UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

PEGGY MCCLELLAND as Personal Representative of the Estate of Breanne A. McClelland,

Plaintiff,

v. CASE NO. 6:11-CV-1444-Orl-36KRS

MEDTRONIC, INC., a foreign corporation,

Defendant.
_____/

ORDER

This cause comes before the Court on the Defendant Medtronic, Inc.'s ("Defendant") Motion to Dismiss Plaintiff Peggy McClelland's ("Plaintiff") Amended Complaint (Doc. 24). Plaintiff filed a Response in opposition to Defendant's Motion to Dismiss (Doc. 26). With leave of the Court, Defendant filed a Reply to Plaintiff's Response (Doc. 30). For the following reasons, Defendant's Motion to Dismiss will be granted.

BACKGROUND[1]

I. Statement of Facts

Breanne McClelland ("the Decedent") was a resident of Orange County, Florida until her death on August 11, 2011. *See* Doc. 20 ¶ 1. Plaintiff is the Decedent's mother and the duly appointed personal representative of the Decedent's Estate. *Id*. at ¶ 2. Defendant is a corporation

[1]The following statement of facts is derived from Plaintiff's Amended Complaint (Doc. 20), the allegations of which the Court must take as true in ruling on a motion to dismiss. *See Quality Food de Centro America, S.A. v. Latin American Agribusiness Development Corp. S.A.*, 711 F.2d 989, 994 (11th Cir. 1983).

operating under the laws of Minnesota, that "researches, develops, tests, manufactures, markets, promotes, advertises, and sells medical devices." *Id.* at ¶¶ 4, 6. Defendant's largest business segment, Cardiac Rhythm Disease Management ("CDRM"), develops products that restore and regulate heart rhythm as well as improve the heart's pumping function. *Id.* at ¶ 6.

In March 2004, Defendant received premarket approval ("PMA") from the United States Food and Drug Administration ("FDA") for the EnPulse pacemaker Model E1DR21 ("E1DR21"). *Id.* at ¶ 8. On or about April 30, 2004, the E1DR21 was surgically implanted inside Breanne McClelland. *Id.* at ¶ 9. Plaintiff alleges that prior to 2009, Defendant had become aware that several of its implantable pulse generators, including the E1DR21, were defective and " . . . likely to cause intense cardiac symptoms and fail to properly regulate cardiac rhythm." *Id.* at ¶ 10.

The Decedent consulted with her cardiologist about recurrent heart palpitations on or about July 22, 2009. *Id.* at ¶ 13. On that date, her cardiologist interrogated and reprogrammed the Decedent's E1DR21, in part due to evidence of atrial under-sensing. *Id*. On or about August 10, 2009, the Decedent informed her cardiologist's office that she was once again suffering from recurrent heart palpitations. *Id.* at ¶ 14. Pursuant to these concerns, the Decedent scheduled an appointment with her cardiologist on August 11, 2009. *Id.* at ¶ 15. On that date, the Decedent's E1DR21 was again interrogated and reprogrammed. *Id*. Upon returning home from the doctor's appointment, the Decedent continued experiencing chest pains and heart palpitations. *Id.* at ¶ 16. Within hours, the Decedent became lethargic, weak and gasped for air, which prompted Plaintiff to drive her to the hospital. *Id*. On the way there, the Decedent became unresponsive and died shortly thereafter. *Id*. On August 12, 2009, one of Defendant's representatives performed an interrogation of the Decedent's E1DR21 and determined that in addition to other deficiencies, her pacemaker had

failed her. *Id.* at ¶ 17. Approximately eighteen months after the Decedent's death, Defendant issued a Class 2 Recall of many models of its implantable pulse generators, including the E1DR21. *Id.* at ¶ 18. After this recall, Defendant released a software update to reprogram the defective devices that were recalled. *Id*.

II. Procedural History

Defendant removed this case based on diversity jurisdiction under 28 U.S.C. § 1332 (Doc. 1). Thereafter, Plaintiff filed a two-count Amended Complaint against Defendant: (1) Count 1 - negligence *per se*; and (2) Count II - failure to warn. *See* Doc. 20. Plaintiff asserts that "[b]y failing to notify the FDA, patients, or physicians of the defect in the [E1DR21], [Defendant] violated FDA regulations and misrepresented the safety of the device, and negligently marketed, advertised, and promoted the device as a safe device to be used for the treatment of patients who needed heart rhythm regulation." *Id.* at ¶ 26. Defendant filed a Motion to Dismiss Plaintiff's Amended Complaint. (Doc. 24), asserting: (1) that the Amended Complaint fails to state a cause of action recognized under Florida law and (2) that Plaintiff's claims are expressly and impliedly preempted.

Both the Plaintiff and the Defendant refer to and attach to their memoranda public records of the FDA, which relate to the medical device involved in this case. Because matters in the public record are susceptible to judicial notice and consideration in resolving a motion to dismiss, the Court has considered these public records. *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002).

STANDARD

To survive a motion to dismiss, a pleading must include a "short and plain statement showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868

(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, et al. v. Twombly, et al.*, 550 U.S. 544, 555 (2007)). Mere naked assertions, too, 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 555). "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*. at 1950. Therefore, "only a claim that states a plausible claim for relief survives a motion to dismiss." *Id*. (citation omitted).

ANALYSIS

I. Statutory Framework of the Medical Device Amendments

The regulation of medical devices entering into the market is governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The FDCA 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 Medical Device Amendments of 1976 ("MDA"), which amended the FDCA and imposed a regime of detailed federal oversight. 21 U.S.C. § 360c *et seq*. The new regulatory regime separated medical devices into three classes based on the risks each pose to the public. *Id.*; *See Riegel v. MedTronic, Inc.*, 552 U.S. 312, 316 (2008); *U.S. 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 those 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)).

A. Premarket Approval Pursuant to the MDA

All Class III devices must undergo the "rigorous" premarket approval process by the FDA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Premarket approval 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, premarket approval is only granted 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 premarket approval, 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 premarket approval, which is evaluated under identical criteria as the initial application. *Id*. (citing 21 U.S.C. § 360e(d)(6)). Moreover, after premarket approval, manufacturers are subject to reporting requirements such as the obligation to inform the FDA of new clinical investigations or scientific studies, 21 C.F.R. § 814.84(b)(2), and 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.

B. Preemptive Effect of the MDA

Until the statutory enactment of the MDA, the introduction of new medical devices was left largely for the states to supervise as they saw fit. *See 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 suggests that the MDA's preemption of certain state obligations in favor of more detailed federal oversight is 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 n. 5. The Supreme Court also noted that "[s]tate 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 only state requirements different from, or in addition to, any requirements applicable . . . to the device under federal law." *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *Riegel*, 552 U.S. at 312). 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 claims premised on violations of FDA regulations that "parrallel," rather than add to federal requirements are not preempted. *Wolicki-Gables*, 634 F.3d at 1300 (quoting *Riegel*, 552 U.S. at 330). In *Wolicki-Gables*, the Eleventh Circuit cites a Seventh Circuit case which elucidates the parallel claim principle:

> 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.

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

II. Adequacy of Plaintiff's Amended Complaint

Plaintiff's Amended Complaint asserts two counts against Defendant: negligence *per se* ("Count I") and failure to warn ("Count II"). *See* Doc. 20. Both Counts allege that Defendant's failure to promptly and accurately report incidents and problems with the E1DR21 to the FDA violated 21 U.S.C. § 360i; 21 C.F.R. § 803.50(a); 21 C.F.R. § 806.10(a); 21 C.F.R. § 814.84(a); and 21 C.F.R. §§ 820.198(a), (c) . *Id*. Defendant argues that Plaintiff's Amended Complaint must be dismissed because Plaintiff's claims fail to state a claim that is recognized by Florida law and are all expressly and impliedly preempted by federal law. *See* Doc. 24.

A. Failure to State a Claim

Defendant asserts that Plaintiff's claims must be dismissed because Plaintiff fails to sufficiently plead her claims as Florida law does not recognize a cause of action for a violation of the FDCA. *See* Doc. 24, pp. 8, 13-16. Plaintiff contends that such a cause of action exists, if not for negligence *per se*, at least for negligence and she should be allowed to amend her complaint accordingly. *See* Doc 26, pp. 13-14.

With regard to Florida recognizing a claim, Defendant asserts that "Florida law does not recognize a cause of action for violations of the FDCA or the regulations promulgated thereunder, which is the premise of Plaintiff's two claims." Doc. 24, p. 8. Defendant relies upon *Murthy v. N.*

Sinha Corp., for the proposition that legislative intent should be the primary factor in determining whether a cause of action exists when a statute does not expressly provide for one. 644 So.2d 983, 985 (Fla. 1994). Defendant argues that the FDCA's mandate that all actions to enforce the Act "shall be by and in the name of the United States" precludes a private cause of action under the FDCA. *See* Doc. 24, pp. 8-9 (citing 21 U.S.C. § 337(a)). In support of this argument, Defendant cites *Blinn v. Smith & Nephew Richards, Inc.*, 55 F.Supp.2d 1353 and *Rounds v. Genzyme Corp.*, 2010 WL 5297180 (M.D.Fla. Dec. 20, 2010). In *Blinn*, the court found that under Florida law, the plaintiff could not use a negligence *per se* claim to create a private cause of action for the defendant's alleged violation of the FDCA. 55 F.Supp.2d at 1361. Similarly, in *Rounds*, the court held that the plaintiff's negligence *per se* claims amounted to violations of the FDCA, which Florida law does not recognize or permit. 2010 WL 5297180 at *3 (M.D.Fla. Dec. 20, 2010).

The Court agrees with the Defendant that under Florida law, the violation of a statute can only give rise to civil liability if the statute indicates an intention to create a private cause of action. *Murthy*, 644 So.2d at 985-86. The FDCA expressly provides that all actions to enforce the Act "shall be by and in the name of the United States." 21 U.S.C. § 337(a). This language evidences legislative intent to prohibit a private right of action for a violation of the FDCA. Therefore, Plaintiff cannot assert a negligence *per se* claim based on violations of the FDCA or the FDA's implementing regulations.

Plaintiff's failure to warn claim is similar to her negligence *per se* claim. It is based on Defendant's duty to warn pursuant to the FDCA and FDA regulations. *See* Doc 20, ¶¶ 38-44. This claim is not based on the common law. In essence, Plaintiff recast her negligence *per se* claim as

a failure to warn claim. Therefore, for the reasons discussed, *supra*, Plaintiff's failure to warn claim also fails to state a cause of action.

B. Express Preemption

Defendant argues that even if Plaintiff's claims are sufficiently pled, the claims are nonetheless expressly preempted because they satisfy both prongs of *Riegel*. *See* Doc. 24, pp. 16-22. Plaintiff contends that her claims are not preempted because they parallel requirements imposed by federal law. *See* Doc 26, pp 7 - 12.

In *Riegel*, the Supreme Court used a two-part test to determine whether a state claim was preempted: (1) determine whether the federal government has established requirements applicable to the medical device, and if so, (2) 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. Since, the PMA imposes device-specific requirements under the MDA, medical devices approved through the PMA automatically satisfy the first prong of the *Riegel* test. *Id*. at 322-23. Therefore, the question is whether Plaintiff's claims seek to impose state law requirements that are in addition to or inconsistent with those imposed by the EnPulse PMA.

Plaintiff's Amended Complaint asserts causes of action for negligence *per se* and for failure to warn. *See* Doc. 20. Plaintiff asserts that "unlike many states, Florida recognizes a cause of action for strict liability failure to warn." Doc. 26, p. 10. Manufacturers are required by Florida law to warn of risks which are discoverable in light of the generally recognized and prevailing best knowledge available and are strictly liable for their failure to do so. *Id*. at 10-11 (quoting *Ferayorni*

v. Hyundai Motor Corp., 711 So.2d 1167, 1172 (Fla. 4th DCA 1998) (internal citations omitted)[2]. Plaintiff further asserts that these violations of federal regulatory requirements constitute negligence per se under Florida tort principles. *Id.* at 11; *see also deJesus v. Seaboard Coast Line R. Co.*, 281 So.2d 198, 201 (Fla. 1973) (finding violation of statutes imposing strict liability are negligence per se). Both of Plaintiff's causes of action are premised upon allegations that Defendant failed to provide adequate warning to the Decedent and her physician by failing to accurately report, or report at all, adverse incidents regarding the defect with the E1DR21, in violation of the reporting requirements imposed on it by the FDA as a condition of the device's PMA.

"To establish strict liability failure to warn, a plaintiff must prove that the defendant is a manufacturer or distributor of the product at issue and the defendant did not adequately warn 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. Crossman Corp.*, 289 F.Supp.2d 1337, 1347 (M.D.Fla. 2003) (citing *Ferayorni*, 711 So.2d at 1172). "In determining the adequacy of the warning, the critical inquiry is whether it is adequate to warn the physician of the possibility that the [medical device] caused the injury by the plaintiff." *Wolicki-Gables v. Arrow Intern., Inc.*, 641 F.Supp.2d 1270, 1286, aff'd., 634 F.3d 1296 (11th Cir. 2011) (citing *Upjohn v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990).

Plaintiff's claims meet the second prong of *Riegel*. Each of the regulations cited in Plaintiff's Amended Complaint discuss manufacturer reporting requirements to the FDA, not physicians or patients. *See* 21 U.S.C. § 360i; 21 C.F.R. § 803.50(a); 21 C.F.R. § 806.10(a); 21

[2]Reversed and remanded in *Hyundai Motor Co. v. Ferayorni*, 795 So.2d 126 (Fla. 4th DCA 2001) (decision quashed and cause remanded in *Ferayorni v. Hyundai Motor Co.*, 822 So.2d 502 (Fla. 2002)).

C.F.R. § 814.84(a); and 21 C.F.R. §§ 820.198(a), (c). Even if Defendant breached a state law duty to warn the decedent or her physician, Plaintiff has not directed the Court to any FDA regulation that requires a device manufacturer to unilaterally contact doctors or patients regarding a potential device defect without FDA involvement. *See e.g. Leonard v. MedTronic, Inc.*, 2011 WL 3652311 at *9 (N.D.Ga. 2011) ("Given that Plaintiffs have not identified any federal law requiring manufacturers to warn individual doctors about the safety and effectiveness of a device, their claim would hold [Defendant] liable under state law without having violated an equivalent federal law."); *Franklin v. Medtronic, Inc.*, 2010 WL 254379 at *6 (D.Colo. 2010) (same). Under Plaintiff's theory of liability, Defendant would be required to provide information to physicians and patients beyond those on the device's labeling. Accordingly, the state and federal requirements are not "genuinely equivalent" because Defendant could be held liable under the state law without having violated the federal law. *Wolicki-Gables*, 634 F.3d at 1300. In other words, Plaintiff's claims are preempted because they seek to impose state law requirements in addition to or inconsistent with those imposed by the EnPulse PMA . *Riegel*, 552 U.S. at 321-22. Plaintiff's Amended Complaint will be dismissed as she has failed to plead a non-preempted claim.

C. Implied Preemption

In addition to being expressly preempted, Defendant argues that Plaintiff's claims are also impliedly preempted because they are based on Defendant's alleged breach of federal disclosure rules. *See* Doc. 24, pp. 22-25. Plaintiff contends that her claims are not preempted because the essence of her claims is that Defendant breached a duty to her and not a duty to the FDA. *See* Doc. 26, pp. 17 - 20.

As discussed above, the MDA provides that all actions to enforce the FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiff's Legal Committee*, the Supreme Court construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." 531 U.S. 341, 349 n. 4 (2001). In other words, claims based upon FDCA disclosure requirements, rather than traditional state tort law are impliedly preempted. *Id*. at 352-353; *see e.g. In re Medtronic, Inc. v. Sprint Fidelis Leads Products Liability Litigation*, 592 F.Supp.2d 1147, 1160-61 (D.Minn. 2009) (finding claims that a defendant violated the FDCA by failing to inform the FDA in a timely fashion of adverse events necessarily fail "because no private right of action exists under the FDCA.").

To the extent Plaintiff's Amended Complaint is construed as alleging the breach of a duty to the Decedent and not the breach of a duty to the FDA, the principles outlined in *Buckman* are not implicated in this case. Though this fact is ultimately fatal to Plaintiff's claim, as it supports express preemption, it nonetheless falls outside of the realm of implied preemption.

To the extent Plaintiff's Amended Complaint is construed as alleging the breach of a duty to the FDA, it is impliedly preempted. Plaintiff appears to allege violations of the FDCA and FDA. See Doc. 20, ¶ ¶ 29, 31, 40 - 42. It is clear that the United States rather than private litigants are authorized to file suit for noncompliance with the medical device provisions.

III. Conclusion

Plaintiff's state law causes of action are expressly preempted as they fail to sufficiently allege a parallel claim. Rather, they seek to impose state law requirements which are in addition to or inconsistent with those requirements imposed by the EnPulse PMA. Additionally, Plaintiff's claims are dismissed because Florida does not recognize a cause of action for a violation of the

FDCA. Further, to the extent Plaintiff alleges the breach of a duty to the FDA, Plaintiff's claims are impliedly preempted.

Accordingly, it is hereby **ORDERED and ADJUDGED**:

1. Defendant Medtronic, Inc.'s Motion to Dismiss Plaintiff's Amended Complaint (Doc. 24) is **GRANTED**.

2. Plaintiff Peggy McClelland's Amended Complaint (Doc. 20) is **DISMISSED**. Although the Court recognizes that, pursuant to *Riegel* and *Buckman*, a narrow gap exists for a plaintiff's state law claim if it is to avoid express or implied preemption, per her request, Plaintiff is granted leave to file a Second Amended Complaint within **fourteen (14) days** from this Order which cures the deficiencies addressed in this Order.

3. Defendant's Unopposed Motion for Leave to File Supplemental Authority (Doc. 42) is **DENIED**, as moot.

DONE AND ORDERED at Orlando, Florida on September 27, 2012.

Charlene Edwards Honeywell

Charlene Edwards Honeywell
United States District Judge

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