UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

SUSAN ROSEN,

Plaintiff,

-against- 1:13-CV-1159 (LEK/CFH)

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

Defendants.

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

In this medical device case, Plaintiff Susan Rosen ("Plaintiff") alleges that she suffered injuries as a result of manufacturing defects and failure to warn by Defendants St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "Defendants"). Dkt. No. 1 ("Complaint"). Defendants filed a Motion to dismiss, and Plaintiff responded with an Amended Complaint. Dkt. Nos. 8; 19 ("Amended Complaint"). Defendants then filed a Motion to Dismiss the Amended Complaint for failure to state a claim upon which relief may be granted. Dkt. No. 25 ("Motion"). For the following reasons, Defendants' Motions to dismiss are denied.

II. BACKGROUND[1]

A. Statutory and Regulatory Background

The Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act

[1] Because this case is before the Court on a motion to dismiss for failure to state a claim, the allegations of the Complaint are accepted as true and form the basis of this section. See Boyd v. Nationwide Mut. Ins. Co., 208 F.3d 406, 408 (2d Cir. 2000); see also Matson v. Bd. of Educ., 631 F.3d 57, 72 (2d Cir. 2011) (noting that, in addressing a motion to dismiss, a court must view a plaintiff's factual allegations "in a light most favorable to the plaintiff and draw[] all reasonable inferences in her favor").

("FDCA"), 21 U.S.C. § 301 et. seq., require certain medical devices to undergo a stringent Pre-Market Approval ("PMA") process by the Food and Drug Administration ("FDA") before they may be marketed and sold to the public. 21 U.S.C. § 360e; Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008). Class III medical devices, which are used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[] a potential unreasonable risk of illness or injury," are subject to the greatest level of scrutiny. Riegel, 552 U.S. at 316; 21 U.S.C. § 360c(a)(1)(c).

Even after a device is FDA-approved and marketed to the public, "all PMA-approved devices are subject to the same federal device-specific regulation[, including] complying with the standards set forth in their individual approved PMA applications." Riegel v. Medtronics, Inc., 451 F.3d 104, 119 (2d Cir. 2006), aff'd, 552 U.S. 312 (2008). A manufacturer is not permitted to, *inter alia*, make changes to design specifications or manufacturing processes without FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i); Riegel, 552 U.S. at 319. Device manufacturers are also subject to continued reporting requirements, "including the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device of which the manufacturer knows or reasonably should know, and the obligation to 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 were it to reoccur." McConologue v. Smith & Nephew, Inc., No. 13-CV-0880, 2014 WL 1246834, at *4 (D. Conn. Mar. 24, 2014); 21 U.S.C. § 360i; 21 C.F.R. §§ 814.84(b)(2), 803.50(a); Riegel, 552 U.S. at 319.

B. Riata Leads

Defendants[2] manufacture a variety of medical devices to treat heart conditions, including implantable cardiac defibrillators ("ICD") and wires, called "leads," which attach the ICD to the heart. Am. Compl. ¶ 2. The leads serve to monitor the heartbeat and correct any irregular rhythms. Id. In 1996, Defendants received approval from the FDA to market and distribute the Ventritex TVI Lead, a Class III medical device. Am. Compl. ¶¶ 3, 20. From 1996 to 2002, Defendants submitted, and the FDA approved, fourteen PMA Supplements, which altered various aspects of the design and manufacturing process. Id. ¶ 29. Based on the original and supplemental PMAs, in 2002, Defendants formally introduced its Riata Leads to replace the Ventritex TVI Lead. Id. ¶ 3. Over the next several years, Defendants submitted and received approval for numerous modifications to the manufacturing and design processes for the Riata Leads. Id. ¶¶ 30-35.

C. Plaintiff's Implantation and Removal of Riata Lead

Plaintiff was implanted with a Riata Lead in 2004. Am. Compl. ¶ 8. On or around September 25, 2012, Plaintiff's treating physician determined that the lead was not operating properly and suspected that it may have fractured. Id. On or around October 8, 2012, Plaintiff's Riata Lead was surgically extracted; the surgeon found that it had indeed fractured, and the conductor coils had "externalized."[3] Id. ¶ 9.

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[2] Defendant Pacesetter, Inc. is a wholly owned subsidiary of Defendant St. Jude Medical, Inc. Am. Compl. ¶¶ 11-13.

[3] Plaintiff defines "externalization" as occurring when the ICD's cables and/or conductors "protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD." Am. Compl. ¶ 87.

D. FDA Inspections and Reports

1. 2009

In 2009, the FDA conducted a for-cause Quality Systems Inspection Technique ("QSIT") of one of Defendants' manufacturing facilities in California. Am. Compl. ¶ 50. The inspection required Defendants to provide a list of all Corrective and Preventative Action ("CAPA") and Product Improvement Requests ("PIR") opened since 2002. Id. ¶ 50. Defendants' list included PIRs, such as, "cable fracture," "Riata coil fracture," "Missing DF-1 crimps," "Riata Lead with incorrect conduction paths," "Riata Lead abrasion," "Insufficient crimp," "Riata perforation," and "Riata Lead cable coating abrasion." Id. The FDA's inspection also revealed deficiencies in Defendants' "handling of complaints, making Medical Device Reporting ("MDR")[4] determinations, CAPA procedures, and receiving protocols." Id. ¶ 51.

As part of the 2009 QSIT, the FDA interviewed Defendants' Director of Regulatory Compliance, who provided the FDA with a spreadsheet of all complaints for the Riata Leads dating back to 2002, when the Riata Leads entered the U.S. market. Am. Compl. ¶ 54. The spreadsheet indicated that since 2002, a total of 8,463 complaints had been filed; however, the FDA "adverse event database" showed only 3,689 MDRs reported. Id. Following the inspection, the FDA's review revealed that "in some cases Defendants failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 C.F.R. § 803.50(b)." Id. ¶ 56. "Specifically, the complaint files show that the complainants reported perforation adverse events for the Riata [Leads], . . . but these events were not reported as 'perforations' in the

[4] "MDRs are the mechanism by which the FDA receives significant medical device adverse events from manufacturers, importers, and user facilities, so that problems can be corrected quickly." Am. Compl. ¶ 65.

associated MDRs submitted to the FDA by [Defendants]." Id.

The FDA also produced an Establishment Inspection Report ("EIR"), which noted that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by [Defendants] per 21 C.F.R. § 820.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 C.F.R. § 803.50 for device manufacturers." Am. Compl. ¶ 58. Specifically, two "perforation events" from 2003 and 2004 were not submitted until 2008, and were submitted "without explanation." Id.

On July 8, 2009, the FDA issued an eight-item FDA-483 report,[5] which cited deficiencies including, *inter alia*: failure to include all information reasonably known to [Defendants] on an MDR report in violation of 21 C.F.R. § 803 et. seq.; failure to timely submit MDRs to the FDA in violation of 21 C.F.R. § 803 et. seq.; failure to define and implement procedures for corrective and preventative actions in violation of 21 C.F.R. § 820 et. seq.; and failure to properly monitor and review adequately a number of "critical" component parts in violation of 21 C.F.R. § 820 et. seq. Am. Compl. ¶ 72.

2. 2011

A 2011 FDA report indicated that Defendants' CAPAs limited their analysis to "externalized cables and [did] not include exposed cables or all other forms of abrasion, which FDA considers important contributors to the published rate of all abrasion presented in [Defendants'] November 2011 Product Performance Report ("PPR")." Am. Compl. ¶ 60. The FDA's report also noted "numerous instances of underreporting and . . . that the terms 'externalized cable' or even 'abrasion'

[5] "An FDA Form 83 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the [FDCA] and related Acts." Am. Compl. ¶ 71.

may not be employed when it is a contributing cause." Id. ¶ 62. It further indicated that Defendants may have failed to report "the diagnosis of the lead mechanical failure," and that Defendants may have been under-reporting "inappropriate high voltage shock delivery" "due to their limiting terminology."[6] Id. ¶¶ 62-63.

E. Dear Doctor Letters and Recall

On December 15, 2010, Defendants published a "Dear Doctor" letter indicating "issues with defects in the insulation" of several Riata Leads models. Am. Compl. ¶ 91. The letter addressed vulnerability of the Leads' insulation to "abrasion," which may prevent the Leads from performing properly, and it also published the Leads' current abrasion rate. Id. ¶¶ 92-93. Defendants did not recall the Leads, but rather noted that they were "phasing out" all Riata Leads by the end of 2010. Id. ¶ 94. On Nov 28, 2011, Defendants published a second Dear Doctor letter, which indicated that the previously published abrasion rate in 2010 had increased. Id. ¶¶ 95-96.

On December 21, 2011, the FDA "reclassified [Defendants'] Dear Doctor letters as a Class I Recall," which is "the most serious level of recall and is defined as a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." Am. Compl. ¶¶ 97-98. The FDA warned that "failures associated with lead insulation abrasion on the [Riata Leads] . . . may cause the conductors to become

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[6] An October 2012 Wall Street Journal ("WSJ") article also reported that at least three physicians "had encountered abrasion in the Riata Leads between 2006 and 2009. However, when these doctors brought the incidents to the attention of [Defendants] they were told by company officials and field representatives that the incidents were isolated." Am. Compl. ¶ 68. Because Defendants "did not adequately submit this information to the FDA and/or otherwise advise the public," "doctors were left with the impression that such problems were rare." Id. ¶ 67. The WSJ article also reported that Defendants had been tracking the abrasion issue for "several years," and conducted an internal audit in 2008, which concluded that the Riata Leads had "potentially serious insulation problems including inside-out abrasion." Id. ¶ 68.

externalized. If this occurs, this product may cause serious adverse health causes, including death." Id. ¶ 99.

F. Review of the Complaint

Plaintiff asserts that her Riata Lead was defective due to Defendants' failure to comply with the "specifications, requirements, federal regulations, and/or the PMAs," in the following ways: (1) failure to manufacture the internal conductors, or cables, at sizes consistent with applicable requirements; (2) inconsistent insulation diameters and/or thickness surrounding the electric conductors; (3) failure to comply with approved methods and/or specifications and requirements of curing and sterilization during the manufacture process; (4) processing the leads in a solution which caused the cables and/or conductors to stretch and then vibrate when exposed to electrical charge through the silicone; and (5) failure to crimp the leads with a controlled, uniform degree of force, which resulted in insecure crimps over the length of the Leads. Am. Compl. ¶¶ 82-86. These defects resulted in "increased tension, bending and/or movement of the internal conductors, or cables, within the insulation thereby causing inside-out abrasion." Id. Ultimately, these defects caused the cables to protrude through the insulation and come in contact with materials and body fluids, which can produce painful shocks and fracture, or otherwise prevent the device from functioning properly. Id. ¶¶ 87-88.

In the Complaint, Plaintiff asserts three causes of action under New York common law: (1) strict liability for manufacturing defect; (2) negligent manufacturing defect; and (3) failure to warn. Am. Compl. ¶¶ 109-124. Plaintiff alleges that she suffered physical, emotional, and economic damages resulting from "extrusion of the conductor, compromised lead insulation, increased lead impedence, and electrical abnormalities in her Riata Lead resulting in invasive and

dangerous surgery." Id. ¶ 10.

III. LEGAL STANDARD

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), 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, 556 U.S. 662, 663 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also FED. R. CIV. P. 12(b)(6). A court must accept as true the factual allegations contained in a complaint and draw all inferences in favor of a plaintiff. See Allaire Corp. v. Okumus, 433 F.3d 248, 249-50 (2d Cir. 2006). A complaint may be dismissed pursuant to Rule 12(b)(6) only where it appears that there are not "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. Plausibility requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the alleged misconduct]." Id. at 556. The plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Id. (citing Twombly, 550 U.S. at 555). Where a court is unable to infer more than the mere possibility of the alleged misconduct based on the pleaded facts, the pleader has not demonstrated that she is entitled to relief and the action is subject to dismissal. See id. at 678-79.

IV. DISCUSSION

Defendants argue that Plaintiff's manufacturing defect claims should be dismissed because they are expressly preempted by federal law, and they fail to satisfy pleading standards under the Federal Rules of Civil Procedure. See Mot. at 10-17. With respect to Plaintiff's failure to warn

claim, Defendants argue that it is expressly and/or impliedly preempted, and also fails to establish causation between Defendants' alleged violation of federal law and Plaintiff's injuries. See id. at 17-24.

A. Manufacturing Defect

1. Express Preemption

a. Preemption Under Riegel and § 360k

Section 360k of the MDA contains an express preemption provision that "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k.

In Riegel, the Supreme Court announced a two-prong test to determine whether a state law claim is expressly preempted under § 360k: (1) whether the federal government has established requirements applicable to the medical device, and (2) if so, whether the state law claim would impose requirements that are "different from or in addition to" the federal requirements. 552 U.S. at 321-22. Medical devices that have received pre-market approval automatically satisfy the first prong. See id. at 328. As to the second prong, the Riegel Court held that "state requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330. However, because the plaintiffs in Riegel did not assert that their claims were parallel, the Court stopped short of specifying what a

plaintiff must show to properly plead a "parallel" claim. See id.

Since Riegel, courts have found that to plead a parallel state law claim, the plaintiff must "allege that the 'defendant violated a particular federal specification referring to the device at issue." See, e.g., Wolicki-Gables v. Arrow Intern, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (quoting Ilaraza v. Medtronic, Inc., 677 F. Supp. 2d, 582, 589 (E.D.N.Y. 2009)). However, a plaintiff may not sue simply because the conduct violates federal law, since there is no private right of action. See Gelber v. Stryker Corp., 788 F. Supp 2d. 145, 155 (S.D.N.Y. 2011). In other words, "section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law." Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010).

While courts agree on this general standard, they are currently split over its application. Specifically, courts are in disagreement as to whether a plaintiff alleging violation of a "particular federal specification" must point to a "device-specific" violation—i.e. the PMAs—or if a plaintiff may rely on a more general violation of federal law. See, e.g., Gale v. Smith & Nephew, Inc., No. 12-CV-3614, 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (discussing cases).

b. Parallel Claim: Device Specific vs. General Requirements

Under 21 C.F.R. § 820.1(a)(1), the FDA has established Current Good Manufacturing Practices ("CGMP"), which set forth general requirements for medical device manufacturers that, *inter alia*, "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." Id. However, the FDA recognizes that these requirements "are intended to serve only as 'an umbrella quality system,' providing 'general objectives' medical device manufacturers

must seek to achieve." Horiwitz v. Stryker Corp., 613 F. Supp. 2d 271, 278 (E.D.N.Y. 2009) (quoting In re Medtronic Inc., 592 F.Supp. 2d at 1157). "The CGMP requirements, therefore, leave it up to the manufacturer to insititute a quality control system specific to the medical device it produces. . . ." Horowitz, 613 F. Sup. 2d at 279. Some courts have cautioned that "[t]he intentionally vague and open-ended nature of the [CGMPs] is the precise reason why they cannot serve as the basis for a parallel claim. Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to . . . standards that are 'different from, or in addition to' those imposed by the MDA." Ilaraza, 677 F. Supp. 2d at 588 (quoting In re Medronic Inc., 592 F. Supp. 2d at 1158).

PMAs, on the other hand, are "device specific," since they require the FDA to review and approve voluminous specifications applicable to that particular device. See Riegel, 552 U.S. at 321. Therefore, requiring a plaintiff to show that the manufacturer violated an applicable PMA ensures that a claim will not impose a requirement "different from or in addition to" the applicable federal regulations. See id. However, the difficulty with requiring a plaintiff to point to violations of specific PMAs at the pleading stage is that the PMAs are kept confidential, and thus a plaintiff does not have access to the PMAs prior to discovery.[7] See Bass v. Stryker Corp., 669 F.3d 501, 511 (5th Cir. 2012).

Thus, at the pleading stage, a dilemma is presented—a Plaintiff must plead with enough specificity the alleged federal violation to satisfy Twombly and to avoid preemption under § 360k,

[7] Because the PMAs involve trade secrets and/or confidential commercial information provided to the government, they are not publicly available in their entirety. See Resp. at 7 n.3; see also 5 U.S.C. § 552(b)(4). Only the PMA number, date, and a brief description of the PMA contents are provided on a publicly-accessible website. See Resp. at 16.

but what level of specificity may a court require of a plaintiff who has limited access to the device-specific violations at the time she files her complaint? Defendants argue that, in order to survive preemption, Plaintiff must identify the specific PMAs that Defendants purportedly violated. Mot. at 13; Reply at 3; see also Riegel, 552 U.S. at 321-29.; Wolicki-Gables, 634 F.3d at 1301 ("To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.") (citation omitted). Plaintiff, on the other hand, argues that allegations that Defendants violated the PMAs and/or CGMPs are sufficient to state a parallel claim. Resp. at 11-14.

The Second Circuit has yet to address this precise issue, and it appears that the district courts within the Circuit disagree as to whether a plaintiff must plead a device-specific violation. Compare Ilaraza, 677 F. Supp. 2d at 588 ("[W]here, as here, a plaintiff relies on nothing more that [sic] CGMPs in support of a parallel cause of action, preemption bars the claim.") and Horowitz, 613 F. Supp. 2d at 280-84 (finding plaintiff's claim preempted where she only referenced violations of CGMPs); with Gelber, 788 F. Supp. 2d at 155-60 (finding plaintiff's allegation that defendant's device was "adulterated" under the CGMPs sufficient to survive preemption). After careful review, the Court finds that these cases do not stand for the broad proposition proposed by Defendant—that, as a matter of law, a plaintiff's allegations must be "device specific" to survive preemption at the pleading stage.

In Horowitz, the court did not explicitly hold that the plaintiff had to plead a PMA violation; rather, it found that the plaintiff failed to state a claim because she could not establish a cognizable link between the alleged violation and her injuries. Horowitz, 613 F. Supp. 2d at 282 (noting the plaintiff's "mere promises of future factual allegations" and reference to recalls and warning letters,

which did not actually refer to the device at issue, and a lack of any enforcement action by the FDA against defendants concerning the defect, insufficient to support a plausible claim). Moreover, in Ilaraza, the plaintiff merely recited verbatim the language of the CGMPs without providing any factual support whatsoever to support her claim. See Ilaraza, 677 F. Supp. 2d at 586-88. Thus, while the plaintiff failed to allege a device-specific regulation, the key issue was that the plaintiff's claim was wholly conclusory. See id.; see also In re Medtronic, Inc. Spring Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1159 (D. Minn. 2009), aff'd sub nom, In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010) ("Plaintiffs cannot simply incant the magic words '[Defendants] violated FDA regulations' in order to avoid preemption."). Indeed, the court concluded dismissal was proper because the "[p]laintiff fail[ed] to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." Ilarraza, 677 F. Supp. 2d at 589.

In contrast, Gelber held that "by pleading the conduct which plaintiff[] allege[s] violated the CGMP requirements, describing evidence of the alleged violation, and directing plaintiffs to the CGMP requirements generally, plaintiffs have given defendants more than ample notice of the alleged violation of federal law." 788 F. Supp. 2d at 156. The Court agrees with this standard at the pleading stage, and finds further support in other Circuit decisions as well.

The Fifth Circuit has held that "if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with *either* the specific processes and procedures that were approved by the FDA [i.e. the PMAs] *or* the CGMPs themselves and that this failure caused the injury, the plaintiff will have pleaded a parallel claim." Bass, 669 F.3d at 510 (emphasis added). "[C]ourts must keep in mind that much of the product-specific information about manufacturing needed to investigate [a

medical device claim] fully is kept confidential by federal law." Id. at 511 (citing Bausch, 630 F.3d at 558) (finding that "asking the plaintiff to make more specific allegations than those found in [the plaintiff's] complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible").

The Seventh Circuit has also held that a plaintiff need not plead a specific PMA violation, cautioning that the "proposed distinction between concrete, product-specific requirements and more general requirements would . . . leave injured patients without any remedy for a wide range of harmful violations of federal law. The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices." Bausch, 630 F.3d at 555. The Bausch court "recognize[d] the possibility that there may be some room for interpretation of the applicable federal requirements, and it is at least conceivable that a jury deciding a common law claim might apply those requirements more stringently than the FDA intended." Id. at 556. However, the court stated that such concerns about imposing requirements "different from or in addition to" federal requirements could be addressed in the following ways:

> First, the meaning of the FDA's requirements will present questions of law for the court to decide, not questions of fact for a jury to decide. Second, those questions of law will be questions of federal law, subject to the usual processes for reconciling conflicting views. Third, the proposed distinction between general requirements and concrete, product-specific requirements seems to us more slippery and less workable than its proponents acknowledge. And fourth . . . we believe the proposed distinction cannot be derived from the language of the statutory preemption provision or from its purpose, to provide preemption for medical device manufacturers to the extent they actually comply with stringent requirements of federal law.[8]

[8] Section 360k states that a state may not impose any requirement that is "different from, or in addition to, *any* requirement applicable under this chapter." 21 U.S.C. § 360k (emphasis added).

Id.

Defendants argue that these two decisions are incorrect, and the Court should instead follow two other circuit court decisions. See Reply at 2. Defendant first relies on In re Medtronic, Inc., which held that a manufacturing defect claim based on noncompliance with CGMPs was preempted. 623 F.3d at 1200. However, Defendants' reliance is misplaced. In that case, the plaintiffs had alleged that *every* person who had been implanted with the defendant's medical device was entitled to equitable relief because the device had an unreasonably high risk of failure. Id. at 1207 (emphasis added). The court held that "*as pleaded and argued*, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks." Id. (emphasis in original). Furthermore, the court stated that the plaintiff's argument—that it was being held to an impossible standard under Twombly because only the defendant and the FDA had access to the PMAs prior to discovery—"would have considerable force in a case where a specific defective Class III device [actually] injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." Id. at 1206. Therefore, not only is In re Medtronics, Inc. factually distinguishable from this case, it also suggests in dicta that a plaintiff could survive preemption, even in the absence of allegations of specific PMA violations, if she could allege an actual injury. See id.

Defendants next rely on Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011). However, in that case, while the court discussed the issue of PMAs versus CGMPs, it did not address it specifically because the plaintiff merely alleged conclusory violations of state law and did not cite any federal violation. Id. at 1301. Therefore, Wolicki-Gables does not remotely stand for

the broad proposition proposed by Defendants.

After careful consideration, the Court finds that at the pleading stage, where a plaintiff has limited access to the PMAs *at the time she files her complaint*, allegations that the defendant violated either the PMAs or CGMPs, so long as they are supported by sufficient factual evidence of the violation and demonstrate a causal connection to the alleged injuries, are all that is required to satisfy Twombly and avoid preemption under § 360k and Riegel. See also Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009) (finding defendant's argument that plaintiff had to allege the specific PMA violation would constitute "an unusually stringent application of Twombly and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage").

c. Application

With that framework in mind, the Court now turns to Plaintiff's allegations. Plaintiff has alleged five specific defects that she claims violated Defendants' PMAs, the CGMPs, and/or other federal specifications. Am. Compl. ¶¶ 82-86. In support of her allegations, Plaintiff references FDA enforcement actions from 2009 and 2011, a Dear Doctor letter from 2010 that indicated defects in insulation in several Riata Leads models, and a 2011 Dear Doctor letter indicating an increased insulation abrasion rate. Id. ¶¶ 93-96. Plaintiff also states that the FDA issued a Class I recall in 2011 due to "failures associated w/ lead insulation abrasion . . . [which] may cause the conductors to become externalized." Id. ¶ 99. Plaintiff alleges that these violations led to abrasion and/or externalization of her Riata Lead, which caused the device to malfunction and/or to "fracture." See id. ¶ 9. Plaintiff further states that when her Riata Lead was surgically extracted in October 2012, it was found to have fractured and the conductor coils had externalized. Id.

The Court finds that Plaintiff has sufficiently pled a parallel state claim under the standard stated *supra* by: (1) alleging that Defendant violated the applicable PMAs and/or CGMPs; (2) providing factual support in the form of Dear Doctor letters and FDA actions, as well as a recall, which further support her allegations of a manufacturer defect; and (3) demonstrating a cognizable link between the violations and her injuries, in that insulation abrasion led to externalization and/or fracturing of her Riata Lead, which her physician determined had occurred when the Lead was surgically extracted. See Gelber, 788 F. Supp. 2d at 156-58 (finding plaintiff's manufacturing defect claims not preempted where she provided supporting evidence in the form of an FDA warning letter and a subsequent voluntary recall); cf. Smith & Nephew, Inc., 2013 WL 563403, at *4 (granting defendant's motion to dismiss where plaintiff merely alleged that defendant's product "contained a design and/or manufacturer defect" and failed to "allege facts supporting an inference that he was implanted with [a medical device] . . . manufactured in contravention of the FDA's premarket approval"). Therefore, Plaintiff has sufficiently pled a parallel manufacturing defect claim to survive preemption under § 360k and Riegel.

2. Sufficiency of the Complaint Under Federal Rule of Civil Procedure 8

Although the Court finds that Plaintiff's manufacturing defect claims survive preemption under § 360k, it must still determine whether her claims are sufficiently plausible under Federal Rule of Civil Procedure 8 and Twombly. See Smith & Nephew, Inc., 2013 WL 563403, at *4. Under New York law, "[t]o state a claim for manufacturing defect under theories of strict liability [or] negligence . . . the plaintiff must allege that (1) the product was defective due to an error in the

manufacturing process and (2) the defect was the proximate cause of plaintiff's injury."[9] Williamson v. Stryker Corp., No. 12 CIV. 7083, 2013 WL 3833081, at *4 (S.D.N.Y. July 23, 2013) (citation omitted).

Defendants argue that Plaintiff's strict liability and negligent manufacturing defect claims fail to meet the pleading standards under Federal Rules of Civil Procedure 8 and 12(b)(6) because Plaintiff has alleged only that Riata Leads were "in general" prone to manufacturing defects, not that her particular lead was defective. Mot. at 10-12. Defendants also claim that simply because Plaintiff's device may have malfunctioned does not mean that it was necessarily defective, as it functioned properly for nearly eight years, and a number of variables, other than a defect, could have caused the device to malfunction.[10] Id.

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[9] Some courts have stated in deciding a motion to dismiss that a plaintiff is required to allege 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." See, e.g., Goldin v. Smith & Nephew, Inc., No. 12 Civ. 9217, 2013 WL 1759575, at *2 (S.D.N.Y. Apr. 24, 2013); Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp., No. 09 Civ. 8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010). However, this standard was taken from Colon v. BIC USA, Inc.,199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001), which involved a motion for summary judgment, not a motion to dismiss. See Ohuche v. Merck & Co., Inc., No. 11 Civ. 2385, 2011 WL 2682133, at *2-3 (S.D.N.Y. July 7, 2011).

[10] Relatedly, Defendants have submitted the PMAs for the Riata Leads and request that the Court both take judicial notice of them and consider their contents in evaluating the sufficiency of Plaintiff's Complaint. See Mot. at 7-10. Because the *existence* of the PMAs is not in dispute, and its accuracy can be "readily determined" and "cannot reasonably be questioned," due to its publication on the FDA website, the Court takes judicial notice of this fact alone. See FED. R. EVID. 201(b); see also Mot. at 7 n.3. However, Plaintiff's reference to the PMAs in her Complaint does not permit the Court to review them for the substance of their content. See id. at 15 n.5. Plaintiff did not have access to complete versions of the PMAs at the time she drafted her Complaint, and her general reference to the PMAs is insufficient to permit the Court to consider them for their substantive content. See Global Network Commc'ns, Inc. v. City of New York, 458 F.3d 150, 156 (2d Cir. 2006) (finding that "the district court committed reversible error when, in ruling that the complaint failed to state a claim for which relief could be granted, it considered matters outside plaintiff's complaint"). Moreover, the Court rejects Defendants' attempt to incorporate factual findings from Pinsonneault v. St. Jude Medical, Inc., No. 12-cv-1717, 2014 WL 2879754, at *6 (D.

In support of their argument, Defendants cite several cases where the plaintiffs failed to plead sufficient facts to survive a motion to dismiss. Mot. at 12; see also Riley v. Cordis Corp., 625 F. Supp. 2d 769, 789 (D. Minn. 2009) (finding plaintiff did "not specify the manufacturing defect" or "specify a causal connection"); Dawson v. Medtronic, Inc., No. 13-CV-663, 2013 WL 4048850, at *7 (D.S.C. Aug. 9, 2013) (dismissing a manufacturing defect claim where the complaint "merely contain[ed] a formulaic recitation of the elements"); Ali v. Allergan USA, Inc., No. 12-CV-115, 2012 WL 3692396, at *13 (E.D. Va. Aug. 23, 2012) (dismissing claim where complaint failed to set forth factual allegations that defendant violated federal requirements); Maness v. Boston Scientific, 751 F. Supp. 2d. 962, 970-71 (E.D. Tenn. 2010) (where plaintiff failed to "allege facts regarding how an alleged defect . . . caused her injuries").

The Court finds that the present case is easily distinguishable from those relied on by Defendants. As discussed in detail *supra*, Plaintiff has alleged specific manufacturing defects and shown a casual connection between those defects, the violations of applicable federal regulations, and her injuries. Plaintiff's claims are neither conclusory nor formulaic. Moreover, "'[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" York v. Ass'n of the Bar of City of N.Y., 286 F.3d 122, 125 (2d Cir. 2002) (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)); see also Twombly, 550 U.S. at 556 (noting plausibility requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the alleged misconduct]"). Additionally, where Plaintiff has limited access to the

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Minn. June 24, 2014) to establish the absence of alleged PMA violations in this case. See Dkt. No. 39 at 3-4. Pinsonneault concerened a motion for summary judgment, which involves a different legal standard than a motion to dismiss, and is submitted after the parties have conducted discovery. See Pinsonneault, 2014 WL 2879754, at *3. Therefore, Pinsonneault's factual findings are irrelevant to the instant Motion.

PMAs before discovery, the Court must apply a "flexible 'plausibility standard,' which obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim plausible." Iqbal v. Hasty, 490 F.3d 143, 157-58 (2d Cir. 2007) (referring to the standard under Twombly).

Accordingly, the Court finds that the Complaint sets forth allegations that have "facutal content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. Therefore, Plaintiff has pled sufficient facts to survive a motion to dismiss on her strict liability and negligent manufacturing defect claims.

B. Failure to Warn

Under New York law, to prevail on a claim for failure to warn, a plaintiff must demonstrate that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm."[11] State Farm Fire & Cas. Co. v. Nutone, Inc., 426 F. App'x. 8, 10 (2d Cir. 2011) (citing Liriano v. Hobart Corp., 700 N.E.2d 303, 305 (N.Y. 1998)). "[T]he manufacturer of a medical device does not have a duty to directly warn a patient of risks associated with the device, but instead discharges its duty by providing the physician with sufficient information concerning the risks of the device." Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999) (citing Fane v. Zimmer, 927 F.2d 124, 129 (2d Cir. 1991)).

[11] The Court notes that Plaintiff has not pled whether her failure to warn claim is based on negligence or strict liability. See Compl. ¶¶ 119-24. However, the lack of specificity, which Defendants do not contest, is inconsequential. See Martin v. Hacker, 628 N.E.2d 1308, 1311 n.1 (N.Y. 1993) ("Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent.") (citing Wolfgruber v. Upjohn Co., 423 N.Y.S.2d 95, 97 (App. Div. 1979).

Additionally, "[t]his duty is a continuous one, and requires that the manufacturer be aware of the current information concerning the safety of its product." Bee v. Novartis Pharm. Corp., No. 12-CV-1421, 2014 WL 1855632, at *10 (E.D.N.Y. May 9, 2014) (quoting Krasnopolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1345-46 (E.D.N.Y. 1992). Specifically, "to avoid liability, drug manufacturers have a two-fold 'continuing obligation.'" Id. at *14 (quoting Baker v. St. Agnes Hosp., 421 N.Y.S.2d 81, 85 (App. Div. 1979)); see also Glucksman v. Halsey Drug Co., 553 N.Y.S.2d 724, 726 (App. Div. 1990). First, they "must keep abreast of knowledge of [their] products as gained through research, adverse reaction reports, scientific literature and other available methods. Second, and equally important, [they] must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." Bee, 2014 WL 1855632, at *14 (quoting Baker, 421 N.Y.S.2d at 85 (citations omitted)). The device manufacturer can satisfy this second requirement by "warn[ing] of all potential dangers . . . that it knew, or, in the exercise of reasonable care, should have known to exist." Davids v. Novartis Pharm. Corp., 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (quoting Sita, 43 F. Supp. 2d at 245).

Plaintiff claims that Defendants have breached their continuing duty to: (1) "monitor the Riata Leads post-approval and to discover and report to the FDA any complaints about product performance and any health consequences of which they [we]re aware that may be attributable to the product"; and (2) "provide ongoing warnings and instructions regarding safety hazards associated with the Leads." Am. Compl. ¶¶ 120-21. Defendants assert that both alleged duties are expressly and impliedly preempted, and that Plaintiff has failed to show causation between the alleged violation and her injuries. Mot. at 18, 22.

1. Express Preemption

Defendants argue that any requirement to provide ongoing warnings beyond the initial, FDA-approved label would be an "additional requirement" in violation of § 360k. Mot. at 18. Plaintiff responds that its failure to warn claim is not based on labeling but rather Defendants' failure to follow federal requirements regarding reporting of adverse event information. Resp. at 17. The Court agrees with Plaintiff's interpretation of her claims, and thus will determine whether Plaintiff's allegation that Defendants failed to comply with their reporting requirements is expressly preempted.

"Once the FDA approves a [Class III medical] device, the manufacturer is required to report any information that reasonably suggests that the device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that any recurring malfunction 'would be likely to cause or contribute to a death or serious injury.'" Medtronic, Inc., 704 F.3d at 1227 (quoting 21 C.F.R. § 803.50(a)). Similar to a manufacturing defect claim, a plaintiff must also allege a parallel state law failure to warn claim to survive preemption under Riegel and § 360k. See Gelber, 788 F. Supp. 2d at 160. The Second Circuit has yet to address the requirements for a parallel claim in this context, and only two other circuits have thus far reached this issue.

In Hughes v. Boston Scientific Corp., the Fifth Circuit held that the plaintiff sufficiently pled a parallel failure to warn claim under Mississippi law based on the defendant's misreporting of adverse health events to the FDA. 631 F.3d 762, 769-70 (5th Cir. 2012) (noting defendant's duty to "provide adequate warnings or instructions" and "reasonable warnings" of risks). In Medtronic, Inc., the Ninth Circuit similarly found that the plaintiff's failure to warn claim, under Arizona law, alleging breach of the device manufacturer's "duty to use reasonable care," was not preempted. 704

F.3d at 1233; see also McConlogue, 2014 WL 1246834 at *11 (citing Medtronic, Inc. to support the proposition that "a failure to warn claim may be based on a violation of the FDA's continuing reporting requirements for manufacturers of Class III devices").

Defendants argue that: (1) these decisions are limited to those particular states; and (2) in New York, a device manufacturer is only required to report to doctors, not the FDA. Reply at 4-9. First, although the Court agrees that those decisions apply only to the particular state laws discussed therein, because New York imposes a similar duty, their principles are nonetheless applicable to this case. Specifically, New York law imposes a "continuing obligation" to use "the exercise of reasonable care" in warning of potential dangers, Davids, 857 F. Supp. 2d at 286, which is virtually identical to Arizona's "duty to use reasonable care," Medtronic, Inc., 704 F.3d at 1233, and Mississippi's duty to provide "reasonable warnings," Hughes, 631 F.3d at 770. Accordingly, the Court finds those decisions persuasive in determining whether Plaintiff's failure to warn claim is expressly preempted.

Second, Plaintiff is not claiming that Defendants breached their duty by failing to inform her physician directly about known risks and dangers; rather, she contends that Defendants failed "to discover and report *to the FDA* any complaints . . . [to] provide ongoing warnings and instructions regarding safety hazards," and in doing so violated state law. Resp. at 20 (emphasis added). Specifically, Plaintiff alleges that Defendants failed to comply with FDA reporting requirements, including 21 C.F.R. § 803.50, and that "because [Defendants] violated the FDCA, [they are] subject to state law liability." Resp. at 18, 20. Plaintiff points out that the FDA publishes adverse events and MDRs in a public, searchable database called the Manufacturer and User Facility Device Experience ("MAUDE"), which physicians and the general public may access to view safety data on

medical devices. Am. Compl. ¶ 66. Thus, Plaintiff argues that Defendants' failure to timely report to the FDA led to a violation of state law, in that Defendants also did not exercise reasonable care in informing the medical community of known risks. See Resp. at 18-20.

Because Plaintiff has alleged a violation of a federal regulation, and New York imposes a similar state duty as those at issue in Hughes and Medtronic, Inc., the Court finds that Plaintiff's failure to warn claim is "parallel" and not "different or in addition to" the applicable requirements under federal law. See Hughes, 631 F.3d at 769 ("[A] failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is 'parallel' to federal requirements as defined in Riegel." (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)). Accordingly, Plaintiff's failure to warn claim is not expressly preempted.

2. Implied Preemption

Defendants next argue that if Plaintiff's failure to warn claim is not expressly preempted, then, alternatively, it is impliedly preempted. Mot. at 22. Defendants argue that their duty to file reports to the FDA exists solely because of the FDCA and corresponding federal regulations, and that Plaintiff is trying to circumvent the bar on private right of action under § 337(a). See Mot. at 22; Reply at 8; see also 21 U.S.C. § 337(a) ("[A[ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Defendants assert that, under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001), "private plaintiffs may not bring claims that depend on the existence of the FDCA and its implementing regulations." Mot. at 22. Plaintiff responds that it is not attempting to enforce the FDCA, and that Buckman only stands for the proposition that a plaintiff cannot bring suit based *solely* on a violation of the FDCA, but that a defendant may still be liable under state law. Resp. at 20. The Court

agrees.

Buckman involved allegations that the defendant manufacturers "made fraudulent representations to the [FDA] in the course of obtaining [pre-market] approval." 531 U.S. at 344. The Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflicted with, and were therefore impliedly pre-empted by, federal law" because the FDA alone was charged with the pre-market approval process.[12] See id. at 348. While Buckman stated that an alleged violation which exists "solely from the violation of FDCA requirements" is preempted, 531 U.S. at 352, it made clear that its decision did not conflict with Lohr, 518 U.S. at 481, which held that "state-law causes of action that *parallel* federal safety requirements" are not preempted, Buckman, 531 U.S. at 353 (emphasis added). As stated *supra*, Plaintiff has pled a state law failure to warn claim that parallels federal safety requirements.

Furthermore, as several recent decisions have made clear, Buckman does not stand for the broad proposition, as Defendants have suggested, that all claims under state law for failure to comply with FDA reporting requirements are barred. See, e.g. Gale v. Smtih & Nephew Inc., 2013 WL 563403, at *6 (stating that "a state-law tort claim based on an alleged violation of a specific premarket approval requirement, [which] links the federal violation to plaintiff's injuries" "successfully threads the needle between Riegel and Buckman") (citing Gelber, 788 F. Supp. 2d at

[12] The Court notes that Defendant's reference to a footnote in Buckman, which states that "[t]he 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," is unavailing. 531 U.S. at 349 n.4. There, the Court was responding specifically to the "variety of enforcement options that allow [the FDA] to make a measured response to suspected *fraud*." Id. at 349 (emphasis added). Here, Plaintiff is not alleging a "fraud on the FDA" claim—that Defendants provided false information to the FDA in order to gain market approval. Rather, Plaintiff asserts that Defendants failed to follow the applicable federal reporting requirements *after* pre-market approval, and in doing so violated parallel state law failure to warn requirements. See Resp. at 18.

155); see also O'Neil v. St. Jude Medical, Inc., No. C13-0661, 2013 WL 6173803, at *3 (W.D. Wash. Nov. 22, 2013) ("Congress has not clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices.") (internal quotations omitted). Therefore, the Court rejects Defendants' application of Buckman and finds that Plaintiff's failure to warn claim is not impliedly preempted.

3. Causation

Plaintiff alleges that "had Defendants properly and timely reported adverse events to the FDA as required by federal law, information regarding the risks and hazards of the Leads would have reached Plaintiff's treating medical professionals in time to prevent or reduce Plaintiff's injuries." Am. Compl. ¶ 123. In support, Plaintiff references Defendants' failure to report specific adverse events in 2003 and 2004, waiting until 2008 to report them to the FDA, as well as under-reporting or mis-classifying other adverse events from 2002 through 2009 regarding perforation and abrasion failure rates. Resp. at 18.

Defendants argue that Plaintiff has failed to show causation because: (1) Plaintiff has not demonstrated how Defendants' alleged reporting violations actually caused her injury; (2) even if Defendants had properly reported adverse events, they would not necessarily have reached Plaintiff's physician because the FDA "may," but is not required, to publish them in the public database under 21 C.F.R. 803.9(a); and (3) even after the FDA published the reports indicating Defendants' previous reporting violations, Plaintiff's treating physician took no immediate remedial action. Mot. at 20; Reply at 6, 9.

In order to show causation, a plaintiff must demonstrate a "causal connection between the wrong and the injury." Assoc. Gen. Contractors of Cal., Inc. v. Carpenters, 459 U.S. 519, 536

(1983). Causation does not lie where the injuries are "too remote," "purely contingent," or "indirect[]." Id. at 268, 271, 274. In other words, a plaintiff must allege "some direct relation between the injury asserted and the injurious conduct alleged." Holmes v. Secs. Inv. Prot. Corp., 503 U.S. 258, 268 (1992).

Here, Plaintiff was implanted with the Riata Lead in 2004 and had it surgically extracted in 2012. Am. Compl. ¶ 8. She alleges that Defendants waited until 2008 to report adverse events from 2004, and that Defendants also under-reported or mis-classified other adverse events from 2002 through 2009. Resp. at 17-20. Thus, Plaintiff's allegations concerning Defendants' failure to comply with its reporting requirements occurred during the relevant time period in which Plaintiff used Defendants' device. cf. Franzese v. St. Jude Medical, Inc., No. 13-CV-3203, 2014 WL 2863087, at *6 (E.D.N.Y. June 23, 2014) (dismissing plaintiffs' failure to warn claim for lack of proximate cause where plaintiffs failed to "allege[] how any shortcomings identified in a 2013 letter relate to the state of affairs in 2010").

Moreover, Plaintiff alleges that, had Defendants reported the adverse events, they would have reached her physician through the MAUDE public database. Resp. at 18. Although the FDA is not required to publish all adverse reports, Defendants do not contest that the FDA nonetheless regularly publishes them, including the reports at issue here. See Reply at 6-9. Therefore, Plaintiff's allegation that her injuries may have been avoided or mitigated had Defendants timely complied with their reporting requirements is not "purely contingent" or speculative. See Carpenters, 459 U.S. at 271; see also Desabio v. Howmedica Osteonics Corp., 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011) (noting that a court's role in a motion to dismiss is simply to determine whether the plaintiff has pled sufficient facts that, if true, would entitle her to relief).

Finally, the Court rejects Defendants' remaining argument that Plaintiff's physician's "failure" to take immediate, remedial action following the FDA's reports eliminates a causal connection between Defendants' reporting violations and Plaintiff's injuries. See Reply at 8-9. The essence of Plaintiff's failure to warn claim is that she was injured by Defendants' several-year delay in reporting relevant adverse information. See Resp. at 18-20. Thus, Plaintiff's alleged injuries had already occurred before her physician learned of Defendants' past reporting violations. Therefore, Defendants' argument is irrelevant to the issue of causation.

Accordingly, Plaintiff's failure to warn claims are not preempted, and Plaintiff has sufficiently pled her allegations to survive Defendants' Motion to dismiss.

V. CONCLUSION

Accordingly, it is hereby:

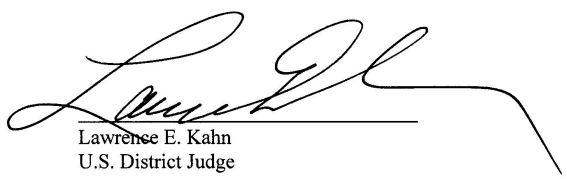
ORDERED, that Defendants' Motion (Dkt. No. 25) to dismiss Plaintiff's Amended Complaint (Dkt. No. 19) for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) is **DENIED**; and it is further

ORDERED, that Defendants' Motion (Dkt. No. 8) to dismiss Plaintiff's original Complaint (Dkt. No. 1) for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) is **DENIED as moot**; and it is further

ORDERED, that the Clerk of the Court serve a copy of this Memorandum-Decision and Order on all parties in accordance with the Local Rules.

IT IS SO ORDERED.

DATED: August 28, 2014
Albany, NY



Lawrence E. Kahn
U.S. District Judge