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

SHERYL D. CLINE, Plaintiff, v. ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION, Defendant.	)	CIVIL ACTION FILE NO. 1:11-CV-04064-AT

DEFENDANT ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

COMES NOW, Advanced Neuromodulation Systems, Inc., d/b/a St. Jude Medical Neuromodulation Division ("SJN"), a Defendant in the above-styled civil action, and moves to dismiss Plaintiff's Amended Complaint for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. Rule 12(b)(6). Plaintiff fails to allege a well-pleaded Complaint pursuant to Fed. R. Civ. P. 8(a)(2) and, moreover, her cause of action is preempted by federal law under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") as set forth in 21 U.S.C. §§ 301 et seq. and Riegel v. Medtronic, 552 U.S. 312, 128 S. Ct. 999 (2008).

In support of this Motion to Dismiss, Defendant SJN relies upon the pleadings of the parties and the Memorandum of Law in Support of its Motion to Dismiss Plaintiff's Amended Complaint filed contemporaneously herewith.

WHEREFORE, Defendant SJN respectfully request that this Court GRANT its Motion to Dismiss Plaintiff's Amended Complaint with Prejudice.

This 23rd day of January, 2012.

/s Moses Kim
MOSES KIM
Georgia Bar No. 335581
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have electronically filed DEFENDANT ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT the Clerk of Court using the CM/ECF system, which automatically provides email notification of the filing to the following attorney of record:

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I FURTHER CERTIFY that the undersigned responsible for service of the above document acknowledges that I am in possession of the original of the foregoing and the custodian thereof, the same to be held in accordance with the local rule.

This 23rd day of January, 2012.

/s Moses Kim
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CERTIFICATE OF FONT SIZE

I hereby certify this document was prepared in Times New Roman 14 pt. in accordance with Local Rule 5.1B.

This 23rd day of January, 2012.

/s Moses Kim
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SHERYL D. CLINE, Plaintiff, v. ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION, Defendant.	)	CIVIL ACTION FILE NO. 1:11-CV-04064-AT

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

COMES NOW, Advanced Neuromodulation Systems, Inc., d/b/a St. Jude Medical Neuromodulation Division ("SJN"), a Defendant in the above-styled civil action, and submits this Memorandum of Law in Support Defendant's Motion to Dismiss Plaintiff's Amended Complaint. The Motion to Dismiss should be granted pursuant to Fed. R. Civ. P. 12(b)(6) because Plaintiff has failed to properly allege a "parallel claim" and asserts a breach of express warranty claim that directly relates to the medical device's safety and effectiveness, which is governed exclusively by the FDA.

I. INTRODUCTION

Plaintiff filed this lawsuit in the State Court of Fulton County, Georgia, on October 24, 2011, alleging that Defendant SJN is liable for Plaintiff's personal injuries when a medical device known as an implantable pulse generator ("IPG") stopped relieving Plaintiff's pre-existing back pain. (Am. Compl. ¶ 6, Doc. 18.) The IPG was an Eon Mini™ Neurostimulation (IPG) System Model 3788 (Serial No. 13751671), which is a medical device that is used as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. (Am. Compl. ¶¶ 4, 5, Doc 18.) The FDA granted premarket approval for this medical device on March 28, 2008.

The Plaintiff had the IPG placed in her back on or about December 24, 2009, but it allegedly stopped functioning in June 2010. (Am. Compl. ¶ 6, Doc 18.) The IPG was removed on or about October 20, 2010, (Am. Compl. ¶ 7, Doc 18), and upon information and belief, Plaintiff had a new IPG placed that same day. Subsequent testing purportedly showed that the IPG stopped working due to the internal battery. (Am. Compl. ¶ 8, Doc 18.)

Defendant SJN removed this case to federal court based upon diversity of citizenship and federal question and filed a Motion to Dismiss Plaintiff's

Complaint pursuant to Fed. R. Civ. P. 12(b)(6) because Plaintiff had failed to set forth a well-pleaded Complaint and had asserted a claim that was preempted by federal law. (Def.'s Mot. to Dismiss, Doc. 3.) Plaintiff agreed, announcing in Plaintiff's Brief in Opposition to Defendant's Motion to Dismiss that "she has now abandoned any preempted state law claims . . . ." (Pl.'s Br. in Opp. to Def.'s Mot. to Dismiss at 2, Doc. 7.) Additionally, Plaintiff sought leave of the Court to amend her Complaint, (Pl.'s Mot. for Leave to File Am. Compl., Doc. 6), and the Court granted it on January 9, 2012, (Order, Doc. 17).

Defendant SJN now moves to dismiss Plaintiff's Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) because she has failed to properly allege a "parallel claim" and asserts a breach of express warranty claim that directly relates to the medical device's safety and effectiveness, which is governed exclusively by the FDA.

II. ARGUMENT AND CITATION OF AUTHORITIES

A. PLAINTIFF HAS FAILED TO PROPERLY ALLEGE A PARALLEL CLAIM. THEREFORE, THE COMPLAINT MUST BE DISMISSED.

1. The subject IPG, including its labeling, underwent a strict and rigorous premarket approval process by the FDA.

The FDA has promulgated numerous regulations that delineate the premarket approval ("PMA") requirements for Class III medical devices. See

Buckman Co. v. Pl.'s Legal Comm., 121 S. Ct. 1012, 531 U.S. 341 (2001). These regulations require a PMA application to include comprehensive data from which the FDA can make a reasoned determination of the device's safety and efficacy, including human clinical trials, design specifications, manufacturing processes and quality controls, and proposed labeling and advertising. See 21 C.F.R. § 814.20; Riegel, 552 U.S. at 318, 128 S. Ct. at 1004 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). The PMA process requires the manufacturer to submit extensive information, and the "FDA spends an average of 1,200 hours reviewing each application." Riegel, 552 U.S. at 318, 128 S. Ct. at 1004.

A manufacturer may not change "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without first obtaining the FDA's approval. Id. at 319, 128 S. Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer must submit and receive a supplemental PMA from the FDA for any changes, and the FDA evaluates the proposed changes "under largely the same criteria as an initial application." Id. (citing 21 U.S.C. § 360e(d)(6)).

Even after FDA approval, the devices are subject to reporting requirements, including informing the FDA of studies, investigations, or incidents where the device caused or could have caused serious injury. Id. The FDA retains the

authority to withdraw approval based on new information, and "must withdraw approval if it determines that a device is unsafe or ineffective under the current conditions in its labeling." Id.

As a result of the FDA's strict and comprehensive regulation of Class III medical devices undergoing premarket approval, Congress set forth the following express preemptive 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) (emphasis added). Accordingly, federal law preempts any of Plaintiff's claims premised upon any state requirement "different from, or in addition to the requirements imposed by federal law" such as claims for negligence, strict liability, and breaches of implied warranties. See Riegel, 552 U.S. at 330, 128 S. Ct. at 1011.

2. Riegel identified a narrow and rare exception to preemption, and a plaintiff must adequately plead this narrow exception called a "parallel" claim or be dismissed.

Federal courts recognize only one narrow and rare exception to preemption. Stevens v. Pacesetter, Inc., No. 3:07-CV-3812, 2008 WL 2637417 (D.S.C. Apr. 1, 2008) (only a "narrow" category of claims survive Riegel). These claims are referred to as "parallel" claims on the theory that the premarket approval process "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," as long as they are not "different from, or in addition to any federal requirements." Riegel, 552 U.S. at 330, 128 S. Ct. at 1011. The Eleventh Circuit has made clear that:

> **Plaintiffs cannot simply incant the magic words** '[defendants] violated FDA regulations' in order to avoid preemption. Parallel claims must be specifically stated in the **initial** pleadings. A plaintiff must allege that "[the] defendant violated a **particular federal specification** referring to the device at issue. To properly allege parallel claims, the complaint **must set forth facts**" pointing to **specific** PMA requirements that have been violated.

Wolicki-Gables, 634 F.3d at 1301 (emphasis added). Moreover, "the plaintiff [is] required to show a link between a specific federal violation, and plaintiff's injury." Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009).

3. Plaintiff cannot adequately plead a parallel claim by merely alleging that the Defendant violated a federal regulation.

Here, Plaintiff ignores the pleading requirements for a parallel claim as she has not alleged any specific facts showing that Defendant SJN deviated from the FDA-approved design, manufacturing processes, or labeling. Id. at 1301-02. Instead, she merely recites a laundry list of various federal regulations from Chapter 21 of the Code of Federal Regulations including, but not limited to:

- § 820.30 (requiring that a manufacturer establish and maintain procedures to control the design of the device);
- § 820.70 (requiring a manufacturer to develop, conduct, control, and monitor production processes);
- § 820.72 (requiring that all inspection and test equipment is accurate);
- § 820.75 (relating to validation activities);
- § 820.80 (requiring procedures for acceptance activities);
- § 820.150 (requiring procedures for the control of storage areas); and,
- § 820.120(b) (requiring labels for devices must accurately provide the expiration date, control number, etc.)

Without alleging any specific facts other than the battery failed and, essentially, the Defendant's product hurt me, Plaintiff restates in her Amended Complaint the exact same claim she alleged in her original Complaint. Evidently, Plaintiff does not even know what FDA violation allegedly occurred, as she alleges in the Amended Complaint that "Defendant failed to meet **one or more** of the requirements imposed by the above noted federal regulations in the design, manufacture, handling, inspection, testing, labeling, packaging, storage, distribution and sale of the subject stimulator in this case." (Am. Compl. ¶ 30, Doc. 18) (emphasis added).

This is exactly what the United States Supreme Court sought to prevent when requiring that a complaint allege something more than "the-defendant-unlawfully-harmed-me accusation," the type of complaint scorned by the Court in Iqbal. See Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937 (2009). Here, the Plaintiff has merely restated the same general allegations from the original Complaint and calls it a violation of a FDA regulation to sidestep Riegel's preemptive power.

Other courts have dismissed similar cases, for example, in In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009). In In re Medtronic, the plaintiffs allegedly suffered injury from the Sprint Fidelis

leads, which were a component of Medtronic's implantable cardiac defibrillators ("ICDs"). Id. at 1153-54. An investigation showed that fractures in the leads were causing the leads to fail, resulting in unnecessary and painful shocks to the recipients. Id. at 1153.

The plaintiffs asserted, in part, that the defendant used inadequate welding techniques, causing defective welds that led to the fractures in the leads. Id. at 1157. The plaintiffs further alleged that the inadequate welding techniques, as well as the testing and quality assurance protocols, did not comply with the Current Good Manufacturing Practices ("CGMPs") and the Quality System Regulation ("QSR"). Id. This was the basis, in part, of their parallel claim. Id.

In response to the Master Consolidated Complaint from the twenty-seven plaintiffs, defendant Medtronic moved to dismiss the action because all of plaintiffs' claims were preempted. Id. at 1154. The court agreed, pointing out that plaintiffs' reliance on CGMPs and QSR did not save the claims from preemption. Id. at 1157. The CGMPs and the QSR were merely "general objectives" and "generic" in nature, such that the plaintiffs were not able to show how the defective welding processes violated any CGMPs or QSR. Id. at 1158.

As the CGMPs and QSR were not specific as to how the leads should be welded, the court concluded that holding Medtronic liable under these

circumstances would impose a requirement that was "different from, or in addition to" those under federal law. Id. In other words, the court concluded that merely referencing the violation of CGMPs or a QSR, without specific facts, is not sufficient to plead a parallel claim and required the dismissal of the claims. Id.; see also Parker v. Stryker Corp., 584 F. Supp. 2d 1301, 1301-02 (D. Colo. 2008) (ruling that mere reference to the CGMPs or Chapter 21 of the Code of Federal Regulations, and even with two FDA warning letters, was insufficient to assert a parallel claim and avoid preemption); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 282 (2009) (ruling that the mere reference to two FDA warning letters mentioning federal violations was insufficient and warranted dismissal).

4. Plaintiff failed to plead specific facts showing a causal link, which is required to successfully plead a parallel claim.

The court in Ilarraza v. Medtronic, Inc. addressed the same issue and also dismissed the plaintiff's case, emphasizing the requirement that a plaintiff must plead specific facts establishing causation. Ilarraza, 677 F. Supp. 2d at 589-90. In Ilarraza, the plaintiff sued for injuries he allegedly sustained from an Intrathecal Drug Delivery System ("medication pump"). Id. at 582. The medication pump allegedly stopped working, and the plaintiff began experiencing withdrawal symptoms when the medication pump stopped delivering pain medication. Id. He

subsequently underwent a CT scan, which showed that there was a break in the catheter portion of the medication pump. Id.

In attempting to allege a parallel claim, the plaintiff claimed that defendant Medtronic failed to manufacture the medication pump in accordance with the federally prescribed CGMPs. Id. at 583. The plaintiff then identified eleven regulations from Chapter 21 of the Code of Federal Regulations, including:

- § 820.20 (Management Responsibility);
- § 820.25 (Personnel);
- § 820.50 (Purchasing Controls);
- § 820.70 (Production and Process Controls);
- § 820.80 (Receiving, In-Process, and Finished Device Acceptance);
- § 820.100 (Corrective and Preventive Action);
- § 820.160 (Distribution); and,
- § 820.181 (Device Master Record).

Id. at 586-88.

The defendant moved to dismiss the Amended Complaint because the plaintiff had failed to raise a "plausible claim" as required by Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955 (2007). The court agreed and granted the defendant's Motion to Dismiss. Id. at 588. In so ruling, the court noted that the

CGMP's are merely general objectives that apply to a broad range of medical devices. Id. "[T]he general pleading of CGMP violations is insufficient to state a 'plausible' parallel claim not subject to dismissal on the ground of preemption." Id. This principle is directly applicable to the case at hand.

The court also found that the plaintiff had merely recited the "unsupported" violations of general regulations, but did not "tie" those allegations to the alleged injuries. Id. at 589. In other words, the plaintiff must show a causal link between the specific federal violation and the alleged injury. Id. Because the plaintiff in Ilarraza had failed on both accounts, the court dismissed the case, explaining that the plaintiff had "fail[ed] to set forth any specific problem, or failure to comply with any FDA regulation that [could] be **linked** to the injury alleged." Id. (emphasis added); see also Horowitz, 613 F. Supp. 2d at 282 (2009) ("[I]n order to survive preemption . . . a plaintiff must demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury"); Desabio v. Howmedica Osteonics Corp., No. 09-CV-287S, 2011 WL 4074391, *2 (W.D.N.Y. Sept. 13, 2011) ("Plaintiffs must also allege a link between the failure to comply and the alleged injury.")

The Plaintiff here failed on both accounts because she does not set forth specific facts that would support a violation of a federal regulation or show how

any such violation actually caused the Plaintiff's alleged injury. First, the Plaintiff has set forth her own laundry list of CGMPs, but has failed to provide any "factual" basis for how Defendant SJN specifically violated any of them. She merely makes the conclusory and general statement that "one or more" of these federal regulations were violated and that she was injured. (Am. Compl. ¶ 30, Doc. 18.) Plaintiff's woefully inadequate claim proves fatal to her Amended Complaint.

Second, the Plaintiff has failed to link any purported violation of a federal regulation to her alleged injury. In other words, the Plaintiff must plead specific facts that demonstrate "but for" the alleged violation of a federal regulation, she would not have been injured. But all she can muster is that "Defendant's violation of **one or more** of these federal regulations was a proximate cause of the injuries and damages suffered by Plaintiff." (Am. Compl. ¶ 32, Doc. 18) (emphasis added). Plaintiff's Amended Complaint is completely devoid of any specific facts that establish a causal or cognizable "link." Because In re Medtronic and Ilarraza are factually and procedurally similar to what happened here, this Court should follow their well-reasoned approach and dismiss the Plaintiff's case.

This conclusion is further supported by the ruling in Covert v. Stryker, No. 1:08CV447, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009), where the magistrate

court recommended the dismissal of the plaintiff's complaint for failure to adequately plead a parallel claim. Id. at *16. The plaintiff in Covert sued because she had been injured due to an allegedly defective artificial hip replacement device made by defendant Stryker Corporation. Id. at *1. In attempting to assert a parallel claim, the plaintiff referenced two warning letters from the FDA, relating to inspections of the defendant's facilities in Ireland and New Jersey. Id. at *12. The plaintiff alleged that these inspections revealed violations of CGMPs. Id. But the plaintiff did not allege that the artificial hip replacement device was manufactured in either the facility in Ireland or New Jersey or that the FDA had determined that the defendant had violated a federal regulation. Id. In determining that the plaintiff had failed to adequately plead a parallel claim, the court in Covert explained that:

> [T]he mere fact that a complaint comes "close to stating a claim" is not enough. Indeed, the plaintiff must cross two theoretical barriers before he "enter[s] the realm of plausible liability." Most obviously, he must cross the "line between the conclusory and the factual." More importantly, however, he must also cross the line "between the factually neutral and the factually suggestive." For this very reason, Twombly stated that "a district court must retain the power to insist upon some specificity in pleading" when deciding a motion to dismiss.

Id. at *14.

In accordance with this pleading standard, the court ruled that the plaintiff must have alleged the factual basis for how a violation of an identifiable federal regulation caused the alleged injury. Id. "The mere allegation that [the defendant] may have violated some federal 'requirement' in **one or more** instances is not enough to 'plausibly suggest' that it has violated any such federal 'requirement' in this particular instance, let alone that such violation actually caused the harm that Plaintiff presently alleges." Id. at *16 (emphasis added). Because the plaintiff did nothing more than reference the warning letters and make conclusory allegations without any factual basis whatsoever or assert the factual basis for how any federal violation caused his injury, the court in Covert dismissed the lawsuit. Id.

Even in the face of an alleged defect in the medical device, the courts in Covert (involving an allegedly defective artificial replacement hip), In re Medtronic (involving improperly welded leads for an ICD), and Ilarraza (involving a medication pump that stopped working) each dismissed the plaintiffs' claims for their failure to adequately plead this narrow exception to preemption. Showing that something went wrong with the medical device is not sufficient to establish a legally viable claim. Given that the Plaintiff here has similarly failed to plead a parallel claim, despite her contention that the battery failed, this Court should dismiss the Plaintiff's Amended Complaint.

Interestingly, Plaintiff relies heavily on Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010), for the proposition that her parallel claims are not preempted. Id.[1] As the defendant noted in response to those arguments, other courts have disagreed with the Bausch decision, underscoring the newness of this developing area of law.

Furthermore, Plaintiff seeks discovery to investigate this case. But as the court in Horowitz pointedly mentioned, "mere promises of future factual allegations are not sufficient to meet this [pleading] standard." 613 F. Supp. 2d 271, 280 (2009). While the Court has allowed Plaintiff the opportunity to amend the Complaint, any promise that discovery will heal the ills of Plaintiff's Amended Complaint should not be considered by the Court. For example, the court in Desabio determined that the plaintiff had failed to adequately allege a parallel claim and could not in any proposed amendment. Id. at *7. Therefore, the trial court denied the plaintiff the opportunity for any discovery and denied the plaintiff's motion for leave to amend the complaint because it was futile. Id. The

[1] In Bausch, the trial court granted the Defendants' Rule 12(b)(6) Motion to Dismiss on the grounds that the plaintiff's common law claims were preempted by federal law and then denied the plaintiff's Motion for Leave to Amend the Complaint for futility because the claims would have still been preempted. Id. at 549, 561. The Seventh Circuit subsequently reversed this decision. Id.

result should be similar here, and this Court should grant the Motion to Dismiss and refuse to entertain Plaintiff's fancy two-step attempt to avoid preemption.

B. PLAINTIFF'S BREACH OF EXPRESS WARRANTY CLAIM RELATES TO SAFETY AND EFFECTIVENESS AND INVADES THE PURVIEW OF THE FDA.

Plaintiff asserts a cause of action on the theory that Defendant SJN breached an express warranty. Plaintiff asserts this claim in an effort to circumvent preemption, nullify the preemptive effect of the Medical Device Amendments and, in effect, bring the exact same product liability claim that the federal courts have already preempted.

Georgia law defines an express warranty as follows:

> (1) Express warranties by the seller are created as follows:
>
> > (a) 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 creates an express warranty that the goods shall conform to the affirmation or promise.
> >
> > (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
> >
> > (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

O.C.G.A. § 11-2-313.

Plaintiff contends that Defendant SJN created an express warranty in two ways. First, Plaintiff contends that Defendant SJN created an express warranty through its Eon Mini™ Charging System User's Guide where it states that the "Eon Mini Charging System [will] be free from defects in material or workmanship within one (1) year from the date of ownership when used as intended in conformance with the instructions for its use and maintenance, subject to the other terms and conditions of this warranty." (Am. Compl. ¶ 12, Doc. 18.) Second, Plaintiff contends that she and her husband were provided a purported "express warranty" that the "subject stimulator could be expected to operate . . . for 10 years . . . ." (Am. Compl. ¶ 13, Doc. 18). [2,3]

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[2] Notwithstanding that Plaintiff has injected unauthenticated evidence into this Motion to Dismiss, Plaintiff also ignored the complete language of the alleged User's Guide, which states that:

> **I. GENERAL WARNING**
>
> A. . . . . The implanted components **may fail during or following implantation** into the body for any one or a number of reasons, including, but not limited to, medical complications, body rejection, phenomena, lead breakage, or improper handling, implantation or sue, or insulation breach.
>
> B. St. Jude Medical Neuromodulation Division **makes no representations or warranties that failure or cessation of function of any component**, or the system, will not occur, that the body will not react adversely to implantation, or that medical complications will not develop . . . .
>
> **II. LIMITED WARRANTY**
>
> *** * ***

1. A conflict of law exists, but it leans toward preemption for breach of express warranty claims.

Although the United States Supreme Court in Riegel concluded that product liability claims based upon negligence, strict liability and breach of implied warranties were preempted, it did not consider—and did not have before it—the question of whether a claim for a breach of express warranties were preempted. Riegel, 128 S. Ct. at 999, 169 L. Ed. 2d at 892, n2. The Eleventh Circuit has also not decided this question. Leonard v. Medtronic, Inc., 2011 WL 3652311, at * 10 (N.D. Ga. Aug. 19, 2011); Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010). But the Plaintiff erroneously informed the Court that a breach of an express warranty claim is **not** preempted, which is patently misleading. (Pl.'s Br. in Opp. to Def.'s Mot. to Dismiss at 9, Doc. 7.)

> B. THIS LIMITED WRITTEN WARRANTY CONTAINS THE FINAL, COMPLETE AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR THE ST. JUDE MEDICAL NEUROMODULATION DIVISION EON MINI CHARGING SYSTEM . . . . ST. JUDE MEDICAL NEUROMODULATION DIVISION DISCLAIMS ALL IMPLIED WARRANTIES . . . . **NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES, OR REPRESENTATIONS ON BEHALF OF THE ST. JUDE MEDICAL NEUROMODULATION DIVISION.**

Id. (emphasis added).

[3] Privity is a requirement for breach of warranty actions in Georgia. Am. Signal Co. v. All Am. Semiconductor of Atlanta, Inc., No. 05-CV-2200, 2006 WL 167956 (N.D. Ga. Jan. 19, 2006). Notwithstanding what privity may or may not exist with the Plaintiff, there is certainly no privity with Plaintiff's husband.

Defendant SJN acknowledges that there are conflicting opinions throughout the federal courts on this issue. But most of the courts that have weighed in on this issue since the seminal 2008 Riegel decision concluded that a breach of express warranty claim is preempted. See, e.g., Leonard, supra; Desabio, supra (ruling that plaintiff's express warranty claim was preempted and denying plaintiff's motion for leave to file a proposed second amended complaint because it was futile); Anthony v. Stryker Corp., No. 1:09-CV-2343, 2010 WL 1387790 (N.D. Ohio Mar. 31, 2010) (dismissing with prejudice a breach of express warranty claim); Wheeler, 706 F. Supp. 2d at 1271 (allowing claim that defendant breached warranty in an FDA-approved document would impose a requirement that was different from or in addition to federal requirements); In re Medtronic, supra (ruling that breach of express warranty claims are preempted as they relate to the device's safety and effectiveness), aff'd sub nom., In re Medtronic, 623 F.3d 1200 (8th Cir. 2010); Horowitz, 613 F. Supp. 2d at 271 (dismissing claim for breach of express and implied warranties); Bencomo v. Guidant Corp., No. 06-2473, 2009 WL 1951821 (E.D. La. June 30, 2009) (ruling that plaintiff's claim for breach of an express warranty must be preempted); Miller v. DePuy Spine, Inc., 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009); Parker, 584 F. Supp. 2d at 1303 (ruling that a breach of express warranty claim is preempted); Gomez v. St. Jude Med. Daig

Div. Inc., 442 F.3d 919, 932 (5th Cir. 2006) (express-warranty claim preempted pursuant to the MDA); Enlow v. St. Jude Med., Inc., 210 F. Supp. 2d 853, 862 (W.D. Ky. 2001) (preempting an express warranty claim).

2. Whether the device lived up to any express warranty is governed by the FDA as it relates to the safety and effectiveness of the medical device.

The FDA's comprehensive premarket approval process includes the review of the device's proposed labeling. Riegel v. Medtronic, Inc., 552 U.S. at 318, 128 S. Ct. 999, 1004. "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). Id. (emphasis added). Defendant SJN's labeling, including its user guide and internet material, were specifically approved or derived from those preapproved representations. Any claim based upon this labeling necessarily invades an area already regulated by the FDA.

The alleged breach of an express warranty premised on the fact that the subject IPG stopped working in less than a year directly relates to this labeling and whether the subject IPG was "safe" for implantation and use and "effective" in relieving her pain. As such, any breach of an express warranty claim should be preempted under Riegel and its progeny given the comprehensive, strict, and

rigorous scrutiny applied to these devices, as a breach of an express warranty claim necessarily impinges on the FDA's duty to regulate these devices.

This premise that a breach of warranty claims goes to the safety and effectiveness of a medical device was set forth clearly in Horowitz in which the court concluded that a breach of an express warranty was preempted. "To permit a jury to decide [the plaintiff's] claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [defendants]." Horowitz, 613 F. Supp. 2d at 285.

Similarly, the court in Parker v. Stryker Corp. also concluded that the plaintiff's express warranty claims should be preempted because the "'FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading.' . . . 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." 584 F. Supp. 2d 1298, 1302 (2008).

Even Judge Carnes of the Northern District of Georgia noted that "the express representation claims in the [Leonard v. Medtronic, Inc.] case *would* interfere with the FDA's premarket approval regime" as it related to the safety and "reliability" of the medical device at issue. Leonard, No. 1:10-CV-03787, 2011 WL 3652311, at *10 (N.D. Ga. Aug. 19, 2011) (emphasis in original). Judge Carnes consequently ruled that express warranty claims were preempted because "[a] finding that [Defendant] 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." Id. at *11.

Here, Plaintiff asserts that it was Defendant SJN's failure to deliver goods that conformed to its "contract" and "representations" that formed the basis of her breach of express warranty claim—in essence that the battery did not last as long as predicted. (Am. Compl. ¶ 18, Doc. 18). To allow Plaintiff's claim would necessarily require a jury to determine that Defendant SJN failed to satisfy those promises in its label, which would necessarily conflict with the FDA's determination that the label was not false or misleading. See Leonard, at *11. Consistent with the reasoning in Leonard, Plaintiff's breach of express warranty claim goes to the safety, effectiveness, and reliability of the subject IPG and, therefore, any breach of an express warranty claim should be preempted.

But Plaintiff now attempts to backdoor a product liability claim under the guise of an express warranty claim. Plaintiff's reliance on Horn v. Boston Scientific Neuromodulation Corp., No. CV409-074, 2011 WL 3893812 (S.D. Ga. Aug. 26, 2011) is misplaced. First and foremost, neither the United States Supreme Court nor the Eleventh Circuit has weighed in on this issue, so that decision from the Southern District of Georgia is not binding upon this Court. Second, the FDA requires that the manufacturer to be truthful, accurate, and not misleading, and must remain consistent with applicable federal and state laws. Third, because of the comprehensive nature of the PMA process, any claim relating to the manufacturing, designing, and labeling of the product falls within the purview of the FDA.

The Third and Seventh Circuits have, admittedly, ruled that breach of express warranty claims are not preempted to the extent they are "voluntarily assumed by the warrantor, and not imposed by the state." Parker, 584 F. Supp. 2d at 1302. But many of these types of cases were decided before Riegel. Even so, and as set forth above, numerous courts have disagreed and found the position of the Third and Seventh Circuits unpersuasive. See, e.g., Parker, 584 F. Supp. 2d at 1302 (ruling that the plaintiff's breach of an express warranty claim was preempted despite being a voluntary contractual obligation); Enlow, supra. And to permit a

cause of action for an alleged defective battery not lasting long enough necessarily requires a determination that the FDA's oversight was insufficient, thus, interfering with the FDA's regulation of the design, manufacturing, and labeling of the device. Such a claim does not run parallel to the FDA's regulations; it invades it.

The federal courts have already confirmed that the FDA will occupy the field of regulating these Class III medical devices. As such, the FDA is the final arbiter of a Class III medical device's safety and effectiveness, and the FDA acts as the sole authority on whether Defendant SJN's device remains safe, effective, reliable, and in conformance with the performance standards for which it achieved premarket approval. See 21 U.S.C.A. § 360e. To allow the plaintiff to proceed on a breach of an express warranty theory would usurp the authority of the FDA to regulate this product and nullify the preemption principles set forth in Riegel. A plaintiff could simply argue that any defect is actionable as it violates the medical device's "limited warranty"—even if given premarket approval. Such a result is unfathomable and completely contrary to the comprehensive scope of the MDA and the integral role of the FDA. Therefore, as Judge Carnes determined in Leonard, federal law preempts Plaintiff's claim for breach of an express warranty. And that should be the result here.

III. CONCLUSION

WHEREFORE, Defendant SJN's Motion to Dismiss Plaintiff's Amended Complaint should be GRANTED with prejudice pursuant to Fed. R. Civ. P. 12(b)(6) because Plaintiff has failed to properly allege a parallel claim and seeks to assert a breach of express warranty claim that goes to the medical device's safety and effectiveness.

This 23rd day of January, 2012.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have electronically filed this MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT with the Clerk of Court using the CM/ECF system, which automatically provides email notification of the filing to the following attorney of record:

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I FURTHER CERTIFY that the undersigned responsible for service of the above document acknowledges that I am in possession of the original of the foregoing and the custodian thereof, the same to be held in accordance with the local rule.

This 23rd day of January, 2012.

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CERTIFICATE OF FONT SIZE

I hereby certify this document was prepared in Times New Roman 14 pt. in accordance with Local Rule 5.1B.

This 23rd day of January, 2012.

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