IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

KARNESHIHA LEONARD, Individually, and as Administrator of the Estate of Lorenzo Leonard, Deceased, CHRISTOPHER LEONARD, YOLANDA WILSON, as Legal Guardian of SHAKIYA RICKS, and JUSHONDA RICKS,

Plaintiffs,

v.

MEDTRONIC, INC.,

Defendant.

CIVIL ACTION NO.
1:10-CV-03787-JEC

ORDER and OPINION

Before the Court is defendant's Motion to Dismiss [5] this case pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Upon review of the parties' arguments and the record, determines that defendant's motion is meritorious. Nevertheless, given the plaintiffs' request to amend their complaint, the Court **DENIES without prejudice** defendant's motion [5].

BACKGROUND

The facts, viewed in the light most favorable to Plaintiffs, are as follows. Plaintiffs are heirs of Lorenzo Leonard

("Leonard"), who is deceased. (Plaintiffs' Complaint [1] at ¶ 5.) Defendant Medtronic, Inc. manufactures and sells implantable cardiac defibrillators ("ICDs").[1] (*Id.* at ¶ 2.) On February 14, 2003, Leonard was implanted with Medtronic's Marquis VR, Model 7230 ICD ("Marquis 7230 ICD"). (*Id.* at ¶ 5.) In February 2005, Medtronic recalled four ICD models, including the model Leonard had, because of a potential battery shorting problem which could cause the device to fail or malfunction. (*Id.* at ¶¶ 54, 57-58.) On November 17, 2007, Leonard was admitted to The Medical Center in Columbus, Georgia. (*Id.* at ¶ 78.) Leonard stated he had felt a spasm and chest pain, and that his ICD "went off" for the first time. (*Id.*) Leonard's ICD fired three times. (*Id.*) On November 20, 2007, while Leonard was still in the hospital, Medtronic reviewed and adjusted his ICD but did not tell him that his device had been recalled. (*Id.*)

Plaintiffs filed this action against Medtronic on November 17, 2010. The complaint raises eight common law claims under Georgia law: (1) negligence; (2) strict liability for a design and manufacturing defect; (3) negligence per se; (4) strict liability

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[1] "ICDs are implantable, silver-dollar size, highly-technical electronic devices designed to detect, and almost-instantaneously treat, ventricular tachycardia, or fibrillation, a life-threatening condition. A properly functioning ICD administers an electrical pulse which reestablishes a regular heartbeat." *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1091 (D. Minn. 2008).

for failure to warn; (5) breach of implied warranty; (6) breach of express warranty; (7) misrepresentation by omission; and (8) unjust enrichment.

Medtronic has filed a motion to dismiss the complaint pursuant to FED. R. CIV. P. 12(b)(6). Medtronic asserts three grounds for dismissal: (1) the complaint is inadequately pled; (2) the claims are untimely under Georgia's two-year statute of limitations; and (3) the claims are preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") under 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The Court will discuss each ground in turn.

DISCUSSION

I. Adequacy of Complaint

A proper pleading requires a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A pleading that fails "to state a claim upon which relief can be granted" is subject to dismissal under Rule 12(b)(6). FED. R. CIV. P. 12(b)(6). The amount of facts necessary to defeat a motion to dismiss must be enough to make the claim "plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570

(2007).[2] A claim is facially plausible if the court can draw a reasonable inference from the factual allegations that the defendant is liable for the alleged wrongdoing. *Ashcroft v. Iqbal*, ___ U.S. ___, ___, 129 S. Ct. 1937, 1949 (2009). A claim is not facially plausible if it shows only "a sheer possibility that a defendant has acted unlawfully." *Id.* Although a court must accept the complaint's factual allegations as true, this tenet does not apply to legal conclusions. *Id.* The Supreme Court has incorporated these principles into a two-step process when analyzing a motion to dismiss: "1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, 'assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir. 2010) (quoting *Iqbal*, 129 S. Ct. at 1950).

Applying this approach, the Court may disregard most of plaintiffs' allegations in the complaint as unsubstantiated legal

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[2] Plaintiffs mistakenly argue that "[a] complaint should not be dismissed for failure to state a claim unless the plaintiff can prove no set of facts entitling him to relief." (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 4.) *Twombly* retired the "no set of facts" test previously used by the Supreme Court, referring to it as "an incomplete, negative gloss on an accepted pleading standard." *Id.* at 562-63; *Speaker v. U.S. Dep't of Health and Human Servs. Ctrs. for Disease Control and Prevention*, 623 F.3d 1371, 1380 (11th Cir. 2010).

conclusions. For example, plaintiffs allege in Count One that "[d]efendant carelessly manufactured, marketed, distributed, and sold" defective ICDs, and that Defendant negligently used a manufacturing process that "did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices." (Pls.' Compl. [1] at ¶¶ 71-72). This count does not specify any particular federal standard the manufacturing process violated or state how Medtronic violated that standard. Further, plaintiffs fail to allege any facts linking Medtronic's alleged violations of the premarket approval standards to Leonard's injuries. Plaintiffs mention earlier in their complaint that the ICD at issue was recalled because of a battery shorting problem, but plaintiffs never allege that Leonard's ICD battery malfunctioned or that a battery failure caused his injuries. Thus, they fail to plead any facts that would lead the Court to infer plausibly that Medtronic's alleged noncompliance with the FDA premarket approval standards caused Leonard harm.

The rest of plaintiffs' claims similarly suffer from a lack of well-pleaded facts. In Count Two, plaintiffs re-allege that Medtronic manufactured an unreasonably dangerous product for which it is strictly liable. In Count Three, plaintiffs assert that Medtronic was negligent per se for violating the adulteration and misbranding provisions of the FDCA. In Count Four, plaintiffs claim

Medtronic failed to provide timely and adequate warnings about the manufacturing and design defects. In Counts Five and Six, plaintiffs allege that Medtronic breached an implied and express warranty that its products are safe and fit for their intended use. In Count Seven, plaintiffs state that Medtronic misrepresented the ICD's mechanical soundness and reliability by concealing its known defects from the public. In Count Eight, plaintiffs allege that Medtronic unjustly benefitted from Leonard's payment for an ICD that was not safe or medically effective.

All of these allegations are nothing more than "naked assertions devoid of further factual enhancement." *Iqbal*, 129 S. Ct. at 1949 (quotation marks and citation omitted). As part of their formulaic recitation of the causes of action, plaintiffs conclude Counts One through Seven with the bare allegation that Leonard suffered injuries and died as "a direct and proximate result of Defendant's conduct." (Pls.' Compl. [1] at ¶¶ 76, 84, 89, 95, 101, 107, 114.) However, as the Supreme Court has instructed, Rule 8(a) "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 129 S. Ct. at 1949.

Once the complaint's conclusory statements and formulaic recitations are excluded, the terse factual allegations contained in the complaint do not satisfy Supreme Court standards. The only facts mentioned about Leonard are that he was implanted with a

Medtronic ICD in February 2003 and he experienced chest pain in November 2007, at which time his ICD fired three times and was reviewed and adjusted by Medtronic. There is no allegation that the ICD improperly fired during the November 2007 incident or that the ICD injured Leonard at that time. In fact, the complaint never alleges that Leonard's ICD malfunctioned at any time. Although the complaint alleges that Leonard died as a result of Medtronic's conduct, the complaint fails to disclose when Leonard died, why he died, or how his death in any way relates to his ICD or Medtronic's actions. Even accepting plaintiffs' factual allegations as true, the Court cannot plausibly infer that Medtronic is liable for the alleged misconduct. *See id.* at 1952 (concluding the complaint required more factual content in order to transform the claim "'from conceivable to plausible'"); *Twombly*, 550 U.S. at 555 (explaining that while a complaint "does not need detailed factual allegations," the allegations "must be enough to raise a right to relief above the speculative level").

In plaintiffs' response to Medtronic's motion to dismiss, they allege for the first time that Leonard suffered pain on November 30, 2008 when his ICD constantly misfired, causing his heart to respond in a tachycardia, and that he died that same day after going into cardiac arrest. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 5.) Plaintiffs assert, without specific citation to the complaint, that

the complaint makes these allegations. But these allegations appear nowhere in the complaint. As pled, none of their claims pass muster as they all fail to state a plausible claim for relief under Rule 8(a). *See Twombly*, 550 U.S. at 555, 570; *Iqbal*, 129 S. Ct. at 1949. Accordingly, all of plaintiffs' claims are due to be dismissed.

II. Timeliness of Complaint

As this case is a diversity action, the Court must apply Georgia's statute of limitations to determine whether the complaint is timely. *See Cambridge Mut. Fire Ins. Co. v. City of Claxton*, 720 F.2d 1230, 1232 (11th Cir. 1983) ("[S]tate statutes of limitations are substantive laws and must be followed by federal courts in diversity actions."). Georgia law requires that "[a]ctions for injuries to the person shall be brought within two years after the right of action accrues . . . ." O.C.G.A. § 9-3-33; *see also Smith, Miller and Patch v. Lorentzson*, 254 Ga. 111, 112 (1985) (applying O.C.G.A. § 9-3-33 to products liability claims based on personal injuries); *Daniel v. Am. Optical Corp.*, 251 Ga. 166, 167 (1983) (holding that O.C.G.A. § 9-3-33 applies to personal injury actions brought under theories of strict liability and negligence). A cause of action accrues "when the plaintiff could first have maintained his or her action to a successful result." *Colormatch Exteriors, Inc. v. Hickey*, 275 Ga. 249, 251 (2002) (brackets, quotation marks, and citation omitted).

Medtronic argues that the complaint is untimely because the latest date specified in the complaint is in November 2007, three years before the complaint was filed in November 2010. Plaintiffs respond that their complaint was filed on November 17, 2010, which is less than two years after Leonard died on November 30, 2008. Although the Court must construe all factual allegations in the complaint as true on a motion to dismiss, *see Iqbal*, 129 S. Ct. at 1949, the date of Leonard's death is not alleged in the complaint itself. Accordingly, as currently pled, the action is untimely because the latest event asserted therein occurred more than two years before the complaint was filed.

III. Preemption

Medtronic's final argument in its motion to dismiss is that all of Plaintiffs' claims are preempted by the MDA. Plaintiffs respond that they have asserted parallel claims which are not subject to preemption.

A. Statutory Framework

Since 1976, the MDA, which are amendments to the Food and Drug Act, has subjected medical devices to detailed federal oversight. *Riegel*, 552 U.S. at 316. As a Class III device, the Marquis 7230 ICD falls into the most strictly regulated category.[3] *Blunt v.*

[3] A Class III device is "'purported or represented to be for a use in supporting or sustaining human life or for a use which is

Medtronic, Inc., 315 Wis. 2d 612, 618 (2009). New Class III devices must undergo a "rigorous" premarket approval process by the FDA. *Riegel*, 552 U.S. at 317 (quotation marks and citation omitted). This process typically involves a multivolume application by the manufacturer, which includes reports of all studies about the device's safety and effectiveness as well as a full description of the manufacturing process. *Id*. at 317-18. "The FDA spends an average of 1,200 hours reviewing each application." *Id*. at 318. After weighing the risks and benefits of the device, the FDA may grant premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id*. (citing 21 U.S.C. § 360e(d)).

Following premarket approval, the FDA continues to oversee the medical device. *Id*. at 319. A manufacturer is prohibited from changing the design, manufacturing process, label, or any other attribute that would affect the device's safety or effectiveness, unless the FDA grants supplemental premarket approval. *Id*. (citing 21 U.S.C. § 360e(d)(6)(A)(I)). Additionally, the manufacturer must report to the FDA any new investigations or studies it knows of about the device and any incidents connecting the device to death or

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of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Riegel*, 552 U.S. at 317 (citing 21 U.S.C. § 360c(a)(1)(C)(ii)).

serious injury. *Id*. The FDA "must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Id*. at 319-20.

The MDA contains the following express preemption clause:

> Except as provided in subsection (b) of this section, no 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). The exception noted in subsection (b) allows exemption of some state and local requirements from preemption. *Riegel*, 552 U.S. at 316.

Riegel established a two-part test for determining if a state-law claim is preempted under § 360k(a). *Id.* at 321-22. A court must first determine whether there are federal law requirements that apply to the device at issue. *Id.* at 321. In *Riegel*, the Supreme Court held that FDA premarket approval for a particular device imposes federal "requirements" for purposes of § 360k. *Id.* at 322-23. Here, Plaintiffs do not contest that the premarket approval for Leonard's ICD imposes federal requirements for that device and therefore satisfies the first prong of *Riegel*'s preemption test.

See id.; see also Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1297-98, 1301 (11th Cir. 2011) (finding that a Class III pump system's premarket approval "imposes specific requirements on it that are sufficient to preempt a state law claim").

Next, a court must decide if the common-law claims are based upon state law "requirements" that are "'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321-22 (citing § 360k(a)). *Riegel* involved state law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of a Class III catheter that had received FDA pre-market approval. *Id.* at 320. All of the plaintiffs' claims related to the safety and effectiveness of the catheter, so the critical inquiry was whether the state claims constituted "requirements" subject to preemption under the MDA. *Id.* at 323. The Supreme Court answered yes. *Id.* at 323-24. "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 325.

Even though state common law claims constitute requirements, they will not be preempted unless they are "'different from, or in addition to,' the requirements imposed by federal law." *Id.* at 330

(citing § 360k(a)(1)). "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Because the claims in *Riegel* alleged the catheter violated state tort law despite compliance with federal requirements, the claims involved state requirements that were different from, or in addition to, federal requirements. *See id.* The *Riegel* plaintiffs belatedly argued that their lawsuit raised parallel claims, but the Supreme Court declined to address that argument. *Id.* Accordingly, the Supreme Court affirmed the dismissal of the plaintiffs' claims as preempted. *See id.* at 320-21, 330.

At issue here is whether the Plaintiffs have sufficiently alleged parallel claims so as to avoid preemption under § 360k and *Riegel*.[4] The Eleventh Circuit recently addressed this issue in *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296 (11th Cir. 2011). In considering whether the plaintiffs had raised a parallel claim, the court noted that a plaintiff "cannot simply incant the magic words" that a defendant has violated federal regulations. *Id.* at

[4] The parties agree that all of Plaintiffs' claims relate to the "safety and effectiveness" of Medtronic's ICD within the meaning of 21 U.S.C. § 360k(a). *See Riegel*, 552 U.S. at 321-22.

1301 (internal citation omitted). Rather, the parallel claims must be specifically stated in the initial pleadings and the plaintiff must allege that the defendant violated a particular federal specification concerning the device at issue. *Id.* To properly allege parallel claims, the complaint must further set forth facts pointing to specific [pre-market approval] requirements that have been violated. *Id.* In short, a bare allegation, devoid of factual detail, that the manufacturing processes did not satisfy the FDA's Pre-Market Approval standards for the device is insufficient to satisfy the requisite elements of a parallel claim, as set forth in *Riegel*. The complaint in *Wolicki-Gables* contained Florida state law claims for strict liability and negligence concerning alleged design and manufacturing defects in a pump system for back pain, as well as a strict liability claim for failure to warn. *Id.* at 1301. The district court determined that each claim was preempted by the MDA and dismissed the claims on summary judgment. *Id.* at 1299. The Eleventh Circuit agreed because none of the claims alleged a failure to comply with a FDA regulation that could be linked to the alleged injury. *Id.* at 1301-02. Accordingly, the Eleventh Circuit concluded that the complaint did not contain the elements of a parallel claim, and the state common law claims were therefore preempted. *Id.* at 1302.

Although the preemption issue in *Wolicki-Gables* arose at the summary judgment stage, rather than pursuant to a Rule 12(b)(6) motion, the Eleventh Circuit's discussion about the pleading requirements for a parallel claim remains instructive here. With these principles in mind, the Court turns to the specific causes of action raised in the complaint.

B. Plaintiffs' Claims

1. Count One–Negligence

In Count One, plaintiffs contend that Medtronic negligently manufactured Leonard's ICD because "the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects(.)" (Pls.' Compl. [1] at ¶ 72.) Besides being a general, conclusory allegation, the complaint does not point to specific premarket approval requirements that have been violated or allege any facts as to how those violations occurred. Without these allegations, Count One amounts to nothing more than the speculative proposition that "full compliance would have resulted in a problem-free device." *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008). Yet, as other courts have recognized, negligence is not the only reason a Medtronic ICD may fail. Other factors such as "medical complications, body rejection phenomena,

allergic reaction, and surgical techniques" can all play a role in its proper operation. *Id.*

Nor does the complaint allege any facts causally linking the alleged violations to injuries or harm suffered by plaintiff Leonard. See *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *10 (D. Colo. May 12, 2010) ("Thus, merely alleging some violation of FDA regulation will not suffice to establish a 'parallel' claim, unless Plaintiff can factually demonstrate that the violation actually caused her injuries."). Plaintiffs allude to Medtronic's recall of ICDs, but never allege in the complaint that Leonard was harmed because his ICD suffered the battery shorting problem that prompted the recall. *Compare Phillips v. Stryker Corp.*, 2010 WL 2270683, at *2, 7 (E.D. Tenn. June 3, 2010) (finding parallel claim raised where complaint alleged plaintiff required surgery because his device had the same manufacturing defect which had caused the device's recall). This causal connection is "a critical element" of a properly pled parallel claim because premarket approval does not mean that a medical device will never result in injuries, only that the benefits outweighs the risks of probable injuries. *Franklin*, 2010 WL 2543579, at *10; *Riegel*, 552 U.S. at 318 (noting approval of a ventricular assist device for children with failing hearts even though the device had less than a 50 percent success rate in keeping those children alive). Accordingly, Count One's unsubstantiated

allegations of FDA violations do not state a proper parallel claim under *Riegel*.[5] *See Wolicki-Gables*, 634 F.3d at 1301; *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (finding that complaint's unsupported allegations that artificial hip implant device did not satisfy the FDA's premarket approval standards "are not sufficient to sustain plaintiff's burden of pleading under *Twombly*"). Accordingly, because Plaintiffs have failed to raise a valid parallel claim, their negligence claim in Count One is preempted under § 360k. *See Wolicki-Gables*, 634 F.3d at 1301-02.

2. Count Two–Strict Liability: Design and Manufacturing Defect

Plaintiffs repeat the same conclusory allegation of an FDA violation in Count Two, *albeit* this time calling the unspecified violation, a strict liability tort. Specifically, plaintiffs state that Medtronic's "manufacturing process for the defibrillators and certain of their components did not satisfy the Food and Drug

[5] Plaintiffs urge the Court to follow *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 840-41 (S.D. Ind. 2009), in which the district court concluded that the plaintiff satisfied *Twombly* merely by alleging that the manufacturing process did not satisfy the FDA's premarket approval standards. The *Hofts* decision has been criticized by several courts for its lax interpretation of *Twombly*'s standards. *See, e.g., Anthony v. Stryker Corp.*, 2010 WL 1387790, at *5 (N.D. Ohio Mar. 31, 2010); *Covert v. Stryker Corp.*, 2009 WL 2424559, at *13 (M.D.N.C. Aug. 5, 2009). More importantly, the Court must apply Eleventh Circuit law, which requires more than a general allegation of an FDA violation to state a valid parallel claim. *See Wolicki-Gables*, 634 F.3d at 1301.

Administration's Pre-Market Approval standards for the devices . . . which resulted in unreasonably dangerous manufacturing defects." (Pls.' Compl. [1] at ¶ 80.) Plaintiffs again allege no facts to identify the particular premarket approval requirements that were violated. The complaint also fails to allege how those requirements were violated, or link any violations to Leonard's alleged injuries and death. Like Count One, Count Two does not raise a valid parallel claim, and it is therefore preempted under § 360k. *See Wolicki-Gables*, 634 F.3d at 1301.

3. Count Three–Negligence Per Se

In Count Three, plaintiffs allege that Medtronic's acts, including designing, manufacturing, labeling, and distributing the recalled ICDs, "constitute an adulteration, misbranding, or both" which is prohibited by the Food and Drug Act. *See* 21 U.S.C. §§ 331(a) and 333(a)(2). (Pls.' Compl. [1] at ¶¶ 87-88.) Plaintiffs further allege that Medtronic's acts constitute a breach of duty subjecting it to civil liability under theories of negligence per se. (*Id.* at ¶ 88.)

In Georgia, a defendant is considered negligent per se based upon violation of a statute if there is evidence that the defendant violated the statute, the injured person was in the class the statute was intended to protect, the injured person suffered the type of harm the statute intended to guard against, and the alleged

negligence per se proximately caused the injuries. *Norman v. Jones Lang LaSalle Americas, Inc.*, 277 Ga. App. 621, 628 (2006). In general, the MDA does not preempt a state law prohibiting the manufacture of adulterated or misbranded devices, unless the state law imposes a substantive requirement--for example, a labeling requirement--that differs from, or adds to, a federal requirement under the MDA. *See* 21 C.F.R. § 808.1(d)(6)(ii) (2008).

Plaintiffs do not, however, allege that Medtronic is negligent per se for violating a state misbranding law. Rather, Count Three alleges that Medtronic violated the FDCA's prohibition against adulteration and misbranding. There is no private right of action for violations of the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."). Instead, all proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Consequently, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA-–that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

For example, the Supreme Court held in *Buckman* that a state-law claim that a defendant made fraudulent statements to the FDA, in violation of FDCA disclosure laws, was impliedly preempted by § 337(a) because the claim "would not be relying on traditional state tort law which had predated the federal enactments in question." *Buckman*, 531 U.S. at 352-53. The same is true here--plaintiffs' claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law. Plaintiffs cannot create a private right of action under the guise of a state law claim. *See Parker*, 584 F. Supp. 2d at 1301 (explaining that plaintiffs "cannot escape preemption by reference to provision of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA"); *accord Franklin*, 2010 WL 2543479, at *8 (concluding that § 337(a) impliedly preempted a negligence per se claim that alleged Medtronic violated the FDCA by selling a misbranded and adulterated ICD). Accordingly, Count Three is impliedly preempted by § 337(a).

4. Count Four–Strict Liability: Failure to Warn

Plaintiffs allege in Count Four that Medtronic "failed in providing timely and adequate warnings or instruction regarding its devices with a known design and/or manufacturing defect." (Pls.' Compl. [1] at ¶ 94.) Additionally, Count Four claims that these

defects render Leonard's ICD "inherently dangerous for its intended use" and that Medtronic is strictly liable to Leonard's heirs for the pain and suffering he suffered as a result of Medtronic's conduct. (*Id.* at ¶¶ 95-96.) In their response, plaintiffs explain that their failure to warn claim is based on a manufacturer's duty under Georgia's learned intermediary doctrine to warn the patient's doctor of dangers involved with a product. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 15.)

This claim is preempted by the MDA. The Eighth Circuit concluded a similar failure to warn claim, about alleged "known defects" associated with a wire in an ICD, was preempted under § 360k:

> In the Master Consolidated Complaint, Plaintiffs alleged that Medtronic failed to adequately warn consumers of "known defects" and that the Sprint Fidelis Leads presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect. These claims are preempted by § 360k. The FDA's [premarket] approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is "different from or in addition to" the federal requirement and therefore preempted. *See Riegel*, 552 U.S. at 330, 128 S. Ct. 999.

In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir. 2010). As in the latter case, plaintiffs do not allege that Medtronic failed to give the FDA-approved

warnings or instructions associated with Leonard's ICD. Nonetheless, plaintiffs contend that Medtronic still violated a state law duty to warn physicians about the ICD's manufacturing and design defects. Plaintiffs' claim would thus impose different requirements under state law than those required under federal law. Consequently, it is preempted under § 360k. *See id.*

Plaintiffs also cannot base a parallel claim on Georgia's learned intermediary doctrine.[6] Even if Medtronic breached a state law duty to warn a physician, plaintiffs have "not pointed the court to any FDA regulation that requires a device manufacturer to unilaterally contact doctors . . . regarding a potential device defect without FDA involvement." *Franklin*, 2010 WL 2543579, at *6. In order to state a parallel claim, the state and federal requirements must be "*genuinely* equivalent." *Wolicki-Gables*, 634 F.3d at 1300 (quotation marks and citations omitted). "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." *Id.* (quotation marks and citation omitted). Given that Plaintiffs have not identified any federal law requiring

[6] Under the learned intermediary doctrine, the manufacturer of a medical device has a duty to give adequate warnings about the device's dangers to the patient's doctor, who serves as a learned intermediary between the manufacturer and the patient. *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253 (2003).

manufacturers to warn individual doctors about the safety and effectiveness of a device, their claim would hold Medtronic liable under state law without having violated an equivalent federal law. Moreover, it would impose a duty under state law that is different from that required under federal law. Accordingly, plaintiffs have failed to raise a parallel claim that escapes preemption under § 360k. *See id.; Franklin*, 2010 WL 2543579, at *6.

5. Count Five–Breach of Implied Warranty

In Count Five, plaintiffs state that Medtronic "impliedly warranted its products to be of merchantable quality and safe and fit for their intended use." (Pls.' Compl. [1] at ¶ 99.) Contrary to this warranty, plaintiffs allege the ICD is unreasonably dangerous and unfit for its intended purpose. (*Id.* at ¶ 100.)

Riegel affirmed the dismissal of this same claim, as preempted under § 360k. *Riegel*, 552 U.S. at 320-21, 330. As the Court explained, state law that requires a device "to be safer, but hence less effective," than the FDA-approved model would interfere with the federal regulatory scheme. *Id.* at 325. In order to avoid preemption and qualify as a parallel claim, the Supreme Court stated the claim would have to be based on a violation of FDA regulations. *Id.* at 330. Here, Count Five does not allege any FDA violation. The claim is therefore not a parallel claim and is preempted under § 360k. *Id.*

In their response, plaintiffs cite a FDA regulation that lists examples of state requirements that are not preempted under the MDA, including the Uniform Commercial Code's warranty of fitness. *See* 21 C.F.R. § 808.1(d)(1). Whether or not this regulation applies to plaintiffs' claim, plaintiffs failed to plead in their complaint a U.C.C. violation. A pleading must give a defendant "'fair notice'" of the basis for a claim. *Am. Dental Ass'n*, 605 F.3d at 1288 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Plaintiffs did not do so here. The Court therefore dismisses Count Five on grounds of preemption.

6. Count Six–Breach of Express Warranty

Plaintiffs state in Count Six that Medtronic's "promotional statements and product literature expressly warranted to plaintiff that the ICD was safe, capable of reducing risk or severity of heart failure, [and] was a highly reliable product in comparison to the conventional product line." (Pls.' Compl. [1] at ¶ 103.) Medtronic allegedly breached this warranty by selling an ICD with known design and manufacturing defects. (*Id.* at ¶ 106.)

Riegel did not address a breach of express warranty claim.[7] Nor has the Eleventh Circuit decided whether a breach of express

[7] Although the district court did not initially dismiss this claim as preempted, the district court subsequently dismissed it on summary judgment, and the plaintiff did not appeal this issue to the Supreme Court. *Riegel*, 552 U.S. at 321 n.2.

warranty claim can be preempted by the MDA. Other federal courts remain divided over the issue. *See Franklin*, 2010 WL 2543579, at *7 (noting "continuing split amongst the courts" post-*Riegel*); *Parker*, 584 F. Supp. 2d at 1302-03 (collecting pre-*Riegel* cases on both sides of the issue). Plaintiffs rely on the Seventh Circuit's pre-*Riegel* observation that express warranties "arise from the representations of the parties and are made as the basis of the bargain between them." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997). The Seventh Circuit suggested that an express warranty claim might escape preemption because a state judgment that a party has breached an express representation might not necessarily interfere with the FDA's premarket approval system. *Id.* These comments were merely dicta, however, because the plaintiffs had not specifically raised an express warranty claim. *Id.*

In any event, the express representation claims in this case *would* interfere with the FDA's premarket approval regime. Plaintiffs claim that Medtronic expressly warranted the ICD to be safe and highly reliable. In order to prove that Medtronic breached this warranty, Plaintiffs would need to show that the ICD was not safe and reliable, a finding that would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective. *See* 21 U.S.C. § 360e(d). Moreover, if these warranties were made in materials approved by the FDA in the premarket approval

process, then allowing a claim to proceed under Georgia law would subject Medtronic to state duties above and beyond the federal requirements. *See Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1271 (S.D. Fla. 2010) (finding preempted a breach of express warranty claim based on statements in a FDA-approved brochure). This claim thus falls within § 360k's preemption clause prohibiting state requirements that are in addition to, or different from, federal requirements. *See In re Medtronic,* 623 F.3d at 1208 ("The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted.").

In their response, plaintiffs argue that their "warranty claim parallels the FDA regulation" because they do not allege that Medtronic's FDA-approved label was defective. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 17.) Plaintiffs declare they are "perfectly happy with the label" but that "Medtronic did not live up to the FDA-approved promises contained in its label and that Lorenzo Leonard died as a result." (*Id.* at 17-18.) Plaintiffs lift this language verbatim from the district court's decision in *Hofts*. *See Hofts*, 597 F. Supp. 2d at 839 (relying on *Mitchell*, 126 F.3d at 915, to find that a breach of express warranty claim is a parallel claim and not preempted).

Hofts, however, conflicts with the Supreme Court's and the Eleventh Circuit's definition that a parallel claim is a state law claim "premised on a violation of FDA regulations[,]" not on a defendant *complying* with one. *Riegel*, 552 U.S. at 330; *Wolicki-Gables*, 634 F.3d at 1300-01. Here, plaintiffs concede that Medtronic complied with the FDA's labeling requirements. A finding that Medtronic violated state law by not living up to the FDA-approved promises in its label would necessarily conflict with the FDA's determination that the label was not false or misleading. *See Riegel*, 552 U.S. at 318 ("The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A)."). Thus, Plaintiffs' claim is not based on state duties that parallel federal requirements. *See id.* at 330; *Parker*, 584 F. Supp. 2d at 1303 ("Plaintiff's express warranty claim would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements."). Count Six is therefore preempted under § 360k.

7. Count Seven–Misrepresentation by Omission

Count Seven alleges that Medtronic "misrepresented the mechanical soundness and reliability of its ICD devices to the

general public through promotional and marketing campaigns." (Pls.' Compl. [1] at ¶ 109.) Further, Count Seven states that Medtronic concealed and withheld information about the ICD's "manufacturing defects and high risks of failure." (*Id.* at ¶ 111.) Plaintiffs clarify in their response that Count Seven is actually a fraud claim; they contend that Medtronic "knowingly concealed, intentionally misrepresented, and knew or should have known the dangers of their ICD."[8] (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 19.)

This claim is preempted because it would require Medtronic to give different, additional warnings about the ICD's safety and effectiveness, which is strictly prohibited without FDA approval. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in . . . labeling . . . that would affect safety or effectiveness." *Riegel*,

[8] In reply, Medtronic contends that plaintiffs have not pled their fraud claim with the requisite particularity under Federal Rule of Civil Procedure 9(b). Rule 9(b) entails a heightened level of specificity which means a complaint must typically identify "(1) the precise statements, documents, or misrepresentations made; (2) the time and place of and person responsible for the statement; (3) the content and manner in which the statements misled the plaintiffs; and (4) what the defendants gained by the alleged fraud." *Ambrosia Coal & Const. Co. v. Pages Morales*, 482 F.3d 1309, 1316-17 (11th Cir. 2007). As previously discussed, all of plaintiffs' claims fail to satisfy the pleading requirements of Rule 8(a). The Court also agrees with Medtronic that the fraud claim's general allegations do not meet any of the particularity requirements of Rule 9(b). *See id.*

552 U.S. at 319. Plaintiffs do not contend in Count Seven that Medtronic violated any FDA regulations concerning the device's FDA-approved warnings and instructions. Plaintiffs' fraud claim thus necessarily imposes state requirements that are "'different from, or in addition to'" the federal ones. *Id.* at 330. Consequently, Count Seven does not state a parallel claim and is preempted under § 360k. *See id.* at 330; *In re Medtronic,* 623 F.3d at 1205 (finding preempted a claim that Medtronic failed to adequately warn consumers of known defects about a device notwithstanding compliance with federal requirements).

8. Count Eight–Unjust Enrichment

Plaintiffs allege in Count Eight that "[a]s an intended and expected result of their conscious wrongdoings as set forth in this Complaint, defendant has profited and benefited [sic] from payments Lorenzo Leonard made for the Medtronic Device." (Pls.' Compl. [1] at ¶ 117.) Plaintiffs claim that Leonard expected the ICD to be safe and medically effective, and that Medtronic's failure to meet this expectation unjustly enriched Medtronic. (*Id.* at ¶¶ 118-19).

As with plaintiffs' other claims, success on this claim depends on a finding that Leonard's ICD was not safe and effective, despite FDA premarket approval. Count Eight does not specifically name a FDA violation by Medtronic, referring only generally to the "wrongdoings" set forth in the complaint. (*Id.* at ¶ 117.) As discussed,

plaintiffs' unsubstantiated allegations in Counts One and Two that Medtronic failed to satisfy the FDA's premarket approval standards do not sufficiently state the elements of a parallel claim. *See Wolicki-Gables*, 634 F.3d at 1301-02. Moreover, "because this claim is entirely contingent upon Defendant's liability for the above preempted claims, this claim is similarly preempted." *Franklin*, 2010 WL 2543579, at *10 (finding preempted plaintiff's claim for negligent infliction of emotional distress because it was derivative of plaintiff's other preempted claims). Plaintiffs' claim of unjust enrichment is therefore preempted under § 360k.

IV. Leave to Amend Complaint

In their response, plaintiffs request an opportunity to amend their complaint should the Court find that dismissal is warranted. (Pls.' Resp. to Def.'s Mot. to Dismiss [9] at 22.) Under Federal Rule of Civil Procedure 15(a), leave to amend shall be freely given "when justice so requires." FED. R. CIV. P. 15(a)(2). Plaintiffs make several new factual allegations in their response related to Leonard's injuries and death which are not in the original complaint. These allegations relate to plaintiffs' ability to state a valid claim for relief and to the timeliness issue. Further, the complaint was filed several months before the Eleventh Circuit's decision in *Wolicki-Gables*, which set the parameters for a valid parallel claim

under *Riegel*. In the interests of justice, the Court will grant plaintiffs leave to amend their complaint.

CONCLUSION

In sum, plaintiffs' complaint is replete with conclusory allegations that fail to state a valid claim for relief under Rule 8(a). Additionally, none of plaintiffs' claims, as currently pled, contain the elements of a parallel claim so as to avoid preemption by the MDA. Defendant's motion to dismiss is therefore meritorious, and the Court would grant this motion, except for the plaintiff's request to be allowed to amend its complaint. Because the Court will permit the plaintiff to amend its complaint, the Court therefore **DENIES WITHOUT PREJUDICE** defendant Medtronic's Motion to Dismiss [5].

Plaintiffs may amend their complaint **within 28 days** of this Order. The plaintiffs are on notice, however, that any defects in an amended complaint will result in dismissal with prejudice of the particular count. Should plaintiffs not amend their complaint within the above time period, the Court will then order the case to be dismissed with prejudice. The Clerk shall submit this action 29 days after the issuance of this Order.

SO ORDERED, this 19th day of August, 2011.

/s/ Julie E. Carnes
JULIE E. CARNES
CHIEF UNITED STATES DISTRICT JUDGE