UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

RICHARD J. PINSONNEAULT,

Plaintiff,

v.

ST. JUDE MEDICAL, INC. and PACESETTER, INC.,

St. Jude.

Civil No: 12-1717 (PJS/JSM)

JOSEPH D. HOULETTE,

Plaintiff,

v.

ST. JUDE MEDICAL, INC. and PACESETTER, INC.,

Defendants.

Civil No: 12-1785 (PJS/JSM)

GARY ROUSE,

Plaintiff,

v.

ST. JUDE MEDICAL, INC. and PACESETTER, INC.,

Defendants.

Civil No: 12-2396 (PJS/JSM)

ORDER

The above matters came on before the undersigned in Civil No. 12-1717 (PJS/JSM) upon Plaintiff's Motion to Amend Complaint [Docket No. 48]; in Civil No. 12-1785 (PJS/JSM) upon Plaintiff's Motion to Amend Complaint [Docket No. 30]; and in

Civil No. 12-2396 (PJS/JSM) upon, Plaintiff's Motion to Amend Complaint [Docket No. 29].

Daniel E. Gustafson, Esq., Yvonne M. Flaherty, Esq. and Amanda M. Williams, Esq. appeared on behalf of plaintiffs Richard J. Pinsonneault and Gary Rouse; Genevieve M. Zimmerman, Esq. appeared on behalf of plaintiff Joseph D. Houlette; and Andrew E. Tauber, Esq., Rebecca K. Wood, Esq., and Blake Shepard, Jr., Esq. appeared on behalf of defendants St. Jude Medical, Inc. and Pacesetter, Inc.

The Court, being duly advised in the premises, upon all of the files, records, and proceedings herein, and for the reasons stated on the record at the hearing and the Memorandum below, now makes and enters the following Order.

IT IS HEREBY ORDERED that:

1. Plaintiffs' Motions to Amend Complaint [Civil No. 12-1717 (PJS/JSM) Docket No. 48], [Civil No. 12-1785 (PJS/JSM) Docket No. 30], and [Civil No. 12-2396 (PJS/JSM) Docket No. 29] are **GRANTED** as it relates to the additional factual allegations and changes to existing factual allegations set forth in the proposed First Amended Complaint, and **DENIED** as it relates to proposed Counts V and VI.

2. Plaintiffs shall serve and file their First Amended Complaints, consistent with this Order, on or before **June 24, 2012**.

3. Defendants shall respond to the First Amended Complaints in a manner that is consistent with the Federal Rules of Civil Procedure.

Dated: June 18, 2013

s/ *Janie S. Mayeron*
JANIE S. MAYERON
United States Magistrate Judge

MEMORANDUM

I. FACTUAL BACKGROUND

Plaintiffs Richard J. Pinsonneault, Joseph D. Houlette, and Gary Rouse (collectively referred to herein as "plaintiffs") commenced individual actions against St. Jude Medical, Inc. and Pacesetter, Inc. (collectively referenced as "St. Jude") claiming injury as a result of alleged defects in the Riata leads manufactured and distributed by St. Jude, which are attached to medical devices used to treat heart conditions, including implantable cardiac defibrillators. See Complaint, ¶¶ 1-2, 8-11 [Docket No. 1].[1] Plaintiffs were implanted with a Riata lead, which allegedly ultimately failed and injured them. Id., ¶¶ 6, 7. The alleged defects pertaining to the Riata leads include among several claimed defects, the increased risk of abrasion of the lead wires or electrical conductors, causing the lead wires to protrude through the insulation and preventing proper functioning of the medical devices. Id., ¶¶ 35-37.

On December 15, 2010, St. Jude published a "Dear Doctor" letter," regarding various Riata lead models, indicating an insulation abrasion rate of 0.47% over nine years of use. Id., ¶¶ 42, 43. No voluntary recall was issued at this time. Id., ¶ 45. On November 28, 2011, St. Jude issued a second "Dear Doctor Letter," advising that it had increased the insulation abrasion rate from its 2010 rate of 0.47% to 0.63%. Id., ¶ 47. No voluntary recall was issued at this time. Id.

On December 21, 2011, the FDA issued a Class I Recall of the Riata leads. A Class I Recall is defined as a situation in which there is a reasonable probability that the

[1] For the purpose of this decision, the Court cites to the Complaint in Pinsonneault, Civil No. 12-1717 (PJS/JSM). However, the Complaints in all three actions contain virtually identical allegations.

use of or exposure to a product will cause serious adverse health consequences or death. Id., ¶¶ 48, 49. Specifically, the issue involved failures associated with lead insulation abrasion on the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation leads. Id., ¶ 50.

Plaintiffs asserted a claim of strict liability based on allegations that the Riata leads contain a manufacturing defect because the actual manufacture of the leads differed from the specifications set forth in the pre-market approval application ("PMA") that was submitted to the FDA and the conditions for approval set by the FDA. Id., ¶¶ 59-62. In addition, plaintiffs asserted a claim for negligence in manufacturing. The basis of this claim was that St. Jude breached its duty to manufacture the Riata leads consistent with the PMA and the Conditions of Approval, which led to their injuries. Id., ¶¶ 65, 66. Further, plaintiffs claimed that St. Jude is culpable under theories of negligence per se based on its alleged failure to abide by applicable Federal Regulations, and under res ipsa loquitur. Id., ¶¶ 67-78.

Plaintiffs' are now seeking to amend the Complaint to add the following claims for relief against St. Jude:

COUNT V
NEGLIGENCE – FAILURE TO WARN

> 94. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
>
> 95. Defendants have a duty to provide ongoing warnings and instructions regarding safety hazards associated with the Leads.
>
> 96. Defendants breached this duty by failing to, inter alia, provide timely and adequate reports regarding safety hazards and/or potential defects associated with the Leads.

97. Defendants also breached this duty by failing to conduct adequate risk analyses, tests, and investigations regarding safety hazards and/or potential defects associated with the Leads.

98. As a direct and proximate result of Defendants' negligence, Plaintiff was injured as described herein.

COUNT VI
BREACH OF EXPRESS WARRANTY

99. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

100. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public, that the Leads were safe, effective, fit and proper for their intended use.

101. In allowing the implantation of the Leads, Plaintiff and his physicians relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Leads were not safe and were unfit for the uses for which they were intended.

102. Through sale of the Leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

103. Defendants breached their warranty of the mechanical soundness of the Leads by continuing sales and marketing campaigns highlighting the safety of its product, while it knew of the defects and risk of product failure.

104. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other relief in an amount to be proven at trial.

See Affidavit of Yvonne M. Flaherty in Support of Plaintiffs' Motion for Leave to Amend the Complaint [Civil No. 12-1717 (PJS/JSM)], Exs. A, B (Proposed First Amended Complaint), ¶¶ 94-104.[2]

The proposed amended complaints also seek to add facts regarding: when St. Jude received approval to market the predecessor to the Riata Leads (the original PMA), as well the fact that St. Jude submitted, and the FDA approved, 14 supplements to the PMA that alter the design and manufacture of the leads; additional supplements to the Riata Series leads; inspections conducted by the FDA in 2009 of defendants' manufacturing facility in Sylmar California, which revealed deficiencies in violation of 21 C.F.R. § 803, et seq., in the handling of complaints, failing to follow procedures for the product design of the leads, failing to include information that was reasonably known to the manufacturer, failing to timely make Medical Device Reporting ("MDR") submissions, failing to define the procedures for implementing corrective and preventative actions, failing to review sampling methods for adequacy of their intended use, failing to perform design reviews at appropriate times, failing to perform a complete risk analysis, failing to establish procedures for the validation, verification, review, and approval of design changes before their implementation, and failing to resolve discrepancies noted at the completion of design verification; an October 17, 2012 inspection by the FDA of St. Jude's manufacturing facility in Sylmar California that revealed additional deficiencies; a FDA order issued in 2012, requiring St. Jude to collect clinical data related to the potential for premature insulation failure in the Riata

[2] All of the proposed amended complaints in the three suits contain virtually the same proposed changes for the purpose of the present motions for leave to amend.

Leads and to conduct a three-year post market surveillance study to address concerns related to premature insulation failure; and a January 2013 study published in the Heart Rhythm Journal, which indicated that St. Jude had advised that the rate of cable externalization was 24% in the Riata 8fr Leads, 9% in the Riata ST 7fr Lead, and that the Riata Leads fail more often than other brands. See Proposed First Amended Complaint, ¶¶ 4, 19, 23, 27, 28, 30, 39, 41-46, 71-72.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 15(a) provides that leave to amend "shall be freely given when justice so requires." The determination as to whether to grant leave to amend is entrusted to the sound discretion of the trial court. See, e.g., Niagara of Wisconsin Paper Corp. v. Paper Indus. Union Mgmt. Pension Fund, 800 F.2d 742, 749 (8th Cir. 1986) (citation omitted). The Eighth Circuit has held that "[a]lthough amendment of a complaint should be allowed liberally to ensure that a case is decided on its merits, . . . there is no absolute right to amend." Ferguson v. Cape Girardeau County, 88 F.3d 647, 650-1 (8th Cir. 1996) (citing Thompson-El v. Jones, 876 F.2d 66, 67 (8th Cir. 1989); Chesnut v. St. Louis County, 656 F.2d 343, 349 (8th Cir. 1981)). Denial of leave to amend may be justified by "undue delay, bad faith on the part of the moving party, futility of the amendment or unfair prejudice to the opposing party." Sanders v. Clemco Indus., 823 F.2d 214, 216 (8th Cir. 1987) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)).

Where, as here, St. Jude has alleged that the proposed amendments are futile, this Court must determine whether the proposed claims state a claim for relief at this stage of the case. See Zutz v. Nelson, 601 F.3d 842, 850-51 (8th Cir. 2010) ("Denial of

a motion for leave to amend on the basis of futility means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Accordingly, in reviewing a denial of leave to amend we ask whether the proposed amended complaint states a cause of action under the Twombly pleading standard....") (citation and marks omitted); In re Senior Cottages of Am., LLC, 482 F.3d 997, 1001 (8th Cir. 2007) (To deny a motion to amend on the ground of futility "means that the court reached a legal conclusion that the amended complaint could not withstand a Rule 12 motion."); United States ex rel. Gaudineer & Comito, L.L.P. v. Iowa, 269 F.3d 932, 936 (8th Cir. 2001) ("The denial of leave to amend based on futility means that the court found that the amended complaint failed to state a claim. . . ."), cert. denied, 536 U.S. 925 (2002).

To "survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2009)). "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." Iqbal, 129 S. Ct. at 1949 (quoting Twombly, 550 U.S. at 556).

III. ANALYSIS

Plaintiffs argued that their motion to amend should be granted as they are not acting in bad faith or unduly delaying litigation, and St. Jude would not be prejudiced by the proposed amendments given that plaintiffs moved to amend in the early stages of litigation. See Plaintiffs' Memorandum of Law in Support of their Motion for Leave to

Amend their Complaints, pp. 4-6 [Docket No. 50]. In addition, plaintiffs contended that the proposed amendments are not futile, as their claims relating to St. Jude's state-law duty to warn consumers of the dangers of their products, parallels their duty under federal regulations to inform the FDA of adverse events and dangers pertaining to their devices. Id., p. 7. Relying on a recent decision by the Ninth Circuit, plaintiffs asserted that their new claims are not preempted because the reporting regulation promulgated under the Food, Drug, and Cosmetic Act ("FDCA") parallels a state-law duty to warn. Id., p. 8 (citing Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013)).[3]

St. Jude responded that while Count V of the proposed first amended complaint alleges a failure-to-warn, it does not allege that St. Jude failed to provide any of the warnings mandated by the PMA process. Accordingly, St. Judge argued that Count V is expressly preempted by 21 U.S.C. § 360k(a). See Memorandum of Law in Opposition to Plaintiff's Motion for Leave to Amend Complaints ("Defs.' Mem."), p. 3 [Docket No. 64]. Further, even if applicable state law recognized a post-sale duty to warn and plaintiffs had pled such a claim, St. Jude asserted that such a duty does not parallel any federal duty to submit MDRs to the FDA. It is not enough that a duty may be similar to or consistent with the federal duty to report; rather, the duties must be identical or genuinely equivalent to survive preemption. Id., pp. 5-6. St. Jude explained that a post-sale duty to warn consumers or their physicians is not identical or genuinely equivalent to a federal duty to submit reports to the FDA, given that doctors are warned of the risks associated with a medical device through a devices' labeling and not through adverse

[3] Plaintiffs did not address their proposed breach of warranty claim in their opening memorandum.

reporting to the FDA. Id., p. 7. Further, St. Jude submitted that MDRs are not necessarily made public and are not by themselves sufficient grounds for a labeling change. Id. Therefore, because the filing of MDRs with the FDA does not change a device's PMA approved labeling, and as a result does not alter the warnings given to doctors, the federal duty to submit MDRs to the FDA is not identical to any state-law-duty to warn doctors or patients, making the claim preempted under § 360k(a). Id. In support of its position, St. Jude pointed to a decision by the Eighth Circuit in which it concluded that a claim that a defendant manufacturer had failed to submit MDRs, either in a timely manner or at all, is expressly preempted. Id., pp. 8-9 (citing In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205-08 (8th Cir. 2010) ("In re Medtronic")).

St. Jude also asserted that even if the failure-to-warn claim survives express preemption, as pled, it fails because plaintiffs failed to allege any facts linking St. Jude's specific alleged failure to submit certain MDRs to plaintiffs' alleged injuries. Id., pp. 9-14.

In addition, St. Jude submitted that to the extent that plaintiffs' claims are not expressly preempted, they are impliedly preempted because they rest on the premise that St. Jude failed to comply with the FDA reporting requirements, and that they are nothing more than an attempt by plaintiffs to enforce Medical Device Amendments ("MDA"), 21 U.S.C. § 360c(a)(1)(C), which amended the FDCA. Id., pp. 14-15. St. Jude asserted that plaintiffs' reliance on the Stengel decision out of the Ninth Circuit is misplaced because the Eighth Circuit has held that a failure-to-warn claim predicated on the alleged failure to submit proper MDRs to the FDA is impliedly preempted under 21

U.S.C. § 337(a). Id.. pp. 15-16 (citing In re Medtronic, Inc., 623 F.3d at 1205-06). In other words, plaintiffs' claims based on the alleged failure by St. Jude to properly submit MDRs to the FDA, is private cause of action to enforce the FDCA and its implementing regulations (under which no cause of action exists), and is impliedly preempted. Id., pp. 16-19.

As to Count VI, alleging a claim of breach-of-express-warranty, St. Jude contended that the claim was inadequately pled because the proposed first amended complaint does not allege facts showing an affirmation of fact or promise made by St. Jude to plaintiffs that relates to goods at issue and becomes part of the basis of the bargain. Id., p. 20. St. Jude further argued that a breach-of-express-warranty claim is expressly preempted because in order for plaintiffs to prevail on this claim, a jury would have to conclude that the Riata leads were not safe or effective as labeled, which would conflict with the FDA's determination through the PMA process that the device was labeled is safe and effective. Id., pp. 21-22.

In reply, plaintiffs claimed that their failure-to-warn claim is not futile because it is based on St. Jude's failure to provide timely and adequate reports regarding potential defects to the FDA, in violation of 21 C.F.R. § 803 et seq., which is also a violation of St. Jude's state-law duty to report risks associated with the use of its leads. See Plaintiffs' Reply Memorandum in Support of their Motion for Leave to Amend their Complaint ("Pl.'s Reply") [Civil No. 12-1717 (PJS/JSM), Docket No. 66], pp. 4-5. Plaintiffs additionally contended that the proposed failure-to-warn claim is not impliedly preempted because it is based on a breach of a state law duty that parallels a duty imposed by the FDCA. Id., pp. 5-6. As to their proposed breach-of-warranty claims,

plaintiffs submitted that these claims are not preempted because they are not based on St. Jude's claims made in the FDA-approved label or on statements approved or mandated by the FDA. Id., p. 6. Rather, the basis for plaintiffs' breach of express warranty claims are the voluntary representations made by St. Jude. Id.

III. ANALYSIS

A. Failure-to-Warn Claim (Count V)

The MDA contains a express preemption provision under 21 U.S.C. § 360k(a). This section provides:

> [N]o 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.

21 U.S.C. § 360k(a).

With regard to express preemption of state-law claims dealing with Class III medical devices, the Eighth Circuit has instructed:

> In Riegel [v. Medtronic, Inc., 552 U.S. 312 (2008)], the Court held that, for § 360k(a) preemption purposes, (i) FDA pre-market approval is "federal safety review" that results in federal "requirements" specific to the approved device, and (ii) common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by PMA approval. 552 U.S. at 322-24, 128 S.Ct. 999. However, the Court noted, § 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. at 330, 128 S.Ct. 999.

In re Medtronic, 623 F.3d at 1203. In other words, for a state-law claim to survive express preemption under § 360k(a), plaintiffs "must be suing for conduct that *violates* the FDCA. . . ." Id. at 1204 (citation and marks omitted) (emphasis in original). The claim must rest on a state law duty that is "identical" or at least "genuinely equivalent" to a duty under federal law. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 496-97 (1996) (concluding that § 360k does not preempt state law or requirements that are "equal" to, or "substantially identical" to requirements under federal law); Wolicki-Gables v. Arrow Intern., Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) ("'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.'") (quoting McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005), citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005)); Riley v. Cordis Corp., 625 F. Supp.2d 769, 776 (D. Minn. 2009) ("To escape preemption by § 360k(a), then, a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA.") (emphasis added).

"The FDA's PMA approval includes specific language for Class III device labels and warnings." In re Medtronic, 623 F.3d at 1205. A manufacturer of a Class-III medical device cannot, after the approval of a PMA, make changes in the device's labeling unless the FDA adopts a supplemental PMA approving the changes. See Rigel, 552 U.S. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design

specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application."); 21 U.S.C.A. § 360e (6)(A)(i) ("A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness."); 21 CFR § 814.39(a) ("After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. . . . While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:. . . Labeling changes.").

After PMA approval, manufacturers of Class III devices are required to comply with the MDR requirements. To this end, the applicable regulations require a manufacturer to report to the FDA dangers associated with a device after MPA approval as follows:

> (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
>
> (1) May have caused or contributed to a death or serious injury; or
>
> (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. § 803.50(a) (emphasis added); see also 21 U.S.C. § 360i(a)(1) (requiring the adoption of regulations that mandate a manufacturer "report to the Secretary" when it becomes aware of information that suggests its marketed device "may have caused or contributed to a death or serious injury," or has malfunctioned in a manner that is "likely to cause or contribute to a death or serious injury if the malfunction were to recur. . . .").

In Riegel, the Supreme Court acknowledged that following pre-market approval, a manufacturer must "report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." 552 U.S. at 319-20 (citations omitted). Any reports submitted by a manufacturer to FDA, including MDRs, "may" be disclosed to the public and the submission of a MDR "is not necessarily an admission that the device . . . caused or contributed to the reportable event. See 21 C.F.R. §§ 803.9(a), 803.16.

According to plaintiffs' counsel's representations at the hearing on the motions to amend, St. Jude's breach of the duty set forth in the failure-to-warn claim was the duty to warn physicians. Hearing Transcript ("Tr.") 22. Counsel conceded that while the filing of the MDRs with the FDA are mandatory, the "making them public or the timing of making them public is with the FDA's discretion;" although it was his experience that these adverse reports are placed into the "MAUDE Database," through which doctors can monitor to collect information. Tr. 20. According to plaintiffs, once the FDA

publishes the report and it becomes accessible, it is the same as warning a physician, even if St. Jude does not have a mandatory duty to warn physicians. Id.

This Court concludes that plaintiffs' failure-to-warn claims are expressly preempted under § 360k(a). First, plaintiffs have not pointed this Court to any applicable jurisdictions that recognize a state common law failure-to-warn claim based on a failure to properly issue reports to a federal agency, such as the FDA. Plaintiffs cited Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517 (D. Minn. 1989) for the proposition that Minnesota recognizes a post-sale duty to warn. Kociemba noted that under Minnesota law, a manufacturer is under a continuing post-sale duty to warn of defects in "special cases." 707 F. Supp. at 1528 (citing Hodder v. Goodyear Tire & Rubber Co., 426 N.W.2d 826, 833 (Minn. 1988)). Nevertheless, neither Kociemba nor Hodder impose a state duty to report warnings to the FDA. Indeed, Hodder, upon which Kociemba was based, dealt with a post-sale duty to directly warn users of a product of its safety hazards. Hodder, 426 N.W.2d at 832-33. Even plaintiffs' counsel acknowledged that Kociemba does not impose a state duty to report to the FDA. Tr. 17. In other words, if the Court were to apply the duty to warn articulated in either Kociemba and Hodder in relation to warning end-users (in this case doctors or patients), as opposed to third parties such as the FDA, it would be mandating a requirement that is different from or in addition to, any requirement applicable under the FDCA. See Kinetic Co., Inc. v. Medtronic, Inc., Civil No. 08-6062 (PJS/AJB), 2011 WL 1485601, *3 (D. Minn. April 19, 2011) ("Kinetic does not claim that Medtronic failed to include FDA-approved warnings and disclosures with the devices. Rather, Kinetic seeks to hold Medtronic liable for failing to include additional warnings—specifically, a warning about

the devices' battery problems and resulting high risk of failure. But Kinetic admits that there is no federal requirement that Medtronic disclose this information to doctors or patients. Because there is no such requirement under the FDCA, Kinetic is seeking to use state law to impose requirements on Medtronic that are 'different from, or in addition to,' the requirements imposed by the FDCA.").

Further, even assuming that the possible applicable jurisdictions permit a state law claim for failure-to-warn a patient based on St. Jude's failure to issue timely or proper MDRs to the FDA, such claims are not genuinely equivalent to a duty imposed by the FDCA. Such a state law claim would necessarily imply that a warning provided by an MDR would automatically reach a physician and then reach affected patients. However, as stated above, under the FDA regulatory scheme, MDRs that are submitted by a manufacturer to the FDA are not automatically made public, and plaintiffs concede that making MDRs public or the timing of making them public is within the FDA's discretion. In essence, such state law failure-to-warn claims would mandate that a Class III Device manufacturer warn (and timely warn) a patient via a MDR through their physicians of any dangers of the device via a MDR, even though there is no requirement that such MDRs be made available to physicians by the FDA. Such a requirement is different from, or in addition to, any requirement applicable under the FDCA and its implementing regulations, and is pre-empted.

This Court also concludes that plaintiffs' failure-to-warn claims are impliedly preempted. Under the FDCA, all actions to enforce its requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Given that only the United States can bring suit for violations on the FDCA, § 337(a) prohibits private suits against

manufacturers for the failure to comply with the medical device requirements. See 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. . . ."). In order to avoid implied preemption under § 337(a), "the plaintiff must not be suing because the conduct violates the FDCA." In re Medtronic, Inc., 623 F.3d at 1204 (citation and marks omitted); see also Kinetic Co., Inc., 2011 WL 1485601 at *2 (citations omitted). "In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law--and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted . . . ." Riley, 625 F.Supp.2d at 777 (citation omitted).

In this case, the asserted malfeasance as it relates to plaintiffs failure-to-warn claims is "that Defendants failed to provide timely and adequate reports regarding safety hazards and/or potential defendant to the FDA in violation of 21 CFR 803 et seq," which is parallel to its state law duty to report risks associated with the use of their medical leads. See Pls.' Reply, pp. 4-5. Similar to Kinetic Co., Inc., where the court found that the plaintiff's reliance on the defendant's failure to disclose device problems in violation of 21 C.F.R. § 803.50 was an attempt to enforce the MDA, (2011 WL 1485601 at *3), plaintiffs in this case rely on the same regulation relating to the MDR reporting requirements to support their failure-to-warn claim. Plaintiffs "cannot make an end run" around the rule precluding suit by re-casting violations of the FDCA reporting

requirements under 21 C.F.R. § 803.50 and 21 C.F.R. § 803.53 as violations of state common law. See In re Medtronic, Inc. Sprint Fidelis Leads Products Liability, 592 F. Supp.2d 1147, 1160-61 (D. Minn. 2009). The Eighth Circuit, in affirming the district court, concluded:

> Plaintiffs alleged that Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations. As the district court concluded, 592 F.Supp.2d at 1161, these claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in Buckman, 531 U.S. at 349, 353, 121 S.Ct. 1012.

In re Medtronic, Inc., 623 F.3d at 1205-06.

In sum, the failure to properly or timely to warn the FDA via the MDR process, as opposed to warning a doctors or patients of a device's dangers, is not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted. Therefore, plaintiffs' reliance on Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) is misplaced. According to the Ninth Circuit, under Arizona law, a warning to a third party, "satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is 'reasonable assurance that the information will reach those whose safety depends on their having it.'" Id. at 1233. The Ninth Circuit concluded that the claim was not impliedly preempted as the Arizona "state-law claim [ ] is independent of the FDA's pre-market approval process that was at issue in Buckman." Id. But here, plaintiffs are alleging that their claims are based on St. Jude's failure to provide reports required under the regulations to the FDA. See Pls.' Reply, p. 4. Plaintiffs' counsel acknowledged that St. Jude's "duty to report to the FDA arises only under federal law." Tr. 17. While a parallel state claim that is based on a

separate state duty may survive preemption, a claim that "'exists solely because of the FDCA disclosure requirement,'" such as the MDR requirements in this case, is impliedly preempted. See Hughes v. Boston Scientific Corp., 631 F.3d 762, 775 (5th Cir. 2011) (quoting Buckman, 531 U.S. at 352-53). Likewise, plaintiffs' reliance on the duty to report post-sale found in Kociemba, is unavailing because there the post-sale duty pertained to disclosures to physicians and patients, as opposed to disclosure to governmental agencies or any other third parties.

For all of the reasons stated above, the Court finds that plaintiffs' proposed failure-to-warn claims are futile because they are expressly and impliedly preempted. As such, plaintiffs' motions to amend as it relates to Count V of the proposed first Amended complaint are denied.[4]

B. Breach of Express Warranty Claim (Count VI)

In their proposed breach of express warranty claim, plaintiffs alleged that St. Jude expressly warranted to them that the leads were "safe, effective, fit and proper for their intended use," which "were false in that the Leads were not safe and were unfit for the uses for which they were intended," and that defendants "breached their warranty of the mechanical soundness of the Leads by continuing sales and marketing campaigns highlighting the safety of its product, while it knew of the defects and risk of product

[4] Even if the Court had determined that the proposed failure-to-warn claims were not preempted, the Court still concludes that the proposed claims are futile given that plaintiffs have failed to alleged how they were harmed by defendants' alleged failure to submit timely and adequate MDRs to the FDA. See, e.g., Drager by Gutzman v. Aluminum Indus., Corp., 495 N.W.2d 879, 882-885 (Minn. Ct. App. 1993) (applying proximate causation analysis to claims of failure to warn), rev. denied (Minn. Apr. 20, 1993). But the Court is not relying on this deficiency for its decision because that is something that plaintiffs could likely cure through further pleading.

failure." See Proposed First Amended Complaint, ¶¶ 100, 101, 103 (emphasis added). According to plaintiffs, these warranties were made by St. Jude "in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public. . . ." Id., ¶ 100.

Relying on the Eighth Circuit's decision in In re Medtronic, Inc., the district court in Kinetic Co., Inc., concluded that a breach of express warranty claim, with similar general language to the claims proposed in this case, was expressly preempted under § 360k:

> Kinetic's claims that Medtronic falsely represented and warranted the safety of the devices are likewise preempted. The amended complaint relies entirely on general warranties and representations by Medtronic that the devices were "safe," Am. Compl. ¶¶ 31, 35, 45(l), 55, 59, 67, 93,109, "sound," id. ¶¶ 36, 49, 55, 59, 107, "reliable," id. ¶¶ 36, 49, 61, 107, 109, "effective," id. ¶¶ 67, 93, "non-defective," id. ¶ 60, and "fit and proper for [their] intended use," id. ¶ 93. These allegations are materially indistinguishable from the allegations in Sprint Fidelis that Medtronic had warranted and represented the Sprint Fidelis leads as "safe, effective, fit and proper for their intended use." Sprint Fidelis, 623 F.3d at 1207. The Eighth Circuit held that claims based on such representations are preempted: "To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement." Sprint Fidelis, 623 F.3d at 1208. Similarly, to succeed on their consumer-protection, express-warranty, and unjust-enrichment claims in this case, Kinetic would have to persuade a jury that the devices were not "safe," "sound," "reliable," "effective," "non-defective," and "fit and proper for [their] intended use"—which is no different than persuading a jury that the devices are not "safe and effective." These claims are therefore preempted under Sprint Fidelis.

Kinetic Co., Inc., 2011 WL 1485601, at *4 (footnote omitted). At the same time, an express breach of warranty claim arising out of voluntary statements made St. Jude that

are not based on claims approved or mandated by the FDA are not expressly preempted:

> To the extent that an express-warranty claim is not based solely on the contents of an FDA-approved label-or on statements that were otherwise approved or mandated by the FDA-the claim is not preempted. Federal law permits, but does not require, manufacturers like Cordis to make warranties, as long as those warranties are truthful and accurate. For example, the PMA requires that any warranties Cordis chooses to make "be truthful, accurate, and not misleading, and ... consistent with applicable Federal and State laws," PMA 1-3, and federal regulations require that the Cypher stent be distributed and advertised consistently with these terms of the PMA, 21 C.F.R. § 814.80. Therefore, to the extent that Riley seeks to impose liability on Cordis for voluntarily making warranties, Riley is not imposing any different or additional requirements on Cordis. Federal law already requires Cordis to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.
>
> In sum, a claim for breach of an express warranty that is based on statements that a manufacturer is required to make-such as statements in an FDA-approved label-is preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer would have to do something "which is different from, or in addition to" what federal law requires. But a breach-of-express-warranty claim based on voluntary statements is not preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer need do nothing more than refrain from making voluntary warranties. Any other result would turn FDA approval of some statements into a free pass to deceive consumers by making other statements.

Riley, 625 F. Supp.2d at 776-77.

As such, to that extent that plaintiffs' breach of express warranty claims are based on representations stated on an FDA-approved label or on statements that were otherwise approved or mandated by the FDA, such claims are preempted, while those

that are voluntarily made and not based on FDA-approved statements, are not preempted. Plaintiffs asserted that their claims are based on voluntary statements by St. Jude. Pls.'s Reply, p. 6. However, the Court cannot even begin to judge the grounds for such claims from the face of the proposed first amended complaint, as plaintiffs failed to articulate the alleged representations made by St. Jude and how they fell outside of what was approved by the FDA. All this Court has before it are general assertions by plaintiffs that St. Jude falsely represented that the leads were "safe, effective, fit and proper for their intended use." Plaintiffs are asking this Court, in a vacuum, to suspend disbelief that the FDA issued the pertinent PMA and supplements relating to the leads without finding that the leads were safe, effective, fit and proper for their intended use. This the Court will not do. Therefore, based on language of the proposed breach of express warranty claims, plaintiffs must persuade a jury that the leads were not safe and effective, a finding that is contrary to the FDA's approval of the PMA and various supplements. On this basis, the Court finds the proposed claims expressly preempted.

For all the above stated reasons, plaintiffs' motions to amend as it relates to Count VI are denied.

C. Additional Proposed Factual Allegations

St. Jude made no objection or argument opposing the additional factual allegations set forth in proposed first amended complaint in their written opposition to the motions to amend. Nevertheless, at the hearing, St. Jude argued for the first time that the Court should deny the motion to amend as to the additional factual allegations because there is no linkage between those factual allegations and the claims in this

case. Tr. 12. Specifically, St. Jude took issue with the proposed facts arising out of the inspections that took place at the Sylmar facility from 2009 to 2012, (¶¶ 41-46 of the proposed amended complaint), given that they are irrelevant to the surgeries that the respective plaintiffs endured in 2003, 2008 and 2009, and the 2012 inspection dealt with the Durata lead, as opposed to the Riata lead. Tr. 43-46.

The Court rejects St. Jude's argument on the basis that it was raised for the first time during the hearing and deprived plaintiffs the proper opportunity to respond to the argument. See Mohammed v. Frazier, Civ. No. 07-3037 (RHK/JSM), 2008 WL 360778, *4 n.3 (D. Minn. Feb. 8, 2008) (rejecting defendants' argument raised for the first time at a hearing as not properly before the Court, as the opposing party had no opportunity to address such a claim). Moreover, St. Jude is asking this Court to make a determination that the factual allegations in the proposed amended complaint are irrelevant to the asserted claims and have gone so far as to suggest this Court base that analysis on evidence outside of the proposed amended complaint to prove its position. Tr. 45. While St. Jude may ultimately be correct that the allegations arising out of the inspections that took place at the Sylmar facility are irrelevant to plaintiffs' injuries, that is not a determination that the Court can make on a motion to amend the complaint.

For all of these reasons, plaintiffs' motions to amend the factual allegations set forth in the proposed first amended complaint are granted.

J.S.M.