UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOHN J. TEIXERIA,

Plaintiff,

-vs-

ST. JUDE MEDICAL S.C., INC., ST JUDE MEDICAL, INC., and PACESETTER, INC., D/B/A ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION,

Defendants.

DECISION AND ORDER
No. 1:14-cv-00789-MAT-HBS

INTRODUCTION

Represented by counsel, John J. Teixeria ("Teixeria" or "Plaintiff") instituted this product liability action in New York State Supreme Court (Erie County) against St. Jude Medical S.C., Inc., St. Jude Medical, Inc., and Pacesetter, Inc., d/b/a St. Jude Medical Cardiac Rhythm Management Division (collectively, "Defendants" or "St. Jude"). Defendants removed the matter to this Court on September 17, 2014, and subsequently filed a Motion to Dismiss or in the Alternative for Summary Judgment (Dkt #4), a Motion to Dismiss for Failure to State a Claim (Dkt #16) ("Motion to Dismiss") and a Motion for Sanctions and to Strike Amended Complaint (Dkt #18) ("Motion to Strike"). On July 15, 2015, Magistrate Judge Hugh B. Scott issued a Report and Recommendation ("Report") (Dkt #26) on the Motion to Dismiss and the Motion to Strike. With regard to the Motion to Dismiss, Magistrate Judge

Scott recommended (1) allowing the first cause of action based on strict liability for a manufacturing defect to proceed; (2) allowing the second cause of action for negligent manufacturing to proceed; (3) dismissing the third and fourth causes of action for failure-to-warn claims based on negligence and strict liability in their entirety; (4) dismissing the fifth cause of action for negligent representation based on St. Jude's failure to provide Plaintiff, his doctors, and the FDA with accurate information about the reliability and safety of the Durata lead; (5) dismissing the claim for breach of implied warranty asserted in the sixth cause of action, to the extent that Teixeira alleges anything other than a deviation from FDA standards that equates to a lack of fitness for intended purposes; (6) dismissing the claim for breach of express warranty asserted in the sixth cause of action, with respect to any allegations other than explicit, personal representations by St. Jude; and (7) denying the motion in all other respects. Magistrate Judge Scott denied the Motion for Sanctions and to Strike the Amended Complaint in its entirety, without prejudice to future motions that may be required to address allegations maintained despite pretrial discovery to the contrary. See Report, pp. 35-36.

Defendants filed partial Objections (Dkt #27) to the Report and Recommendation, and Plaintiff filed a Reply/Response (Dkt #28) to Defendants' objections, to which Defendants filed a

Reply/Response (Dkt #30). The matter was transferred to the undersigned on May 6, 2016 (Dkt #48).

FACTUAL BACKGROUND

The underlying facts are set out comprehensively in the Report. Briefly, however, Teixeira had surgery on September 6, 2011, to place an implantable cardioverter-defibrillator ("ICD") (Durata Model CD1231-40Q) and lead (Durata Model 7121Q/65),[1] which were designed, manufactured, and sold by St. Jude.[2] On September 20, 2011, Teixeria underwent a second surgery to replace the lead for reasons not articulated in the Amended Complaint. Although the Amended Complaint contains no allegations indicating that anyone has ever examined the Durata device that was explanted and replaced, Plaintiff theorizes that the lead insulation became abraded in situ and resulted in an "externalization" of the lead,

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1 An ICD is implanted in patients to help treat certain heart conditions and symptoms of heart failure. A lead is a thin, insulated wire that delivers electronic pulses from the ICD to the heart. Premature lead abrasion is a known and disclosed risk of harm. See Amended Complaint ("Am. Compl.") ¶ 72; Viserta v. St. Jude Med. Inc., C.A. No. 8:11-cv-00505-JMC, 2012 WL 667814, at *4 (D. S.C. Feb. 29, 2012).

2 The Durata ICD and lead are categorized in the highest risk classification level (Class III) under the 1976 Medical Device Act ("MDA"), which "imposed a regime of detailed federal oversight" over medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316-17 (2008); see also 21 U.S.C. § 360c(a)(1)(C)(ii). As a Class III device, the Durata was required to undergo the FDA's rigorous Premarket Approval ("PMA") process, which involves an extensive application, disclosure of all investigations related to the device's safety and effectiveness, disclosure of all ingredients or device components, review of manufacturing processes and facilities, submission of device samples, and submission of device labeling. See 21 U.S.C. § 360e(c)(1). The Durata's completion of the PMA process means that the FDA has approved the design, manufacturing method, and labeling of the ICD and lead as appropriate and reasonably safe. The FDA continues to oversee Class III devices after the grant of PMA. See 21 U.S.C. § 360i.

i.e., the lead wires began protruding through the insulation. According to Plaintiff, this caused the wires to come into contact with bodily substances that prevented the ICD from functioning properly. Defendants argue that Plaintiff's theory is based on issues that occurred with a different model of lead, the Riata, a predecessor to the Durata that differs from it in several respects. Moreover, Defendants contend, when "externalization" has occurred, it has been many months, if not years, after implantation of the device. Therefore, Defendants argue, externalization could not have happened here, since Plaintiff had his device replaced only 14 days after implantation. Defendants urge dismissal of the Amended Complaint, asserting that Plaintiff has failed to allege a violation of federal requirements specific to the Durata lead and has failed to plausibly allege a causal link between any alleged violation of federal law and his purported injuries.

GENERAL LEGAL PRINCIPLES

I. Review of Reports and Recommendations

Where no objection is made to a report and recommendation, or the parties make frivolous, conclusive, or general objections, only "clear error" review is required by the district court. See FED. R. CIV. P. 72(b), Advisory Comm. Notes (1983); Camardo v. General Motors Hourly-Rate Employees Pension Plan, 806 F. Supp. 380, 382 (W.D.N.Y. 1992)). In such case, the district court "need only satisfy itself that there is no clear error on the face of the

record in order to accept the recommendation." FED. R. CIV. P. 72(b), Advisory Comm. Notes (1983).

However, a district court must review de novo those portions of the magistrate judge's findings and recommendations to which a party has made specific and timely objections. See 28 U.S.C. § 636(b)(1)(C); FED. R. CIV. P. 72(b). The de novo standard requires that the district court "'give fresh consideration to those issues to which specific objections have been made'" and "examine the entire record," and "mak[ing] an independent assessment of the magistrate judge's factual and legal conclusions." United States v. Raddatz, 447 U.S. 667, 675 (1980) (quoting legislative history). After conducting the appropriate review, the district judge may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1)(C).

II. Rule 12(b)(6) Motions to Dismiss

When deciding motions to dismiss under Rule 12(b)(6), the court must apply a "plausibility standard," guided by "[t]wo working principles." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). First, although the court must accept all factual allegations as true, this tenet is "inapplicable to legal conclusions[.]" Id. Second, only complaints that state a "plausible claim for relief" can survive a Rule 12(b)(6) motion to dismiss. Id. at 679. A plaintiff must provide "factual content that allows the court to

draw the reasonable inference that the defendant is liable for the misconduct alleged[,]" a standard that requires "more than a sheer possibility that a defendant has acted unlawfully." Id. at 678. If the plaintiff has not "nudged [his] claims across the line from conceivable to plausible," they "must be dismissed." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007); accord Iqbal, 556 U.S. at 669.

DEFENDANTS' MOTION TO DISMISS

I. Review of the Portions of the Report to Which the Parties Have Not Objected

Plaintiff indicates that he agrees with the Report and requests that the Court accept in full the findings and recommendations therein. Thus, Plaintiff does not object to the dismissal of the third (negligent failure to warn), fourth (failure to warn under a theory of strict liability), and fifth (negligent misrepresentation) causes of action. Defendants likewise do not object to these portions of the Report. Because the Court finds that the Report's recommendations as to these causes of action are not clearly erroneous, the Court adopts them and dismisses the third, fourth, and fifth causes of action with prejudice.

II. Review of Defendants' Objections

In their Objections, Defendants discuss four issues that they assert were not resolved or considered in the Report, i.e., "(1) [w]hether Plaintiff has stated a claim for breach of express warranty; (2) whether the FDA's 2013 Warning Letter has any

applicability in this case; (3) whether to state a parallel[ ]claim[3] under Twombly a plaintiff must plead facts based on a device inspection or medical records that put the plaintiff within the alleged zone of danger; and (4) whether Twombly requires that any allegations made on 'information or belief' not be made up, but rather, be supported by a reasonable and plausible inference from well-pled facts." Objections (Dkt #27), p. 2. In his Response, Plaintiff contends that he has provided well-pled factual allegations, sufficient to substantiate plausible causes of action.

A. First Objection: Whether Plaintiff Has Stated a Non-Preempted Claim for Breach of Express Warranty

St. Jude agrees with the Report's recommendation that the breach of express warranty claim is preempted to the extent it is based on St. Jude's packaging and labeling, which were approved by the FDA in the PMA process. St. Jude objects to the Report's recommended finding that the claim is not preempted to the extent

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[3] "The MDA's pre-emption clause provides that no State '"may establish or continue in effect with respect to a device . . . any requirement"' relating to safety or effectiveness that is different from, or in addition to, federal requirements."'" Altria Grp., Inc. v. Good, 555 U.S. 70, 86 (2008) (quoting Riegel, 552 U.S. at 328 (quoting 21 U.S.C. § 360k(a)); emphasis deleted in original; ellipsis in original). In Riegel, the Supreme Court held that state-law design and manufacturing defect claims are preempted under the MDA where they impose safety requirements on medical device manufacturers that are different from, or in addition to federal requirements, but allowed a narrow exception for state-law claims based on state-law duties that merely "'parallel,' rather than add to, federal requirements." 552 U.S. at 330 (dismissing as preempted state common-law claims related to the safety and effectiveness of a medical device approved by FDA where plaintiffs alleged that the device violated state tort law notwithstanding compliance with the federal requirements, the state claims were preempted).

that it is based on "explicit, personal representations," Report, p. 29, that were "volunteered," id., by St. Jude, and in which St. Jude "stepped outside," id., of the FDA-approved labeling for the Durata lead.

The Court agrees with St. Jude that the first rationale, i.e., that the representations were "volunteered," is not a basis to deny the motion to dismiss because, whether volunteered by the manufacturer or required by law, claims based on written or oral statements whose content falls within the parameters of FDA-approved labeling are expressly preempted under the MDA. See Horowitz v. Stryker Corp., 613 F. Supp.2d 271, 285 (E.D.N.Y. 2009) ("Plaintiff's breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer.") (citing Lake v. Kardjian, 874 N.Y.S.2d 751, 754 (Sup. Ct. 2008) (finding that "a breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted . . . , because such a claim would impose requirements different from, or in addition to, the federal requirements, potentially resulting in the imposition of liability on a manufacturer who has fully complied with federal law")).

The Court turns next to the Report's recommendation that Plaintiff's breach of express warranty claim should survive to the extent it is based on "explicit, personal representations," in which St. Jude allegedly "stepped outside," Report, p. 29, of the

FDA-approved labeling for the Durata lead. Under New York state law, "representations which are the subject of breach of express warranty claims are considered to be requirements imposed by the warrantor, not by the state." Horowitz, 613 F. Supp.2d at 285-86 (citing Wallace v. Parks Corp., 629 N.Y.S.2d 570, 574 (4th Dep't 1995) (finding that liability under "[b]reach of express warranty claims . . . arises . . . from a promise voluntarily made by the manufacturer") (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525 & n.23 (1992)). An express warranty is an "affirmation of fact or promise made by the seller to the buyer which . . . becomes part of the basis of the bargain." N.Y. UNIFORM COMMERCIAL CODE § 2-313(1)(a). Thus, "an action for breach of express warranty requires both the existence of an express promise or representation and reliance on that promise or representation." Horowitz, 613 F. Supp.2d at 286 (citing CBS Inc. v. Ziff-Davis Publ'g Co., 75 N.Y.2d 496, 503 (1990)).

Defendants argue that Plaintiff has not specifically pled any explicit, personal representation made by an agent or employee of St. Jude, much less a representation the substance of which was not approved by the FDA. After independently examining Plaintiff's allegations in the Amended Complaint regarding the representations by St. Jude, contained in Paragraphs 169, 173, and 174, the Court agrees, as discussed further below.

First, in Paragraph 169, Plaintiff alleges that St. Jude

> expressly or impliedly warranted and represented to the Plaintiff that the aforesaid defibrillator and Durata lead were safe, proper, merchantable and fixable, foreseeable [sic] and intended uses [sic] for which it [sic] were designed, manufactured and assembled; were not a danger to the user; would not be dangerous or present a risk of injury; were free from defects, were reasonably safe, were of merchantable quality and reasonably fit for the purposes for which it was designed, manufactured, assembled, inspected, tested, sold and purchased and intended to be used.
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> . . .

Am. Compl. ¶ 169. These bare-bones allegations are too generic to set forth a claim for breach of an express warranty. See, e.g., Fisher, 783 F. Supp.2d at 431-32 (dismissing breach of express warranty where complaint merely stated that "[d]efendants expressly warranted to [the plaintiff] and his physicians that the product was of merchantable quality and safe for the use for which it was intended"; stating that the "failure to allege any specific words, promises or statements made by [the defendants] to [the plaintiff] or his physicians that would create an express warranty is fatal to the claim").

Next, Plaintiff asserts that

> [r]epresentatives of Defendants made personal representations to Plaintiff and/or his treating medical providers that the devices utilized on Plaintiff were safe, long lasting, and would not prematurely erode.

Am. Compl. ¶ 173. While courts have held that "[a]ffirmations of fact regarding the safety of a product are actionable on a claim for breach of express warranty[,]" Williamson v. Stryker Corp.,

No. 12 CIV. 7083 CM, 2013 WL 3833081, at *9 (S.D.N.Y. July 23, 2013) (citations omitted),[4] the plaintiff nevertheless "must allege where, when or how the alleged promise or statement was provided to [himself] or his physicians." Fisher v. APP Pharm., LLC, 783 F. Supp.2d 424, 431 (S.D.N.Y. 2011). Here, Plaintiff has not pleaded *any* facts regarding where, when, and how the alleged statements and promises regarding the Durata lead were made to him or his physicians by a representative of St. Jude. See Gelber v. Stryker Corp., 788 F. Supp.2d 145, 166 (S.D.N.Y. 2011) (complaint alleging that manufacturers of artificial hip prosthesis represented that prosthesis was safe and effective for its intended purpose, and that manufacturers complied with manufacturing specifications set forth in PMA application submitted to FDA, failed to state claim for breach of express warranty under New York law, absent allegations of where alleged representations appeared or to whom they were made); Cordova v. Smith & Nephew, Inc., No. 14-CV-351 JFB ARL, 2014 WL 3749421, at *8 (E.D.N.Y. July 30, 2014) (finding that complaint did not state a breach of warranty claim where plaintiff alleged in a "wholly conclusory fashion" that defendant "breached express warranties 'regarding the performance of the [R3 Ceramic System]' including warranties 'that it would be safe to use', and

[4] See, e.g., Rice v. Kawasaki Heavy Indus., Ltd., No. CV-07-4031(SJF)(ARL), 2008 WL 4646184, at *10 (E.D.N.Y. Oct. 17, 2008); Spiegel v. Saks 34th St., 252 N.Y.S.2d 852, 857-58 (N.Y. Sup. App. Term. 1964), aff'd, 272 N.Y.S.2d 972 (2d Dept' 1966).

that it was 'inspected and accepted in accordance with this defendant's own and other recognized safety standards'").

Finally, Plaintiff asserts that

> [u]pon information and belief, Representatives of Defendants made personal representations to Plaintiff and/or his treating medical providers that the devices utilized on Plaintiff would not require a surgical intervention.

Am. Compl. ¶ 174. The Second Circuit has explained that the Twombly/Iqbal plausibility standard "does not prevent a plaintiff from "pleading facts alleged 'upon information and belief'" where the facts are peculiarly within the possession and control of the defendant," Arista Records, LLC v. Doe 3, 604 F.3d 110, 120 (2d Cir. 2010) (citation omitted), "or where the belief is based on factual information that makes the inference of culpability plausible," id. (citing Iqbal, 129 S. Ct. at 1949). However, whether representations were made to Plaintiff or his medical providers are factual matters that are peculiarly within the possession of *Plaintiff himself*, or could be obtained by Plaintiff simply asking his doctors or reviewing his own medical records. For Plaintiff to make an allegation "on information and belief" in such circumstances is an improper use of this pleading device. This speculative allegation does not assist Plaintiff in stating a claim for breach of express warranty.

Finally, the Court must address the Report's finding that "Teixeira will have to conform through discovery what

representations St. Jude explicitly made, but for now, explicit personal representations from a manufacturer eager to sell a device *plausibly could have happened*." Report, p. 29 (emphasis supplied). The Court respectfully must disagree with this recommendation, given the clear statement by the Supreme Court in Iqbal that Rule 8 of the Federal Rules of Civil Procedure "does not unlock the doors of discovery for a plaintiff[,]" such as Teixeria, "armed with nothing more than conclusions." 556 U.S. at 678-79.

Because the Court finds that Plaintiff has failed to plead, under Twombly/Iqbal, a plausible claim for breach of express warranty, it need not decide whether such a claim, if well-pled, would be expressly or impliedly preempted by federal law. The claim for breach of express warranty, asserted in the sixth cause of action, is dismissed for failure to state a claim.

B. Objections Two and Three: The Relevance of the FDA's 2013 Warning Letter and the Lack of Factual Allegations Specific to Plaintiff's Durata Device

St. Jude objects to Plaintiff's reliance on the FDA's 2013 Warning letter and argues that its issuance does not assist Plaintiff in articulating plausible parallel, non-preempted claims for strict liability, negligent manufacturing, and breach of implied warranty.

"To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in

the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that *the defect was the cause* of plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp.2d 53, 85 (S.D.N.Y. 2001) (emphasis supplied; quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 129 (1981)). "A breach of implied warranty claim requires proof . . . (1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the *defect is the proximate cause* of the accident." Plemmons v. Steelcase Inc., No. 04 CV 4023(LAP), 2007 WL 950137, at *3 (S.D.N.Y. Mar. 29, 2007) (internal quotation marks and citation omitted; emphasis supplied). As the Second Circuit has observed, "[t]here is . . . no older requirement in th[e] area of [tort] law than the need to show such a [causative] link between the defendant's actions and the plaintiff's loss." Zuchowicz v. United States, 140 F.3d 381, 383 (2d Cir. 1998). In the context of product liability claims involving FDA-regulated devices, showing a "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." Leonard v. Medtronic, Inc., No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *6 (N.D. Ga. Aug. 19, 2011) (quoting Franklin v. Medtronic, Inc., No. 09-CV-02301REBKMT,

2010 WL 2543579, at *10 (D. Colo. May 12, 2010), report and recommendation adopted, No. 09-CV-02301-REB-KMT, 2010 WL 2543570 (D. Colo. June 22, 2010); citing Reigel, 552 U.S. at 319).

With these general principles in mind, the Court evaluates St. Jude's objection regarding Plaintiff's reliance on the Warning Letter issued by the FDA in 2013, following an inspection of St. Jude's production facility located in Sylmar, California, on September 25, 2012, through October 17, 2012. The FDA's inspection revealed that the Durata devices manufactured at the facility "are adulturated within the meaning of Section 501(h) of the [FDCA], 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice [("CGMP")] requirements of the Quality System regulation found at [21 C.F.R. Pt. 820]. . . ." Am. Compl. ¶ 15. St. Jude argues, inter alia, the Amended Complaint does not factually link the Warning Letter to the alleged defect, namely, the supposed externalization of a conductor in Plaintiff's lead, given that the FDA inspection that led to the Warning Letter took place more than two years after Plaintiff's first surgery to implant the Durata ICD and lead. Plaintiff has set forth no allegations regarding how his Durata ICD and lead, implanted in September 2011, could have been affected by FDA investigations that occurred a year later. See Horowitz, 613 F. Supp.2d at 282-83

(dismissing complaint where "Plaintiff provide[d] no explanation as to how her Trident System, which was implanted in her body in 2005, relates to investigations conducted by the FDA in 2006 and 2007. Her complaint also fail[ed] to specify in which of defendants' facilities her hip replacement device, or any components included in the device, was manufactured, making it unclear which, if either, of the two letters she [was] using to substantiate her claims.") (citation omitted). The Court agrees that specific allegations of a plausible causal connection between the 2013 Warning Letter and Plaintiff's device are entirely lacking. See, e.g., Franzese v. St. Jude Med., Inc., No. 13-CV-3203 JS WDW, 2014 WL 2863087 (E.D.N.Y. June 23, 2014).

In Franzese, the district court found that a plaintiff who had been implanted with a Durata device failed to state a parallel claim where he incorporated the same FDA Warning Letter relied on by Teixeria, and urged the same theory of product defect, i.e., that the Durata lead suffered premature deterioration. See 2014 WL 2863087, at *5 (plaintiff alleged that Durata lead was adulterated in violation of Section 501(h) of the FDCA and that the lead and/or defibrillator had an impurity, imperfection, or other product defect). The district court in Franzese found that "[e]ven assuming that such allegations [based on the Warning Letter] assert a sufficient violation of federal regulations," the plaintiffs had "not sufficiently alleged how this violation caused [their]

injuries." Franzese, 2014 WL 2863087, at *5. In Franzese, similar to the present case, the plaintiff alleged that St. Jude "'violated federal law by making unsanctioned adulterations' to the Durata lead[,]'" but, as the district court noted, "such assertions appear to be based on the FDA warning letter, which simply stated that the Durata lead was considered adulterated within the meaning of Section 501(h) because 'the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation' are not in conformity with CGMPs." Id. The specific CGMPs identified in the 2013 Warning Letter, however, "do not have any direct implications on how or why the Durata lead prematurely deteriorated." Franzese, 2014 WL 2863087, at *5 (internal citations to record omitted). As in Franzese, Plaintiff here has not alleged any facts connecting the 2013 Warning Letter to his case; nor has he attempted to articulate how or why the product defect he alleges (externalization of the lead) could have been caused by any of the regulatory violations cited in the Warning Letter.

Relatedly, St. Jude objects to the Report's reference to unspecified "red flags" regarding the Durata lead. The Amended Complaint contains page after page of allegations concerning problems with the Riata lead, an earlier model of lead manufactured by St. Jude, such as the fact that it was the subject of a Class I Recall by the FDA in December 2011. However, the FDA has *not* instituted a recall of the Durata lead, which has a different

design and structure than the Riata lead.[5] Given these differences, Plaintiff's allegations regarding Riata leads are irrelevant and do not assist Plaintiff in stating plausible parallel claims in connection with the Durata lead. See, e.g., Horowitz, 613 F. Supp.2d at 282 (finding that the plaintiff failed to "demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury"; noting that "[a]lthough plaintiff cites to recalls instituted by defendants [for other devices], such recalls did not include the Trident System or any of its components" with which she was implanted).

The Court further finds that Plaintiff's reliance on Rosen v. St. Jude Med., Inc., 41 F. Supp.3d 170 (N.D.N.Y. 2014), is misplaced. First, Rosen involved a different device manufactured by St. Jude, a Riata lead. Second, unlike the Durata, the Riata lead *was* the subject of a recall by the FDA. Third, the plaintiff in Rosen pled specific facts regarding an inspection of his particular device, namely, that his surgeon examined the lead after it was removed, finding that it had indeed fractured, and that the conductor coils had "externalized[,]" Rosen, 41 F. Supp.3d at 174.

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[5] St. Jude, in connection with the Motion to Strike, submitted a screenshot from the FDA's website showing the PMA of St. Jude's Riata ST Optim leads, which were created by placing a second, additional layer of insulation consisting of Optim, a proprietary material, over the silicon lead body of the Riata ST leads. Malynn Decl. ¶ 5 & Ex. 4. In 2008, the FDA approved St. Jude's request to change the tradename for the Riata ST Optim lead to Durata. Id. ¶ 6 (citing http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm (enter "P950022" in the PMA Number field and "1/10/2008" as both the "from" and "to" dates in the Decision Date fields; execute "Search") (last visited June 29, 2016)).

Although Teixeria urges the same theory as the plaintiff in Rosen regarding how and why his device malfunctioned, Teixeria does *not* allege *any* facts supporting his theory that externalization actually occurred. The Amended Complaint contains no allegations regarding an examination of Teixeria's explanted Durata lead, no allegations regarding statements or observations made by Teixeria's physicians, and no allegations referencing notes from Teixeria's medical records—which the Report acknowledges. See Report, p. 3 ("The record contains no allegation or other information about where the replaced lead is and whether anyone has examined it.").[6]

Moreover, Plaintiff's theory of liability—that premature lead abrasions resulted in externalization of the lead wires shortly after implantation—is undermined by documentation he has submitted in connection with his Amended Complaint. Where, as here, a plaintiff has "reli[ed] on the terms and effect of a document in drafting the complaint,'" and that document is thus "'integral to the complaint,'" the court "may consider its contents even if it is not formally incorporated by reference." Broder v. Cablevision Sys. Corp., 418 F.3d 187, 196 (2d Cir. 2005) (quotation omitted;

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[6] For essentially the same reasons, the other two cases based on Riata devices that Plaintiff cites are unhelpful to his argument. First, they involved Riata leads, and second, the plaintiff in those cases pled facts regarding the results of actual testing or examination of the explanted, defective leads. See Waltenburg v. St. Jude Med, Inc., No. 3:13-CV-01106, 2014 WL 3586471, at * 1 (W.D. Ky. July 21, 2014) (complaint alleged externalization shown from diagnostic testing of recalled Riata lead); O'Neil v. St. Jude Med., Inc., No. C13-0661, 2013 WL 6173803, at *1 (W.D. Wash. Nov. 22, 2013) (allegations that plaintiff's surgeon confirmed Riata lead was defective).

brackets in original). As noted above, the Durata has an additional layer of insulation made of a proprietary material called OPTIM®. Plaintiff has submitted a 2012 article published in the journal, HeartRhythm, authored by Dr. Robert G. Hauser, who has performed several studies on ICDs and leads manufactured by St. Jude. In that article, Dr. Hauser acknowledged that "there are no reports in the medical literature of inside-out abrasions involving St. Jude Medical leads that employ Optim insulation." Exhibit ("Ex.") F, p. 9 (Dkt #20-6), attached to Declaration of Joseph Manna, Esq. ("Manna Decl.") (Dkt #20), referenced in Am. Compl. ¶ 105. Moreover, the results of this study indicate that externalization of a Riata lead (which does not have the extra layer of OPTIM® insulation), takes at least a year to occur. See Ex. F (Dkt #20-6), p. 4 ("The average age of the 105 analyzed [Riata] leads was 62.1 ± 18.6 months (range 15-108 months). . . .") to Manna Decl. (Dkt #20). These factors render Plaintiff's claims concerning the Durata even less plausible.

It bears noting that allegations which are "merely consistent with" a plaintiff's theory of liability are insufficient to meet the "plausibility" standard. See Iqbal, 556 U.S. at 678 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" (quoting Twombly, 550 U.S. at 557; brackets omitted in original). Based on

his own documentary submissions, Plaintiff's theory of liability is not even consistent with the facts he has alleged.

C. Objection Four: Whether the Allegations Made "On Information and Belief" Are Sufficiently Supported

St. Jude objects to the Report's acceptance of Plaintiff's allegations that are made "on information and belief," see Report, pp. 31-33. According to St. Jude, Plaintiff has not properly used this pleading device, and the Report ignored the principle that allegations based "on information and belief" cannot be wholly unsupported. Cf. Arista Records, LLC, 604 F.3d at 121 (rejecting defendant's assertion that complaint's allegations were too vague and conclusory to state a plausible claim where, "[t]o the extent that . . . allegations are made on information and belief, virtually all of them are supported by factual assertions in [the attached] [e]xhibit").

The Court notes that the allegations Plaintiff makes "on information and belief" were also the subject of the Motion to Strike, in which St. Jude argued that Plaintiff copied them, more or less verbatim, from a case out of the District of Minnesota, Pinsonneault v. St. Jude Med., Inc., No. 12-CV-1717 PJS/JSM (D. Minn. June 24, 2014), which involved a Riata lead (not a Durata lead). As Defendants noted in their Motion to Strike, Plaintiff's initial 4-page Complaint failed to identify which medical device (the ICD or the lead) was allegedly defective and also failed to

identify the name of the device. However, a mere 21 days after Defendants' Motion to Dismiss was filed, Plaintiff filed a 44-page Amended Complaint containing numerous allegations that are identical, or nearly identical, to allegations in the Pinsonneault complaint. See Declaration of Todd Malynn, Esq. ("Malynn Decl.") (Dkt #18-2), Ex. 2 (Pinsonneault complaint); Ex. 3 (comparison of excerpts from Teixeria's Amended Complaint and the Pinsonneault complaint). For instance, a review of the paragraphs under the heading, "Manufacturing Defects with Regard to Riata and Durata Leads," in Teixeria's Amended Complaint reveals that counsel simply inserted the word "Durata" into that heading and copied it into the Amended Complaint; apparently the same cutting-and-pasting was done with many of the paragraphs from the Pinsonneault complaint, either without making any changes or just altering the verbiage slightly in Teixeria's Amended Complaint. In the representative sample set forth below, the struck-through words and numerals were in the Pinsonneault complant; the italicized words and numerals were added in Teixeria's Amended Complaint:

> ~~47~~*67*. From 2005-2010 St. Jude applied for ~~over 27~~ several manufacturing or process changes to the Riata ~~Leads.~~ *and Durata lead family*. The FDA approved these changes in a PMA and multiple supplements. Upon information and belief, ~~Defendants~~ *St. Jude* failed to manufacture the Riata *and Durata* Leads consistent with ~~design specifications and/or~~ these approved changes, thereby creating *a* defective products.
> . . .
>
> ~~50~~*73*. The breach of insulation and externalization of the lead wires on the Riata *and Durata* Leads can cause the

~~L~~*l*eads to short, and to transmit incorrect information or noise to the pacemaker/defibrillator thereby causing it to produce unnecessary and very painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator at which point the life-saving therapies of the device are unavailable.

. . .

~~52~~*74*. Additionally, St. Jude applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata *and Durata* Leads. Upon information and belief, St. Jude, failed to comply with the approved methods ~~and/or specifications~~ of curing and sterilization during the manufacture of the Leads. Upon information and belief, failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation.

~~75.~~ *53.* ~~Finally,~~ St. Jude applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata *and Durata* Leads. Upon information and belief, *the PMA and Conditions of Approval required the application of* a controlled, uniform degree of force ~~was required~~ when applying the crimp. Upon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps ~~over~~, *lead wire length differences both longer and/or shorter than specification for* the length of the Lead.

. . .

Dkt #18-2, Ex. 3.

The factual similarities between Teixeria's Amended Complaint and the Pinsonneault complaint are striking and impossible to ignore.[7] Plaintiff's attorney, however, denies copying allegations

[7] Courts in this Circuit have dismissed complaints when presented with such similarities. See Grimes v. Fremont Gen. Corp., 933 F. Supp.2d 584, 601 (S.D.N.Y. 2013) ("The fact that so many of Plaintiff's factual allegations are copied from pleadings in unrelated cases is an independent basis for the Court to dismiss Plaintiffs' Civil Rights Act claims.") (citing Triano v. Town of Harrison, 895

from Pinsonneault, and states that his office was not aware either of the complaint in that case or the decision granting summary judgment to St. Jude. In Pinsonneault, the plaintiffs asserted state-law claims of strict liability/manufacturing defect, negligent manufacturing, negligence per se, and negligence res ipsa loquitur based on St. Jude's violation of alleged federal requirements with respect to insulation thickness, crimp force,[8] curing, and lubricious interface. See Pinsonneault, 2014 WL 2879754, at *4, *8. The district court noted that if there were no such federal requirements, then the state-law claims would be preempted under the MDA because they would impose requirements "in addition to" the requirements imposed on the device by virtue of the PMA process. See Pinsonneault, 2014 WL 2879754, at *8. The district court found that St. Jude had "come forward with evidence that, standing alone, prove[d] by a preponderance of the evidence that there are no federal requirements with respect to insulation thickness, crimp force, curing, or lubricious interface." Id. The

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F. Supp.2d 526, 537 (S.D.N.Y. 2012) (dismissing municipal liability claim; plaintiff's allegations were "troubling," because he had "copied [a] list of 'systematic flaws' in his Amended Complaint—which he claim[ed] support[ed] the existence of a municipal custom of tolerating and covering up police abuse—almost verbatim from the allegations made by another plaintiff" in a case in which the Monell claim had survived a motion to dismiss); other citations omitted).

[8] Here, Plaintiff alleges, inter alia, that "[u]pon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps, lead wire length differences both longer and/or shorter than specification for the length of the Lead." The plaintiff in Pinsonneault similarly alleged that "[u]pon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over, the length of the Lead[.]" See Dkt #18-2, Ex. 3.

plaintiff, however, failed to rebut that evidence. See 2014 WL 2879754, at *10 ("[T]here is no evidence of any requirement for a controlled, uniform degree of force when crimping, plaintiffs' claims that the leads were defective . . . ."); see also id. at *8-10.

Where, as here, the Court is evaluating the sufficiency of "information and belief" allegations, its "task is to determine whether-viewing all of the Amended Complaint's factual allegations in the light most favorable to Plaintiff-the pleadings made on "information and belief" "'raise a reasonable expectation that discovery will reveal evidence' proving . . . Plaintiff's claim." Installed Bldg. Products, LLC v. Cottrell, No. 13-CV-1112-ASC, 2014 WL 3729369, at *4 (W.D.N.Y. July 25, 2014) (quoting Twombly, 550 U.S. at 556 ("Asking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement.")). Contrary to Plaintiff's attorney's suggestion, the Court is not invoking collateral estoppel based on Pinsonneault. However, the Court believes that the summary judgment decision in that case drastically decreases the reasonableness of Teixeria's expectation that discovery will reveal evidence proving his claims. The manufacturing standards for the Riata lead which the plaintiff in Pinsonneault claimed were violated by St. Jude violated, were

found—after extensive discovery—to lack a factual basis in any federal requirements. See Pinsonneault, 2014 WL 2879754, at *10 ("Plaintiffs allege that St. Jude failed to apply a 'controlled, uniform degree of force' when crimping the lead wires, which resulted in insecure crimps over the length of the leads. To support their claim that the FDA imposed such a requirement, plaintiffs offer a 'crimp schedule' which refers to crimp depth '[r]equirement[s].' Plaintiffs cite no evidence that this document is part of the PMA, however. . . . Plaintiffs' claims could only be viable, however, if the crimp had to be a particular depth. But that is not the case; the crimp schedule allows for a range of permissible depths. . . ."") (internal citations to record omitted).[9] Moreover, it bears emphasizing that Pinsonneault involved a Riata lead, *not* a Durata lead. Yet Plaintiff is asserting the *same* theory of manufacturing defect urged in Pinsonneault with regard to an entirely different model of lead, the Durata.

Plaintiff's attorney asserts that in performing research in connection with the Amended Complaint, his "office found other cases involving either the Durata or Riata leads that had not been

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[9] See also Pinsonneault, 2014 WL 2879754, at *8, *9-11 (finding that there was no evidence that the FDA required the Riata leads be made with uniform insulation thickness and no evidence of any federal requirements as to curing or inclusion of a lubricious interface). Teixeria also has included allegations that St. Jude failed to follow federal requirements regarding insulation thickness, curing of the materials, and necessity of a lubricious interface.

dismissed[.]" Manna Decl. (Dkt #20) ¶ 11 (emphasis omitted). Again, the Court questions why cases involving Riata leads are even relevant to this inquiry. Nonetheless, the Court reviewed them and found that they do not help Plaintiff's cause. First, as noted, Waltenburg v. St. Jude Med., Inc., No. 3:13-CV-01106-TBR, 2014 WL 3586471 (W.D. Ky. July 21, 2014), involved a Riata lead, not a Durata lead. Plaintiff's attorney asserts, without citation, that the medical research cited in the Waltenburg complaint "indicated" that the Durata lead "may suffer from the same complications that plagued the . . . Riata lead, given their similarities in design." Manna Decl. ¶ 12. In the Waltenburg complaint (Dkt #20-3), the only allegations regarding medical research bear the heading, "Physicians Expose the *Riata* Lead Defects." Dkt #20-3, ¶¶ 89-84, p. 24 of 46 (emphasis supplied). The word "Durata" does not appear in any of the paragraphs under that heading. Furthermore, the medical research articles cited in the Waltenburg complaint studied defects in the Riata and Riata ST leads—not the Durata leads. See id.

Plaintiff also has submitted a copy of the complaint filed in Robert and Margaret Loiseau v. St. Jude Medical, Inc., et al., No. 2:14-1391-JVS(ANx) (C.D. Cal. Feb. 24, 2014). Plaintiff states that St. Jude did not file a Rule 11 motion for sanctions in that case "despite several nearly identical paragraphs between" that complaint and the Waltenburg complaint. See Manna Decl. ¶ 15.

Although the complaint in Loiseau purports to seek damages for "injuries caused by manufacturing defects in the St. Jude Riata and Durata family of cardiac defibrillator leads," Mr. Loiseau only was "implanted with a defective Rialta [sic] Lead and suffered a related injury first discovered several years later when the device failed and had to be surgically removed in April 2012." Dkt. #20-3, ¶ 3. Thus, the Loiseau complaint adds nothing to the reasonableness of Teixeria's expectation that discovery will reveal evidence proving his claims regarding the Durata lead.

Next, Plaintiff's attorney has submitted voluminous exhibits containing "information . . . found from publicly available sources," see Manna Decl. ¶ 12, that allegedly supports Plaintiff's theory of liability. However, again, the vast majority of these documents relate to studies conducted on the Riata lead, *not* the Durata lead. See Id. ¶¶ 13-40 & Exs. D-BB. As an initial matter, with regard to the exhibits Plaintiff submitted that include regulatory notices and warning issued by the FDA, and news articles regarding such notices and warnings, the Court notes that they have been addressed in the portion of this Decision and Order discussing Plaintiff's failure to allege causation. Thus, they will not be discussed again here. The remaining exhibits that mention the Durata lead are as follows: Ex. H (Dkt #20-8), a copy of the New York Times article dated August 16, 2012; Ex. I (Dkt #20-9), a copy of a New York Times article, published on August 21, 2012; and

Ex. J (Dkt #20-10), an article from the New York Times dated September 7, 2012. Turning first to Ex. H, the article merely states that the FDA has "called for studies of other types of leads, including a new model called the Durata." See Ex. H, Dkt. #20-8. This fact does not make Plaintiff's claims plausible. Although the FDA is actively monitoring the Durata lead,[10] Plaintiff has not alleged that the FDA has taken any corrective action with regard to the Durata lead for any regulatory violation connected to lead abrasions or externalization, the defected alleged by Plaintiff here. Next, Ex. I, references a study published by Dr. Robert G. Hauser in EP Europace, an British cardiology journal, "suggest[ing] that a proprietary material used by St. Jude to coat wires that connect an implanted defibrillator to a patient's heart is breaking down prematurely and, in some cases, leading to failure of the device." Dkt. #20-9, p. 1. The article goes on to state that Dr. Hauser "focused on reports that suggested an abrasion problem with both the Durata and another model that also carries the newer coating, the Riata ST Optim[,]" and "found 15 such reports for the Riata ST Optim and 37 for the Durata[,]" in which "the abrasion had occurred within four years of being implanted." Id., p. 3. The article later quotes a financial services analyst from CreditSuisse

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See Ex. I (Dkt #20-9) to Manna Decl. (Dkt #20) (article dated August 21, 2012, noting that the FDA has "ordered St. Jude Medical to conduct additional studies on both the older generation of leads, called the Riata, and the new generation of Durata leads").

who said that "Dr. Hauser's most recent article didn't provide any conclusive evidence of flaws with the Durata lead" and failed to uncover any "smoking guns[.]" Dkt #20-9, p. 4. The Court finds it significant that Plaintiff has not provided a copy of this study by Dr. Hauser or attempted to plead a theory of liability based on any findings from this study by Dr. Hauser, instead relying on allegations from unrelated lawsuits involving an entirely different model of St. Jude lead. Finally, Ex. J adds nothing to Plaintiff's argument, since it merely references in passing an unnamed study, which the Court presumes is the Hauser study that was the subject of Ex. I. In sum, like the rest of the exhibits submitted by Plaintiff, these New York Times articles do not provide any factual support so as to make his "information and belief" allegations plausible. See, e.g., Williams v. Calderoni, No. 11-3020, 2012 WL 691832, at *7 (S.D.N.Y. Mar. 1, 2012) (finding pleadings based upon information and belief insufficient where plaintiff pointed to no information that would render his statements anything more than speculative claims or conclusory assertions). At most, these articles intimate "a sheer possibility that [St. Jude] has acted unlawfully." Iqbal, 556 U.S. at 678. The pleadings, however, "must contain something more than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." Twombly, 550 U.S. at 555 (quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1216 (3d ed. 2004)). To

paraphrase Judge Cardozo, "proof of [product liability] in the air, so to speak, will not do." Palsgraf v. Long Island R. Co., 248 N.Y. 339, 341 (1928).

DEFENDANTS' MOTION TO STRIKE AND FOR SANCTIONS

Because the Court is dismissing the Amended Complaint in its entirety, the branch of the motion seeking to strike certain allegations is moot.

The request for sanctions presents a closer question. Where, as here, "a plaintiff sets out allegations on information and belief, he is representing that he has a good-faith reason for believing what he is saying, but acknowledging that his allegations are 'based on secondhand information that [he] believes to be true.'" Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co., 631 F.3d 436, 442 (7th Cir. 2011) (quoting BLACK'S LAW DICTIONARY 783 (7th ed. 1999)) (alteration in original; citations omitted). The Court has its concerns about the good faith basis for the "information and belief" pleadings, but it is mindful that "[i]n determining whether a pleading lacked a good faith basis the court must be mindful of the fine 'line between zealous advocacy and frivolous conduct.'" Knipe v. Skinner, 146 F.R.D. 58, 60 (N.D.N.Y. 1993) (quoting United States v. International Bhd. of Teamsters, 948 F.2d 1338, 1343 (2d Cir. 1991)). "Only where it is 'patently clear' at the time of the signing that a claim has no chance of success under existing law, and where no reasonable

argument can be advanced to modify existing law are sanctions warranted." Knipe, 146 F.R.D. at 60. The Court is only reviewing this portion of the Report for clear error, since Defendants did not lodge specific objections to it. Upon careful consideration, the Court cannot find that the Report clearly erred in denying sanctions without prejudice to renew after discovery. Since this Decision and Order is terminating this case short of discovery, the Court adopts the Report's recommendation to dismiss the request for sanctions, but with prejudice.

CONCLUSION

For the foregoing reasons, the Court adopts the Report and Recommendation (Dkt #26) in part and rejects it in part. The Motion to Dismiss for Failure to State a Claim (Dkt #16) is granted, and the Amended Complaint (Dkt #8) is dismissed in its entirety. The joint Motion for Sanctions and to Strike Amended Complaint (Dkt #18) is dismissed; specifically, the Motion to Strike is dismissed as moot, and the Motion for Sanctions is dismissed with prejudice.

The Clerk of the Court is directed to close this case.

SO ORDERED.

S/Michael A. Telesca

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HON. MICHAEL A. TELESCA
United States District Judge

Dated: June 30, 2016
Rochester, New York.