****NOT FOR PUBLICATION****

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BARBARA A. CHESTER, as Administratrix ad Prosequendum of Estate of Michael Chester, and BARBARA A. CHESTER, as an Individual, Plaintiff, v. BOSTON SCIENTIFIC CORP., GUIDANT CORPORATION, GUIDANT LLC, CARDIAC DEFIBRILLATORS, INC., Defendants.	Civil Action No. 16-02421 (FLW) **OPINION**

WOLFSON, United States District Judge:

Before the Court is the motion of Defendants Boston Scientific, Corp., Guidant Corporation, Guidant LLC, and Cardiac Defibrillators, Inc., to dismiss the product liability and common law tort claims of Plaintiff Barbara A. Chester. Plaintiff contends that her deceased husband, Michael Chester, suffered harm and died due to the defective connective wires in the defibrillator device designed, manufactured, and sold by Defendants. For the reasons set forth below, the Court finds that the New Jersey Products Liability Act ("PLA") subsumes Plaintiff's state law tort claims into her strict product liability claim, and that Plaintiff's strict product liability claim is, in turn, preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). Accordingly, Defendants' motion to dismiss is granted.

FACTUAL BACKGROUND & PROCEDURAL HISTORY

Plaintiff was the lawful wife of Michael Chester. Compl. ¶ 11. In or about May 2004, Michael Chester, who suffered from cardiac problems, underwent a surgical procedure to have a defibrillator device implanted in his chest to treat his heart condition. *Id.* at ¶ 12. In or about May 2012, Mr. Chester, who continued to suffer from cardiac problems, underwent an additional surgical procedure to implant another defibrillator device. *Id.* at ¶ 13. The devices that were finally implanted after both surgeries were (1) a Boston Scientific Incepta CRT-D Model # N164 Serial # 100005 defibrillator device and (2) an Endotak Edurance EZ lead, Model # 0154 Serial # 354220 (collectively, the "Defibrillator" or the "device"). *Id.* at ¶ 15. Defendants Boston Scientific Corp., Guidant Corporation, and Guidant LLC, and Cardiac Defibrillators, Inc., designed, manufactured, fabricated, supplied, and sold the Defibrillator. *Id.* at ¶ 16.

In October 2013, Mr. Chester underwent another defibrillator implantation surgery at the University of Pennsylvania. *Id.* at ¶ 20. An unidentified representative of Defendant Boston Scientific was present in the operating room during the implantation surgery. *Id.* at ¶ 21. After the implantation surgery, a representative of Defendant Boston Scientific informed Plaintiff and Mr. Chester's daughter, acting as his next of kin, that Boston Scientific was having a "newer" and "better" model of defibrillator implanted in Mr. Chester, because the prior Defibrillator was defective. *Id.* at ¶ 20. The representative, stated that the "leads" or wires connecting the device to Mr. Chester's heart, were known to "slip." *Id.* at ¶¶ 28-29. The representative informed Plaintiff and Mr. Chester's daughter that this propensity of the leads to slip was the reason why the October 2013 surgery was necessary to remove the leads from Mr. Chester. *Id.* at ¶ 29.[1]

[1] The Court notes that a slightly different version of the conversation with the Boston Scientific representative appears in the supplemental certification of Barbara Ann Eisenstein, Mr. Chester's daughter, which was submitted in the state court proceeding before removal in support of the

On June 2, 2014, Mr. Chester died. *Id.* at ¶ 23. Plaintiff alleges that, due to the defective leads, the device was unfit for the purpose for which it was sold — the treatment of heart failure — and that the device, in an unspecified manner, caused Mr. Chester serious physical harm and lead to his death.[2] *Id.* at ¶¶ 47-49.

On October 8, 2015, Plaintiff filed the Original Complaint in this case in the Superior Court of New Jersey, Law Division, Ocean County. The Original Complaint contained eight (8) Counts and named Defendants, as well as hospitals, healthcare providers, and fictitious entities (collectively the "Medical Provider Defendants"). Defendants moved to dismiss on MDA preemption and other grounds, and, on January 27, 2016, Plaintiff cross-moved for leave to amend the Original Complaint to cure her pleading defects. In mid-April 2016, Plaintiff's claims against the Medical Provider Defendants were dismissed by a series of stipulations of the parties, resulting in diversity of citizenship among the parties. Defendants removed the case to this Court on April 29, 2016, before the state court adjudicated the motion to dismiss and cross-motion for leave to amend.

Original Complaint and again in opposition to the motion. The version of events in the Amended Complaint is reproduced in this Opinion and controls for purposes of this motion. On a motion to dismiss, only the pleadings, and not the supplementary certifications of the parties, may be considered. In either case, the fact of the conversation is immaterial to the Court's decision.

[2] The Court notes the unorthodox nature of the Complaint in this products liability action in failing to specify the manner in which the allegedly defective device actually harmed Mr. Chester or caused his death. As Defendants observe in their briefing, no causal connection between the allegedly defective device and Mr. Chester's alleged injuries and death is alleged. To the contrary, the complaint alleges that the device was removed from Mr. Chester in October 2013, seven months before his June 2014 death. Far from alleging that faulty connective wires harmed or killed Mr. Chester, therefore, the Complaint actually suggests that the wires were removed and replaced far in advance of his death. Although the Defendants move for dismissal on the basis of this and other pleading deficiencies under Rules 8 and 9, the Court need not reach those arguments as dismissal is warranted on other bases.

On May 26, 2016, this Court entered a Consent Order granting Plaintiff leave to file an Amended Complaint in substantial conformity with the proposed Amended Complaint submitted with Plaintiff's cross-motion for leave to amend that had been filed in the New Jersey Superior Court. On June 24, 2016, Plaintiff filed her Amended Complaint, the Complaint currently before the Court on Defendants' motion. The Amended Complaint presents five (5) claims against Defendants, claiming wrongful death and survival damages arising from Plaintiff's husband, Mr. Chester's injury and death due to the alleged design, manufacturing, and labeling defect of Defendants' Defibrillator. In Count I, Plaintiff raises a strict product liability failure to warn claim under the New Jersey Products Liability Act ("PLA"), which, through its paragraph incorporating prior allegations by reference, also appears to raise a breach of implied warranty claim. Compl. ¶¶ 17, 50-62. In Count II, Plaintiff raises common law consumer fraud, deceit, and fraudulent concealment claims, again based on Defendants' alleged failure to warn. *Id.* at ¶¶63-73. In Count III, Plaintiff raises a common law claim for negligent misrepresentation. *Id.* at ¶¶ 74-80. In Count IV, Plaintiff raises a common law claim for intentional infliction of emotional distress. *Id.* at ¶¶ 81-85. Finally, in Count V, Plaintiff raises a common law claim for loss of consortium. *Id.* at ¶¶ 86-89.

Defendants moved to dismiss the Amended Complaint on July 8, 2016, on the grounds that (i) Plaintiff's state common law claims are subsumed by the PLA into her Count I strict liability failure to warn claim and are not separately actionable; (ii) the Medical Device Amendments to the Federal Food, Drug, and Cosmetics Act expressly and impliedly preempt both Plaintiff's PLA and common law claims; and (iii) Plaintiff fails to meet the pleading standards of Federal R. Civ. P. 8 and Rule 9(b). Plaintiff opposed the motion on July 27, 2016. Plaintiff's Opposition does not respond to Defendants' PLA subsumption argument, but contends

that Plaintiff's claims are "parallel claims" falling within a recognized exception to MDA preemption, that Plaintiff has adequately pleaded her claims, and that, in the alternative, Plaintiff should be granted discovery to obtain additional facts to support her claims.

JURISDICTION

The Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332 because the amount in controversy is greater than $75,000, and there is complete diversity of the parties. The parties do not contest subject matter or personal jurisdiction, and agree that venue is appropriate in this Court.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a claim "for failure to state a claim upon which relief can be granted."[3] When reviewing a motion to dismiss, courts must first separate the factual and legal elements of the claims, and accept all of the well-pleaded facts as true. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). All reasonable inferences must be made in the plaintiff's favor. *See In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir. 2010). In order to survive a motion to dismiss, the plaintiff must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp.*

[3] The Third Circuit has held that "because federal preemption is an affirmative defense on which the defendant bears the burden of proof[,] . . . a motion under Rule 12(c) for judgment on the pleadings is a more appropriate procedural vehicle for dismissing cases on preemption grounds, instead of a motion under Rule 12(b)(6), except for cases in which preemption is manifest in the complaint itself." *In re Asbestos Prod. Liab. Litig. (No. VI)*, 822 F.3d 125, 1330 n.6 (3d Cir. 2016). The Court will apply the standard under Rule 12(b)(6) in this case because all of the facts assertedly giving rise to federal preemption are present in the Complaint itself. In any event, application of the other standard in Rule 12(c) would not affect the outcome in this case because "[i]n deciding a motion under Rule 12(c), the court must view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party, and may not grant the motion unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id.* (citations omitted).

v. Twombly, 550 U.S. 544, 570 (2007). This standard requires the plaintiff to show "more than a sheer possibility that a defendant has acted unlawfully," but does not create as high of a standard as to be a "probability requirement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The Third Circuit requires a three-step analysis to meet the plausibility standard mandated by *Twombly* and *Iqbal.* First, the court should "outline the elements a plaintiff must plead to a state a claim for relief." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Next, the court should "peel away" legal conclusions that are not entitled to the assumption of truth. *Id.; see also Iqbal*, 556 U.S. at 678-79 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). It is well-established that a proper complaint "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). Finally, the court should assume the veracity of all well-pled factual allegations, and then "determine whether they plausibly give rise to an entitlement to relief." *Bistrian*, 696 F.3d at 365 (quoting *Iqbal*, 556 U.S. at 679). A claim is facially plausible when there is sufficient factual content to draw a "reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The third step of the analysis is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

ANALYSIS

A. Subsumption of Tort Claims Under the PLA[4]

[4] Plaintiff does not provide any arguments against PLA subsumption in her Opposition, and indeed may have waived her common law claims. *See* Opposition at 13 ("Plaintiff's claims are premised, *inter alia*, on the Product Liability Act . . . which governs all claims for harm caused by a product other than breach of an express warranty."). As Plaintiff's arguments elsewhere in her Opposition suggest she did not intend to waive her claims, despite failing to oppose Defendants' motion on the basis of subsumption, the Court nevertheless analyzes the application of the PLA to these claims at length.

"The PLA 'established the sole method to prosecute a product liability action' such that 'only a single product liability action remains.'" *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015) (quoting *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99, (App. Div. 1991)). *See also In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.*, 588 F. App'x 171, 178 (3d Cir. 2014) (same). "The language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 191 N.J. 405, 436–47 (2007). It "effectively creates an exclusive statutory cause of action for claims falling within its purview." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). *See also id.* (correctly anticipating that "the New Jersey Supreme Court would hold that the NJPLA generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to consumers injured by a defective product."); *Sinclair v. Merck & Co.*, 195 N.J. 51, 65 (2008) (finding "the clear intention of our Legislature to include all [product liability] claims within the scope of the PLA") (quotation omitted, alterations in original).

Under the PLA, a product liability action is defined as "any claim or action brought by a claimant *for harm caused by a product*, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." *N.J.S.A.* 2A:58C–1(b)(3) (emphasis added).[5] In determining whether a tort claim is subsumed under the PLA, the New Jersey Supreme Court has observed that "[t]he essential question is whether plaintiffs' effort to recover .

[5] The PLA contains two exceptions for causes of action for breach of an express warranty and environmental torts, neither of which is applicable in this case. *Sinclair*, 195 N.J. at 62.

. . damages is limited by the definition of 'harm' in the PLA." *Sinclair*, 195 N.J. at 62. "Harm" is defined in the PLA as

> (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. 2A:58C–1(b)(2). "In short, those former common-law causes of action . . . have merged into a single cause of action under the PLA," and thus are no longer recognized "as viable separate claims for harm deriving from a defective product." *Clements*, 111 F. Supp. 3d at 596. Courts in this Circuit therefore consistently dismiss product liability claims based on those common-law theories. *Id.* at 597 n. 5 (collecting cases).

Here, all five Counts of the Complaint, although presenting different common law theories, allege the same harm caused by Defendants' defective product. Count I alleges:

> As a direct and proximate result of the foregoing, . . . [Plaintiffs] were caused to sustain the loss of income, support, society, love, grief, consortium, services, guidance, care, comfort, companionship, and inheritance of the decedent and suffered mental anguish, mental pain and suffering, emotional distress, and were caused to incur other necessary and reasonable expenses as a result of the decedent's death, including but not limited to, funeral and burial costs, medical expenses, and were otherwise damaged.

Compl. ¶ 61. Counts II, III, and IV incorporate the exact same language by reference. Compl. ¶¶ 72, 79, 84. Count V explicitly seeks damages only for loss of consortium. Compl. ¶ 89. As these harms fall within the PLA, the common law causes of action in Count I and the entirety of Counts II, III, IV, and V, which allege only common law causes of action, are therefore subsumed by the PLA.

Accordingly, Count I is dismissed to the extent that it presents an implied warranty (Compl. ¶ 17, incorporated into Count I by ¶ 50) theory of liability. *See, e.g.*, *Mendez v. Shah*, 28 F. Supp. 3d 282, 294 (D.N.J. 2014) (implied warranty claim subsumed by PLA). Count II

(consumer fraud, deceit, and fraudulent concealment) is dismissed. *See Delaney v. Stryker Orthopaedics*, No. CIV.A. 08-03210DMC, 2009 WL 564243, at *7 (D.N.J. Mar. 5, 2009) (consumer fraud claim subsumed by PLA); *Sinclair*, 195 N.J. at 66 (same). Count III (negligent misrepresentation) is dismissed. *See Calender v. NVR Inc.*, 548 F. App'x 761, 764 (3d Cir. 2013) ("The PLA does not recognize negligence or implied breach of warranty as separate claims for harm caused by a product. Rather, the PLA is the exclusive remedy for such actions and other claims are subsumed within the statutory cause of action."). Count IV (intentional infliction of emotional distress) is dismissed. *See N.J.S.A.* 2A:58C–1(b)(2)(c) (subsuming product actions for "pain and suffering, mental anguish or emotional harm"). And Count V (loss of consortium) is dismissed. *See id.* at 2A:58C–1(b)(2)(d) (subsuming product actions for "loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c)").

The only claim in Plaintiff's complaint properly brought, pursuant to the PLA, is Plaintiff's Count I strict product liability claim for failure to provide adequate warning. Defendant contends that, even if proper under state law, Plaintiff's failure to warn claim nevertheless must be dismissed as preempted by the federal MDA. This Court agrees.

B. Preemption Under the MDA

In Count I, Plaintiff alleges that Defendants failed to adequately warn of the substantial dangers of the Defibrillator, due to defects in the design, manufacture, and distribution of the device and its components, namely the Endotak Edurance EZ Leads, Model # 0154 Serial # 354220. Compl. ¶ 55. Defendants' failure to warn is alleged to have two constituent parts. First, Defendants are alleged to have "failed to provide adequate warnings, instructions, guidelines, or admonitions to members of the public, including decedent [Mr. Chester], of the design and

manufacturing defects, which defendants knew, or in the exercise of reasonable care should have known, to have existed in the defibrillator device and leads." *Id.*at ¶ 57. Second, Defendants are alleged to have "had a continuing obligation to notify the FDA of product defects causing serious injury or death, and defendants failed to abide by this federally mandated obligation." *Id.* at ¶ 56. As explained below, both parts are essential to Plaintiff's theory of liability, but, even together, do not save Plaintiff's claim from federal preemption.

"The Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, has long required FDA approval for the introduction of new drugs into the market." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). It did not, however, originally govern medical devices. "[T]he introduction of new medical devices was left largely for the States to supervise as they saw fit." *Ibid.*

Congress "swept back some state obligations and imposed a regime of detailed federal oversight" with the passage of the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* (MDA). *Id.* at 316. "The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Riegel*, 552 U.S. at 317. Under the MDA, such devices are subject to a regime of "premarket approval" ("PMA") by the FDA before they can be marketed and sold to the public. "Premarket approval is a 'rigorous' process." *Id.* at 317 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 317 (quoting 21 U.S.C. § 360e(d)). "The agency must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.' It may thus approve devices that present great

risks if they nonetheless offer great benefits in light of available alternatives." *Id.* at 318 (quoting § 360c(a)(2)(C)).

"The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A)." *Id.* at 318. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c)." *Id.* at 319.

"After premarket approval, the devices are subject to reporting requirements. § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and 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 if it recurred, § 803.50(a)." *Id.* at 319.

1. Express Preemption

The MDA includes an express pre-emption provision that states:

> Except as provided in subsection (b) of this section,[6] no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

[6] The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption and is not at issue here.

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360k(a). "In *Riegel v. Medtronic, Inc.,* the Supreme Court held that state-imposed requirements are preempted by the MDA if (1) the Federal Government has established requirements applicable to the device and (2) the plaintiff's claims are based on state requirements related to safety and effectiveness that are 'different from, or in addition to' the federal requirements." *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) (quoting *Riegel*, 552 U.S. at 321-22). "*Riegel* concluded that the first prong of the preemption test is automatically satisfied where a medical device has received premarket approval. The PMA process necessarily imposes federal requirements, the Court found, because the FDA requires that a medical device be 'made with almost no deviations from the specifications in [the PMA] application.'" *Clements*, 111 F. Supp. 3d at 597 (quoting *Riegel*, 552 U.S. at 321-23. *See also Cornett v. Johnson & Johnson*, 211 N.J. 362, 387 (2012) *abrogated on other grounds by McCarrell v. Hoffmann–La Roche, Inc.*, No. 076524, 2017 WL 344449 (N.J. Jan. 24, 2017) (where the product "underwent the rigorous and individualized PMA process for Class III medical devices . . . [t]he approval provided by the FDA communicates that defendants demonstrated the safety and effectiveness of the product for its approved uses. Moreover, that approval includes the label and instructions that accompany the device. The totality of the approval represents a specific federal requirement.").

The Defibrillator and its components are Class-III medical devices that were required to undergo and have received Premarket Approval from the FDA conditioned upon continued

compliance with FDA regulations. Compl. ¶ 31.[7] Under *Riegel*, prong one of the preemption analysis is met. The only question before the Court, therefore, is whether the state requirements imposed by Plaintiff's failure to warn PLA claim relate to the "safety and effectiveness of the device" and are "different from, or in addition to" the federal requirements of the PMA process.

In passing the PLA, the New Jersey "Legislature intended . . . to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." *Sinclair*, 195 N.J. at 62. Plaintiff's product liability claim under New Jersey law is thus subject to a strict limitation on liability.

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C-2.

> As relevant to this action, the PLA further provides:
>
> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.

N.J.S.A. 2A:58C–4. Accordingly, "[i]n a failure-to-warn case, 'the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that the

[7] Although the Court relies only upon the allegations in the Complaint, it also notes that the parties do not dispute that the Defibrillator and its components are Class-III medical devices that have received Premarket Approval from the FDA. *See, e.g.*, Opposition at 5 (Defendants' contention on the motion that "the claims against movants concern a Class III medical device, regulated by the Food and Drug Administration ('FDA'), and approved through the FDA's Pre-Market Approval ('PMA') process."); *id.* at 16 (Plaintiff requesting discovery into the PMA process on the Defibrillator, attaching documents showing PMA status of Defibrillator).

product can potentially cause injury.'" *Mendez v. Shah*, 28 F. Supp. 3d 282, 299 (D.N.J. 2014) (quoting *Clark v. Safety–Kleen Corp.*, 179 N.J. 318, 336 (2004)). "The plaintiff must establish that the defendant had a duty to warn, and then establish that an adequate warning was not provided." *Id.* (citing *James v. Bessemer Processing Co.*, 155 N.J. 279 (1998)). "Plaintiff must then prove the breach of duty (the absence of a warning) was a proximate cause of the accident." (citing *Coffman v. Keene Corp.*, 133 N.J. 581 (1993)).

Under the PLA then, a manufacturer is liable for failure to warn only if the plaintiff can prove that the device was defective — meaning not fit, suitable, or safe for its intended purpose absent the desired warning, *N.J.S.A.* 2A:58C-2 — and that the warning was not actually provided, *N.J.S.A.* 2A:58C–4. These state requirements impose different and additional obligations on Defendants than the federal obligations of the PMA process. In granting the Defibrillator PMA, the FDA already evaluated the safety and effectiveness of the device under the conditions set forth on the label and determined that the labeling was not false or misleading. *Riegel*, 552 U.S. at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). To find that the device is unsafe and defective *because* of the omission of a warning from the FDA-approved label would therefore overturn the FDA's determination and impose a stricter state standard. The MDA does not permit such additional and more stringent state requirements, and so Plaintiff's PLA claim is dismissed. *Horn v. Thoratec Corp*., 376 F.3d 163, 173-177 (3d Cir. 2004) ("The only state requirements asserted by [plaintiff] are general requirements stemming from state common law: the HeartMate [device] was designed in a defective manner, it was manufactured in a defective manner, and the manufacturer had failed to warn of the alleged defects. . . . Because these state common law claims and duties are in severe tension with § 360k(a) in that they are either in addition to, or different from, the federal requirements established by the FDA

in approving the HeartMate, they are necessarily preempted by federally imposed PMA requirements under § 360k(a).").[8]

In concluding that Plaintiff's PLA claim is expressly preempted by the MDA, this Court is in accord with the only other court in this district to specifically address an alleged PLA claim arising from defective leads in a defibrillator device. In a closely factually analogous case, another judge in this District found that

> Plaintiffs' claims of, *inter alia*, negligence, defective design, and failure to warn stem from state common law. Plaintiffs would only be able to prevail on the New Jersey PLA claims if they proved that the lead wire, as designed, manufactured, and distributed, was defective and unreasonably dangerous. It follows that liability would necessitate a finding that the lead wire—designed, manufactured, and labeled in a way that the FDA deemed safe and effective—was both defective and unreasonably dangerous. Such a determination would necessarily constitute a requirement different from, or in addition to, the standard required by federal authorities. . . . This is the exact situation when the MDA requires preemption.

Desai v. Sorin CRM USA, Inc., No. CIV. 12-2995, 2013 WL 163298, at *5 (D.N.J. Jan. 15, 2013) (quotation omitted). This Court's decision and the decision in *Desai*, are also consistent with the overwhelming weight of precedent in this District. *See, e.g.*, *Millman v. Medtronic*, No. 14-CV-1465, 2015 WL 778779, at *5 (D.N.J. Feb. 24, 2015) ("Because the FDA determined, by granting PMA, that the Activa System [device] was safe and effective as manufactured and designed in the PMA application, this Court finds that Plaintiffs' claims based on a manufacturing defect, design defect, failure to warn, negligence and a breach of contract/warranty theory are preempted because they impose requirements that are different from the federal requirements set forth in the PMA process. Each claim, as currently alleged, seeks to impose requirements that are either different from or in addition to those required by federal

[8] The state law claims at issue in *Horn* were brought under the common law of Pennsylvania, but were of a type — design defect, manufacturing defect, and failure to warn — that would clearly have been subsumed by the PLA had they been brought under New Jersey law.

law."); *id.* at *6 n. 3 ("Plaintiffs do not allege that Medtronic failed to provide any warnings required by FDA through the PMA process. To the extent Plaintiffs assert that, to comply with state law, Medtronic was required to give additional or different warnings than those required by FDA, this claim is preempted."); *Mendez v. Shah*, 28 F. Supp. 3d 282, 292 (D.N.J. 2014) ("To the extent that any of plaintiff's state law claims assert that the warnings on the Infuse/LT–Cage device were insufficient because they did not warn of dangers . . . such claims are expressly preempted. To require defendant to add language to the warning would impose an additional requirement relating the safety or effectiveness of the device."); *Delaney v. Stryker Orthopaedics*, No. CIV.A. 08-03210DMC, 2009 WL 564243, at *3 (D.N.J. Mar. 5, 2009) (quotations omitted) ("Counts One and Three of Plaintiff's Complaint assert claims for failure to warn and defective design. . . . As in *Riegel*, these claims are expressly preempted because they assert general tort duties of care, allege that a device was designed, labeled, or manufactured in an unsafe or ineffective manner, and impose different or additional requirements related to the safety and effectiveness of the Trident™ device.").[9]

[9] The Court also notes that the Supreme Court's holding in *Riegel* constitutes an alternative and sufficient basis for the dismissal of Plaintiff's common law tort claims subsumed by the PLA. The *Riegel* Court considered state common law tort claims and found that they too impose state requirements different from, or in addition to the federal PMA requirements. *Id.* at 323. It reasoned that safety and effectiveness are "the very subjects" of such tort causes of action, while also the primary concerns reserved to the FDA in the federal PMA process. *Ibid.* As another court in this District aptly observed:

> The upshot of *Riegel*, then, is that the MDA preempts state tort claims to the extent that they would impose requirements on device manufacturers that deviate from those imposed by federal law—particularly, those imposed in the PMA process. Accordingly, courts within the Third Circuit have consistently held that tort claims based on negligence, manufacturing and design defects, strict liability, breach of warranty, and failure to warn, including such claims as subsumed by the New Jersey PLA, are preempted by MDA.

2. No Parallel Claim

In the Amended Complaint and in her Opposition to the motion to dismiss, Plaintiff contends that, despite directly bearing on issues addressed by the FDA in the PMA process, Plaintiff's PLA claims may nevertheless proceed because they fall within a category of state claims identified in *Riegel*, which impose requirements "parallel" and not in addition to the federal requirements of the MDA, and therefore escape express preemption. Plaintiff is correct that not all state law claims are expressly preempted by the MDA. The Supreme Court has held that "[s]tate 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. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S., at 495). Accordingly, to fall within the parallel claim exemption, Plaintiff must allege (i) violation of FDA regulations; (ii) an independent state law cause of action providing a damages remedy for the violation of FDA regulations; and (iii) a "cognizable link" between the violation of FDA regulations and Plaintiff's injury. *Desai*, 2013 WL 163298, at *6.

In attempting to establish the first prong, Plaintiff, in the Amended Complaint, provides a laundry list of FDA regulations with which Defendants were obligated to comply in designing, manufacturing, and selling the Defibrillator. *See* Compl. ¶ 36 (requirement to report if a device

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Clements, 111 F. Supp. 3d at 598. *See also Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) ("Generalized common law theories of liability . . . are precisely the type of claims the MDA sought to preempt."); *ibid.* ("Success on appellants' . . . claims would require them to show that the . . . device was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA, which has preempted safety and effectiveness determinations for a device.").

may have caused death or serious injury or device malfunction, and duty to investigate each adverse event, 21 C.F.R. § 803.50); ¶ 37 (duty to provide detailed descriptions of adverse events to the FDA, 21 C.F.R. § 803.52); ¶ 38 (duty to conduct trend analysis or undertake remedial action to prevent unreasonable risk to the public, 21 C.F.R. § 803.53); ¶ 39 (duty to report device corrections or removals, 21 C.F.R. § 806.10); ¶ 40 (duty to implement design-control systems and conduct design validation, 21 C.F.R. § 820); ¶ 42 (duty to submit a supplementary report to the FDA when unanticipated adverse effects of device or device failures require labeling, manufacturing or design modification, 21 C.F.R. § 814.39). In support of the dismissed common law counts (all Counts except Count I), Plaintiff also alleges that Defendants are liable pursuant to 21 C.F.R. § 814.84(b)(2) (requirement that periodic reports to the FDA contain a summary of information not previously submitted); and 21 C.F.R. § 803.50(a) (obligation of device manufactures to report to the FDA).

What is missing from Plaintiff's first prong allegations is any plausible pleading of if, how, or when Defendants violated any of the listed regulations. Instead, the Amended Complaint alleges only that "Defendants have a long history of failure to report adverse effects related to their defibrillator and/or lead devices pursuant to federal law and such was the case here," *id.* at ¶ 44, and that "Defendants' failure to meet federal regulations applicable to the medical device at issue herein, and defendants' other acts and omissions as described herein directly and proximately caused the device at issue to be in violation of federal law and unfit for sale," *id.* at ¶ 47. These conclusory, legal allegations are insufficient to allege a *violation* of an FDA regulation sufficient to state a parallel claim. *Iqbal*, 556 U.S. at 678-79 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). *See also Clements*, 111 F. Supp. 3d at 598 ("The parallel claim exception to preemption, however,

requires more than just a change of terminology; a plaintiff cannot simply incant the magic words [Defendant] violated FDA regulations in order to avoid preemption." (quotation omitted)); *Desai*, 2013 WL 163298, at *6–7 ("broad references to federal regulations in pleadings are insufficient . . . . Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel,* as well as the pleading requirements articulated in *Twombly, Iqbal,* and *Fowler*." (quotation omitted)).

Even had Plaintiff pleaded identifiable violations of FDA regulations, Plaintiff's claim would still fail at the second prong for failure to identify a state cause of action based on those violations. The facts of this case are substantially analogous to those in the persuasive decision of the Eighth Circuit in *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.,* also dealing with implanted leads. The complaint there alleged that Defendants

> failed to adequately warn consumers of "known defects" and that the . . . [l]eads presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect. These claims are preempted by § 360k. The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is "different from or in addition to" the federal requirement and therefore preempted.

623 F.3d 1200, 1205 (8th Cir. 2010) (quoting *Riegel*, 552 U.S. at 330). In short, Plaintiff here was required to allege that the violation of the FDA reporting requirements listed in the Amended Complaint was the basis of her state law cause of action. This Plaintiff failed to do, instead alleging that the Defibrillator's FDA-approved warnings, rather than violating FDA reporting requirements, violated the New Jersey PLA by failing to provide adequate notice of danger. *See* Compl. ¶ 59 ("Because information concerning the inherently dangerous characteristics of the subject devices were unknown to and concealed from the general public and to the decedent, . . . defendants were under a duty, yet intentionally failed to disclose to

patients, the consuming public, and the medical community, that their product was defective, unsafe, and inherently dangerous for their intended use by consumers such as the decedent."). Such claims are expressly preempted as explained above.

Although Defendants also argue that to the extent Plaintiff alleges a violation of FDA regulations, her claims based upon such violations are impliedly preempted as impermissible attempts to enforce FDA reporting requirements under the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001), the Court does not read the Amended Complaint as asserting any "fraud-on-the-FDA" claim based on the alleged reporting regulations. The MDA does, however, provide that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a), and, in *Buckman*, the Supreme Court construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." 531 U.S. 341, 349 n. 4. Thus, to the extent, Plaintiff attempts to raise some claim, independent of her PLA claim for fraud on the FDA as a result of reporting violations, such claim would be impliedly preempted.[10] *See Mendez*, 28 F. Supp. 3d at 291 ("If not expressly preempted, the state law claim may be still be barred under implied preemption. The holding in *Buckman*, however, is often limited to "fraud-on-the-agency" claims and not extended

[10] Certain paragraphs of the Amended Complaint, could lend support to the idea that Plaintiff sought to raise a fraud-on-the-agency claim. *See, e.g.*, Compl. ¶ 46 ("While Boston Scientific was aware that the Defibrillator might be subject to certain random and infrequent failure, Boston Scientific was also aware of specific, potentially fatal, and nonrandom failure that would occur in the device, but failed to disclose any of the subject risks and problems of the device to the FDA and/or to the public who relies on said device, and failed to take remedial steps to correct them."); ¶ 48 ("Defendants, including Boston Scientific and Guidant Corp.'s prior history, demonstrates that while said defendants had provided some information to the FDA, that information was incomplete and misleading and did not adequately disclose the device defects. Boston Scientific's flawed disclosures did not comply with FDA regulations and violated the conditions of approval for the devices."). In the actual Counts of the Amended Complaint, however, Plaintiff raises only New Jersey PLA and common law theories of liability, undermining the existence of any fraud-on-the-agency claim.

to claims based on state law tort principles."); *Cornett*, 211 N.J. at 389 ("Moreover, to the extent plaintiffs' failure to warn claim is based *solely* on a contention that defendants obtained FDA approval for the device only after submitting fraudulent representations to or withholding material information from the FDA, this claim falls squarely within the *Buckman* implied preemption rule. We affirm its dismissal. So, too, plaintiffs' failure to warn claim is preempted and dismissed to the extent that it can be established *solely* by evidence of fraud on the agency.").

Perhaps acknowledging the great weight of precedent aligned against her position, Plaintiff, in her Opposition, focuses on a narrow-category of strict products liability failure to warn cases in which the federal and state courts of this Circuit have found parallel claims not preempted by the MDA. Citing mostly *Mendez*, 28 F. Supp. 3d at 291, and cases cited therein, but relying, without citation, primarily on the reasoning in *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 400 (App. Div. 2010), *aff'd as modified*, 211 N.J. 362 (2012),[11] Plaintiff argues that "[w]hen a claim alleging failure to warn related to adverse reactions caused by a medical device is combined with allegations of nondisclosure, it becomes a claim within a traditional area of state regulation that would have existed even in the absence of federal requirements. To that extent, the claims satisfy and warrant avoidance of preemption." Opp. at 15.

It is concerning that Plaintiff so heavily paraphrased the holding of the Appellate Division in *Cornett* without any citation to that case, because a proper citation would have alerted both the Court and Plaintiff immediately to the fact that the New Jersey Supreme Court accepted certiorari in *Cornett* and modified the holding. Specifically, the Appellate Division's

[11] Although the interpretations of federal law by the New Jersey courts are not binding on the courts of this District, this Court finds the reasoning in the *Cornett* line of cases persuasive and discusses them as persuasive authority, *infra*.

holding, although somewhat opaque, at least facially appears to support Plaintiff's position that a failure to warn claim coupled with allegations of intentional non-disclosure of information required by the FDA regulations states a claim not expressly or impliedly preempted by the MDA. The Appellate Division held that:

> The FDCA's rebuttable presumption thus barred a claim about the failure to give such warnings for approved uses *in the absence of deliberate nondisclosure*, and such a claim was also expressly preempted under *Riegel* as an additional state requirement on defendants. *Hughes, supra,* 669 *F.Supp.*2d at 710; *Riley, supra,* 625 *F.Supp.*2d at 780–81.
>
> However, *when the claim about the failure to warn for approved uses was combined with allegations of nondisclosure, it became a claim within a traditional area of state regulation that would have existed even in the absence of federal requirements.* To that extent, it satisfied *Buckman* 's test for avoiding implied preemption as a claim that amounted to no more than "fraud on the FDA." *Hughes, supra,* 669 *F.Supp.*2d at 709–10. While it is true that the "misconduct" underlying plaintiffs' claims also constitutes a violation of federal regulations—indeed that is precisely why the claims are parallel—the suit was brought to vindicate plaintiffs' rights, not the FDA's. Plaintiffs adequately pled that claim.

Cornett, 414 N.J. Super. at 399–400 (emphasis added).

The New Jersey Supreme Court, however, eloquently disentangled the Appellate Division's holding. Under New Jersey law, "Defendants who comply with FDA requirements are granted a rebuttable presumption that the labeling is adequate." *Cornett*, 211 N.J. at 388. "To overcome this presumption, a plaintiff asserting a failure to warn claim based on an inadequate label or instructions has stricter pleading requirements. A plaintiff must plead specific facts alleging deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Ibid.* (quotation omitted). The New Jersey Supreme Court observed that "[t]his pleading specificity also serves to permit a determination whether a failure to warn claim is preempted by the MDA or is a permissible parallel state claim." *Ibid.* The court explained that the Master Complaint in *Cornett* included both state law claims for failure to warn the public about the dangers of unapproved uses of the device, in that case a stent, which were not part of the PMA

process (also called off-label uses) and state law claims for failure to warn of the dangers of FDA-approved uses. *Ibid*. The New Jersey Supreme Court found that the plaintiff's claims for failure to warn of the dangers of the *approved* uses of the device were clearly, expressly preempted under *Riegel*. The *Cornett* Court held

> The failure to warn claim alleged by plaintiffs includes approved and off-label uses of the device. As to the approved uses of the . . . stent, the failure to warn claim . . . is nothing more than a challenge to the adequacy of the information required by the FDA during the PMA process and label approved by the agency. This failure to warn claim falls within the PLA rebuttable presumption and the *Riegel* express preemption rule.

Id. at 389. Those claims were distinguished from the plaintiffs' *unapproved* or *off-label* use claims for failure to warn which were not preempted. For the unapproved claims, the New Jersey Supreme Court found that the plaintiffs had adequately alleged "specific conditions of the PMA of the device and regulations prohibiting promotion of adulterated and misbranded product and off-label marketing" that had been violated. *Id.* at 388. Such failure to warn claims concerned adverse information gathered about the device and parts of the Defendants' labeling and instructions that "were not part of the PMA process," and as such fell "within a traditional area of state concern and regulation because fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA." *Id.* at 390. Accordingly, the failure to warn claims based on unapproved or off-label uses of the device were not necessarily preempted.[12]

The other case, from this District, upon which Plaintiff principally relies, *Mendez*, came to the same conclusion that failure to warn causes of action in off-label promotion cases are not

[12] Having so held, the New Jersey Supreme Court observed that even the off-label claims might be preempted by the safe harbor provisions of the MDA. *Cornett*, 211 N.J. at 391 ("nevertheless, if defendants complied with the safe harbor requirements of the MDA in disseminating information about the off-label uses of the device, plaintiffs' claim is preempted."). As Plaintiff in this case does not raise any off-label claims, no safe harbor analysis by this Court is necessary.

necessarily preempted by the MDA. *Mendez,* 28 F. Supp. 3d at 293 ("plaintiff's claims based on a theory of off-label promotion of the . . . device is not different from or in addition to federal requirements, and therefore are not preempted by federal law. . . . Likewise, since plaintiff's theory is not based on Medtronic defendants committing fraud against the FDA, their off-label promotion claims are not barred by implied preemption under *Buckman.*"); *id.* at 300 ("plaintiff's failure to warn claim is not preempted" because "[p]laintiff's theory is based on the idea that [defendant's] actions modified the warning label so that the prohibition against using the [device] with any other component . . . was nullified. Plaintiff is not arguing that [defendant] should have given warnings that were different from or in addition to the warning provided."). It is worthy of note that even though the off-label failure to warn claim in *Mendez* was not preempted by the MDA, the district court still dismissed it for failure to clearly state the violated "federal regulation that parallels [plaintiff's] state law claim." *Ibid.* The off-label claim in *Cornett* survived because the plaintiffs had alleged the specific regulations violated.

Here, Plaintiff's failure to warn claim is not based on unapproved or off-label uses of the Defibrillator. Instead, Plaintiff clearly asserts that the Defibrillator was defectively designed, manufactured, and labeled, and the inadequacy of the FDA-approved warnings, which failed to provide notice of that defectiveness, resulted in injury to the Plaintiff. Such a claim is expressly preempted by the MDA and does not fall within the category of parallel claims identified in *Cornett* and *Mendez*. Plaintiff simply cannot shoehorn her claim into the mold of a parallel claim under *Riegel*, because Plaintiff has failed to allege a violation of FDA regulations and has failed to allege an independent state law cause of action parallel and not in addition to the federal requirements that provides a remedy for such violation. Accordingly, Plaintiff's Count I claim for strict product liability for failure to warn, along with the common law claims in Counts II-V

subsumed within Count I by action of the PLA as explained above, is expressly preempted by the MDA and is dismissed.

C. Discovery Not Warranted

Lastly, Plaintiff, in her Opposition, requests discovery into Defendants' compliance with pre-and-post-PMA approval requirements in order to identify specific violations of FDA regulations in a future amended complaint. Plaintiff cites no binding authority suggesting that such discovery would be appropriate. On the contrary, in an unreported opinion, the Third Circuit noted that "many PMA preemption motions are decided without any discovery." *Smith v. Depuy Orthopaedics Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014). The *Smith* Court went on to hold that [b]ecause the device components at issue in the products liability action "were approved by the FDA through the PMA process . . . no discovery was necessary to determine that these components were also subject to PMA preemption." *Ibid.* The courts of this district have thus consistently found that PMA preemption motions may be resolved before the grant of discovery. *Clements*, 111 F. Supp. 3d at 599 ("From the face of the complaint, it is apparent that these counts, at least as currently alleged, are preempted by the MDA and thus should be dismissed as a matter of law."); *Becker v. Smith & Nephew, Inc.*, No. CIV. 15-2538 WHW CLW, 2015 WL 4647982, at *3 (D.N.J. Aug. 5, 2015) ("Plaintiffs contend that they should be permitted to allege unspecified deviations from FDA requirements at the pleading stage, and fill in the blanks through discovery. . . . But a plaintiff must successfully plead a claim before obtaining discovery, not the other way around. Such a premature request for discovery conflicts with Rules 8 and 11(b) of the Federal Rules of Civil Procedure."); *Desai*, 2013 WL 163298, at *7 (same).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is granted, and the Amended Complaint is dismissed.

Dated: 2/27/2017

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge