent that the claim is based on Medtronic's failure to warn the medical community of the dangers associated with the off-label use of Infuse, including any purported inadequacies in the warnings and labels accompanying Infuse, it is expressly preempted. Critically, Plaintiffs have not identified any federal requirement to inform the public or to update warning labels regarding the dangers of off-label use. *Accord McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1199 (M.D. Fla. 2013). Accordingly, regardless of whether Medtronic engaged in off-label promotion of Infuse, such requirements would clearly be different from, or in addition to, the federal requirements. *See Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 703 (S.D. Tex. 2014) ("[F]or a plaintiff to prevail on a failure-to-warn claim, a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the

Infuse Device in an off-label manner. Either scenario would violate *Riegel*'s express preemption framework.") (quotation marks and citations omitted).

Second, to the extent that the claim is based on Medtronic's failure to report adverse events to the FDA, it is impliedly preempted. Although federal law requires medical device manufacturers to file adverse event reports whenever the device "may have caused or contributed to a death or serious injury," 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a), Plaintiffs have failed to identify any Florida state law duty to report to the FDA. Accordingly, such a claim is impliedly preempted, as it is merely "[an] attempt to recast a claim for violation of the FDCA as a state-law negligence claim." *McClelland*, 944 F. Supp. 2d at 1200; *see also In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liability Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010).

It is unclear whether Medtronic believes that this claim is preempted even to the extent that it is premised on the affirmative misrepresentations it allegedly made to promote the off-label use of Infuse. *See* Doc. 32 at 11 (arguing that "[Plaintiffs'] claims are—with the *possible exception* of claims predicated on certain alleged affirmative misrepresentations—the exact type of claim that is expressly preempted under § 360k(a)") (emphasis added). If that is Medtronic's position, the Court disagrees. Such a claim is not expressly preempted because, as many courts have explained, "federal law bars off-label promotion when it is false or misleading." *Schouest*, 13 F. Supp. 3d at 702 (referencing 21 U.S.C. §§ 331(a), 352(q)(1)). And such a claim is not impliedly preempted because "it sounds in traditional state common law that exists independently from the FDCA and not solely by virtue of the FDCA." *Brady v. Medtronic, Inc.*, Case No. 13-cv-62199, 2014 WL 1377830, at *7 (S.D. Fla. Apr. 8, 2014).[2]

[2] The Court emphasizes that its ruling applies only to *untruthful* off-label promotion, because that is what has been alleged in this case, *see* Doc. 36 at 9 ("As Plaintiffs have alleged throughout their Complaint, MEDTRONIC aggressively promoted *untruthful* off-label use of

The Court nevertheless agrees that this Cause of Action must be dismissed in its entirety, because, to the extent it relies on affirmative falsehoods and is not preempted, Plaintiffs have failed to plead fraud with the requisite particularity. *See* Fed. R. Civ. P. 9(b) ("a party must state with particularity the circumstances constituting fraud or mistake"). Indeed, Plaintiffs only allege in a vague and conclusory manner that Medtronic "fraudulently concealed and misrepresented" the dangers of the off-label use of Infuse, Compl. ¶¶ 265-67, but fail to identify with particularity any misrepresentations and/or concealments that were actually relied upon by Dr. Small, or how those misrepresentations and/or concealments proximately caused Ms. Byrnes' injuries. The Court, however, will afford Plaintiffs an opportunity to amend the claim to conform to the heightened pleading requirements of claims for fraud.

2. Failure to Warn (Second Cause of Action)

For the reasons discussed in Section III.C.1, *supra*, Ms. Byrnes' failure to warn claim is preempted. Further, because this claim does not entail any affirmative falsehoods, it is preempted in its entirety. The Court, therefore, will dismiss this claim with prejudice.

3. Design Defect Claim (Third Cause of Action)

Medtronic argues that Ms. Byrnes' design defect claim is expressly preempted. The Court agrees. The Third Cause of Action alleges that Infuse was defectively designed because "the risks of danger in the design outweigh the benefits of the design," and that "[t]he foreseeable risks of harm . . . could have been reduced or avoided by adopting a reasonably [sic] alternative design."

Infuse"); 12 ("the case at hand revolves around fraudulent (and untruthful) off-label promotion by MEDTRONIC"). To the extent that Plaintiffs are suggesting that a claim premised on *truthful* off-label promotion is not preempted, *see* Doc. 36 at 10, the Court disagrees. Such a claim would be impliedly preempted because, even if off-label promotion were prohibited under the FDCA, Plaintiffs have failed to identify a state law duty to refrain from off-label promotion, *see Schouest*, 13 F. Supp. 3d at 705 ("Mere 'off-label' promotion, divorced from any negligent or fraudulent misrepresentations, would likely not run afoul of state tort law.").

Compl. ¶¶ 301, 303. Accordingly, to prevail on this claim, Ms. Byrnes necessarily would have to prove that Medtronic should have employed a design different from the one approved by the FDA—the consequence of which would be to impose requirements that are "different from, or in addition to" the federal requirements.

Plaintiffs contend that the design defect claim is not preempted because they are not arguing that the Infuse device should have been designed differently from that approved by the FDA through the PMA process, but rather that Infuse was defectively designed for the off-label use that Medtronic had been promoting. The Court is not persuaded. The first step of the *Riegel* test requires a court simply to determine whether the federal government has established requirements applicable to the *medical device*, not whether the federal government has established requirements applicable *to a specific use* of the medical device. *See Riegel*, 552 U.S. at 321. And the second step of the *Riegel* test requires a court simply to determine whether the state law claims would impose requirements that are different from, or in addition to, the federal ones that relate to safety and efficacy. *See id.* at 321-22. The design defect claim clearly meets both prongs.

To the extent Plaintiffs rely on *Ramirez*, 961 F. Supp. 2d 977, 999 (D. Ariz. 2013), which held that such a claim was not preempted, the Court begins by noting that *Ramirez* is not binding authority. More importantly, the Court disagrees with the reasoning in *Ramirez*, and therefore declines to follow it. *Ramirez*'s holding draws a distinction not only between on-label and off-label use, but also between off-label use that has been promoted and off-label use that has not been promoted. *See id.* However, such a fine distinction appears nowhere in *Riegel*'s preemption test, and, as noted by Medtronic, is patently illogical—adopting this standard would result in a design defect claim being preempted if a doctor were to unilaterally decide to use a device in an off-label

manner, but not being preempted if off-label promotion induced the doctor to use the device in the exact same manner.

Accordingly, the Court finds that the Third Cause of Action is expressly preempted, and will dismiss it with prejudice.

4. Misrepresentation (Fourth Cause of Action)

Medtronic argues that Ms. Byrnes' strict products liability claim for misrepresentation is preempted, and that even if it is not, it must be dismissed pursuant to comment k to Section 402A of the Restatements (Second) of Torts.[3] The Court agrees in part and disagrees in part. For the reasons discussed in Section III.C.1, *supra*, this claim is preempted to the extent it relies on any failure-to-warn theory. Because this claim also contains allegations of affirmative misrepresentations, however, it is not preempted in its entirety, also for the reasons discussed in Section III.C.1, *supra*. Moreover, Medtronic has failed to establish that, for purposes of the motion to dismiss, it is entitled to a defense based on comment k to Section 402A of the Restatements (Second) of Torts. Comment k, which has been adopted by Florida courts as an affirmative defense to a strict products liability claim for medical devices, *see Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728, 733 (Fla. 2d DCA 1991), essentially provides that a medical device manufacturer escapes strict liability for "unavoidably unsafe products" if it can demonstrate that the device was (1) incapable of being made safe; (2) properly prepared and marketed; and (3) accompanied by a proper warning, *see* comment k, Restatement (Second) of Torts § 402A; *see also Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1520 (S.D. Fla. 1990). Although Plaintiffs do not dispute that the first element has been met, *see* Compl. ¶ 64 ("Class III devices pose the greatest risk of death

[3] Because these are the only grounds for dismissal advanced by Medtronic and briefed by the parties, the Court assumes, without deciding, that such a claim is otherwise cognizable under Florida law.

or complications . . . . Infuse® is a Class III device"), and cannot challenge the third element because such a claim would be expressly preempted, *see* Section III.C.1, *supra*, their allegations that Medtronic made affirmative misrepresentations in promoting the off-label use of Infuse undermine the second element, that the product was properly marketed.

Nevertheless, for the reasons discussed in Section III.C.1, *supra*, to the extent this claim is not preempted, it has been inadequately pleaded. Accordingly, the Court will dismiss the Fourth Cause of Action, but will also grant Plaintiffs leave to amend.

5. Negligence (Fifth Cause of Action)

Ms. Byrnes' negligence claim appears to be premised on several theories: (1) Medtronic's promotion and marketing of Infuse for off-label use; (2) Medtronic's failure to warn physicians and Ms. Byrnes of the dangers of the off-label use of Infuse; (3) Medtronic's failure to comply with federal law and regulations; and (4) Medtronic's failure to exercise reasonable care to prevent Infuse from creating an unreasonable risk of harm to Ms. Byrnes and other consumers. Compl. ¶ 329. Each of these grounds, as alleged, is preempted. *First*, to the extent the negligence claim is premised on a failure-to-warn theory (grounds 2 and 4), it is expressly preempted. *See* Section III.C.1, *supra*. *Second*, to the extent that the claim is premised on the mere fact that Medtronic engaged in off-label promotion (ground 1), it is impliedly preempted, because Plaintiffs have not identified any state law duty to refrain from truthful off-label promotion and have not alleged any affirmative misrepresentations. *See supra* note 2. *Finally*, to the extent that the claim is premised on Medtronic's failure to comply with federal law and regulations (ground 3), it is impliedly preempted. *See* Section III.C.1, *supra*.

Although this claim, as pleaded, is preempted, the Court will give Plaintiffs an opportunity to amend to assert a claim that falls in the narrow gap through which a plaintiff's state-law claim

must fit if it is to escape express or implied preemption. Accordingly, the Court will dismiss this claim, but without prejudice.

6. Breach of Express Warranty Claim (Sixth Cause of Action)

Medtronic argues that Ms. Byrnes' breach of express warranty claim is preempted because to prevail on that claim, Plaintiffs must prove that Infuse was not safe and effective as labeled. And, according to Medtronic, such a finding would impose requirements different from or in addition to those imposed by the FDA.

The Court disagrees. As the Complaint makes clear, Ms. Byrnes' breach of warranty claim is premised on voluntary, affirmative (but false) warranty statements made by Medtronic, aside from any FDA-approved label or warning, to promote the off-label use of Infuse. *See, e.g.*, Compl. ¶ 339. And, as Plaintiffs note, "[f]ederal law already requires Medtronic to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Brady*, 2014 WL 1377830, at *8 (quotation marks, alterations, and citations omitted); *see also* 21 U.S.C. § 331(b). A state law requirement that holds medical manufacturers to the voluntary express warranties it makes during off-label promotion therefore would not impose requirements different from, or in addition to, the federal requirements. *Accord id.* Moreover, such a claim is not impliedly preempted because it stands independently under Florida state law, and does not seek simply to enforce the requirements of the FDCA. *Accord id.*

The Court declines to follow the cases cited by Medtronic, because they are not binding, and because they fail to convincingly address why such a state law requirement would be different from, or in addition to, the federal requirements. For example, the court in *Gavin v. Medtronic, Inc.*, Case No. 12-cv-851, 2013 WL 3791612, at *15-16 (E.D. La. July 19, 2013), cited *Gomez v. St. Jude Med. Daig Division Inc.*, 442 F.3d 919 (5th Cir. 2006), to hold that the plaintiff's breach

of express warranty claim was preempted. *Gomez*, however, did not deal with warranties made in the off-label promotion of a medical device; rather, its preemption holding was based on the fact that "[the] express warranty was part of the IFU, which is itself part of the PMA process." *Gomez*, 442 F.3d at 932. *See also Caplinger v. Medtronic*, 921 F. Supp. 2d 1206, 1222 (W.D. Okla. 2013) (holding that the plaintiff's breach of express warranty claim was preempted because it would require a plaintiff to "persuade a jury that the Infuse Device was not safe and effective . . . contrary to the FDA's approval," but failing to address the fact that the FDA did not approve the off-label use).

Although the Court finds that the breach of express warranty claim is not preempted, the Court nevertheless agrees with Medtronic that this Cause of Action must be dismissed because Plaintiffs' allegations are insufficient. Indeed, Plaintiffs have failed to allege specifically what affirmations of fact were made by Medtronic to Dr. Small, or how those express warranties proximately caused Ms. Byrnes' injury. *See* Compl. ¶¶ 339, 342 (with regard to the alleged express warranties, asserting only that Medtronic made them to unspecified "physicians and other members of the general public and medical community"; and, with regard to causation, alleging only that "Defendants thus breached their express warranty which was a direct and proximate cause of Plaintiff's injuries and damages."); Fla. Stat. § 672.313(1)(a) ("Express warranties by the seller are created as follows: 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 . . . .") (emphasis added).

The Court will therefore dismiss this Cause of Action, but will also grant Plaintiffs leave to amend to cure any defects in the pleadings.[4]

[4] To the extent Medtronic argues that this claim fails because Infuse's FDA-approved label expressly disclaims any warranties, *see* Doc. 32 at 34, the Court rejects this argument as a basis for dismissal. In ruling on a motion to dismiss, a court must accept all the allegations of the

7. Loss of Consortium (Ninth Cause of Action)

Because all of Ms. Byrnes' Causes of Action have now been dismissed, *see also* Doc. 55, the Court must also dismiss Mr. Byrnes' claim for loss of consortium. *See Gates v. Foley*, 247 So. 2d 40, 45 (Fla. 1971) (a claim for loss of consortium is derivative and may proceed "only if [the spouse] has a cause of action against the same defendant"). However, because the dismissal of some of Ms. Byrnes' claims against Medtronic are without prejudice, the dismissal of Mr. Byrnes' loss of consortium claim is also without prejudice.

8. Punitive Damages

As is clear from the above discussion, all of Plaintiffs' substantive causes of actions must be dismissed. Accordingly, Plaintiffs' claim for punitive damages must also be dismissed. *See Oliveira v. Ilion Taxi Aero LTDA*, 830 So. 2d 241, 242 (Fla. 4th DCA 2002). The dismissal of Plaintiffs' claim for punitive damages is without prejudice. The allegations in the Amended Complaint will control any determination by the Court as to whether Plaintiffs have adequately alleged a basis for punitive damages.

IV. CONCLUSION

Many courts have addressed issues that are nearly-identical, if not identical, to the ones currently before this Court. Many have reached conclusions that differ in a multitude of ways, and cannot be reconciled easily, if at all. Having conducted an exhaustive review of those opinions and the reasoning behind them, the Court has applied the general principle that claims premised on voluntary, affirmative falsehoods are not preempted. *Accord Buccelli v. Mayer*, Case No. 2014-CA-1667, Order on Motion to Dismiss of Defendants Medtronic, Inc. and Medtronic Sofamore

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complaint as true, and draw all reasonable inferences in favor of the non-moving party. Accordingly, this argument is premature.

Danek USA, Inc. (Fla. Cir. Ct. 12th Jud. Cir. Jan. 27, 2015) (Doc. 71-1). However, even though some of Ms. Byrnes' claims are not preempted under this principle, they still must be dismissed, because they have not been pleaded with sufficient specificity.

Accordingly, it is hereby **ORDERED**:

1. Medtronic's Motion to Dismiss (Doc. 32) is **GRANTED**.
2. Plaintiffs' Second and Third Causes of Action are **DISMISSED with prejudice**.
3. Plaintiffs' First, Fourth, Fifth, Sixth, and Ninth Causes of Action are **DISMISSED without prejudice**.
4. Plaintiffs' request for punitive damages is **DISMISSED without prejudice**.
5. Plaintiffs are granted leave to file an Amended Complaint within fourteen (14) days from the date of this Order which cures the deficiencies identified in this Order.

DONE AND ORDERED in Tampa, Florida on March 18, 2015.

Charlene Edwards Honeywell
Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any