UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARIA MENDEZ,	:	
Plaintiff,	:	Civil Action No. 13-1585
v.	:	
RAHUL V. SHAH, M.D., *et al.*,	:	**OPINION**
Defendants.	:	

Appearances:

MICHAEL T. ROONEY
ROONEY & ROONEY
TWO PENN CENTER PLAZA
1500 JFK BLVD., SUITE 200
PHILADELPHIA, PA 19102
Attorney for Plaintiff

JOHN F. BRENNER
MELISSA ANNE CHUDEREWICZ
PEPPER HAMILTON, LLP
301 CARNEGIE CENTER
SUITE 400
PRINCETON, NJ 08543-5276
Attorneys for defendants Medtronic Sofamaor Danesk USA Inc., Medtronic Spine LLC, Medtronic USA Inc., and Medtronic Inc.

HILLMAN, District Judge:

Before the Court is a motion to dismiss the second amended complaint filed by defendants Medtronic Sofamaor Danesk USA Inc., Medtronic Spine LLC, Medtronic USA Inc., and Medtronic Inc. (collectively "Medtronic"). For the reasons stated below, the motion will be granted in part and denied in part.

I. BACKGROUND

Plaintiff, Maria Mendez, suffered from chronic back pain. Defendant Dr. Shah performed surgery on her back on March 21, 2011 and implanted various medical devices in her back that plaintiff alleges failed and caused her injury. Plaintiff's allegations against the Medtronic defendants concern the implantation of Medtronic's "Infuse Bone Graft/LT-Cage Lumbar Fusion" device as well as "the Capstone Spinal System, Infuse Bone Graft, MasterGraft Matrix, CD Horizon Legacy screws, Cancellous chips, and surgical putty." Plaintiff states that Capstone cages and Infuse bone graft were inserted into the spaces between her fourth and fifth lumbar vertebrae (L4/L5) and between the fifth lumbar vertebra and the sacrum (L5/S1). Plaintiff asserts that a Medtronic sales representative, "Ken," was present in the operating room.

Due to increasing pain and disabili1y over several weeks post-operatively, films were taken that showed that the cages had migrated. A revision surgery was performed on May 18, 2011 and similar products in a smaller size were implanted. Plaintiff states that the L5/S1 hardware had allegedly failed, with the L4/L5 implant remaining well fixed. The second surgery involved "shav[ing] the space of the L5/S1" joint, "remov[ing] the loose and migrated Capstone interbody spacer," and

“insert[ing]” a “new larger Capstone spacer.” Plaintiff alleges she sustained "drop foot," and other complications resulting from these surgeries. She alleges that she is disabled and suffers excruciating pain every day. It is not expected that any further treatment will help her.

Plaintiff brought claims of negligence, medical malpractice, battery, lack of informed consent, breach of the implied warranty of fitness for a particular purpose, breach of express warranty, breach of contract, fraudulent concealment, fraud and misrepresentation, as well as claims pursuant to the New Jersey Product Liability Act (“PLA”) and a third party beneficiary claim. Plaintiff seeks compensatory and punitive damages.

The Medtronic defendants argue that claims against one of the devices, the “Infuse Bone Graft/LT-Cage Lumbar Fusion” devince, is preempted by federal law because it received premarket approval from the Food and Drug Administration. They also seek to dismiss plaintiff’s claims for implied and express warranties, third party beneficiary, fraud, and claims brought pursuant to the PLA. Finally, they request to have plaintiff’s request for punitive damages stricken.

II. JURISDICTION

This Court exercises jurisdiction pursuant to 28

U.S.C. § 1332(a), diversity of citizenship. Plaintiff is a citizen of the Commonwealth of Pennsylvania and the defendants, are citizens of either the States of New Jersey, Tennessee, Delaware, or Minnesota. The amount in controversy exceeds the jurisdictional limit exclusive of interest and costs.

A Court exercising diversity jurisdiction must apply the law of the forum state within which it sits, and therefore, New Jersey law will apply to plaintiff's state law claims. See Chemical Leaman Tank Lines, Inc. V. Aetna Casualty and Surety Co., 89 F.3d 976, 983 (3d Cir. 1996) (stating that "[a]s a federal court sitting in diversity, we must apply the substantive law of New Jersey.") (citing Borse v. Piece Goods Shop, Inc., 963 F.2d 611, 613 (3d Cir. 1992)).

III. DISCUSSION

A. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to

relief." Fed. R. Civ. P. 8(a)(2). Under the liberal federal pleading rules, it is not necessary to plead evidence, and it is not necessary to plead all the facts that serve as a basis for the claim. Bogosian v. Gulf Oil Corp., 562 F.2d 434, 446 (3d Cir. 1977). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." Baldwin County Welcome Ctr. v. Brown, 466 U.S. 147, 149-50 n.3 (1984) (quotation and citation omitted).

A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" Bell Atlantic v. Twombly, 127 S. Ct. 1955, 1969 n.8 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before Twombly.").

Following the Twombly/Iqbal standard, the Third

Circuit has instructed a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, the factual and legal elements of a claim should be separated; a district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Fowler, 578 F.3d at 210 (citing Iqbal, 129 S. Ct. at 1950). Second, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "'plausible claim for relief.'" Id. (quoting Iqbal, 129 S. Ct. at 1950). A complaint must do more than allege the plaintiff's entitlement to relief. Id.; see also Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (stating that the "Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element"). A court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. Hedges v.

U.S., 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

B. Premarket Approval of The Device

The parties do not dispute that the device, Medtronic's "Infuse Bone Graft/LT-Cage Lumbar Fusion" device (the "Infuse/LT-Cage device") is a Class III medical device that received pre-market approval ("PMA").[1] Premarket approval

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> The MDA [Medical Device Amendments] separates devices into three categories: Class I devices are those that present no unreasonable risk of illness

imposes "requirements" under the Medical Device Amendments of 1976 ("MDA") and is specific to individual devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23, 128 S.Ct. 999, 1007 (2008). "[I]t is federal safety review." Id. 552 at 321. The MDA "... expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law... ." Id. (citing 21 U.S.C.A. § 360k(a)(1)).

"[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the

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> or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices "presen[t] a potential unreasonable risk of illness or injury" and therefore incur the FDA's strictest regulation.
> § 360c(a)(1)(C)(ii)(II).
>
> ...
>
> Class III devices must complete a thorough review process with the FDA before they may be marketed. This premarket approval (PMA) process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe ... [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."
> §§ 360e(d)(2)(A), (B).

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 344, 121 S.Ct. 1012, 1015 (2001).

specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Id.

A Class III medical device presents a "potential unreasonable risk of illness or injury," or purports or represents "to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." See 21 U.S.C. § 360c(a)(l)(C)(ii). "Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective. Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240 (1996) (citing 21 U.S.C. § 360e(d)(2)). The Supreme Court has recognized this process of establishing "reasonable assurance," known as the "premarket approval," or "PMA" process, to be "rigorous."[2] Id.; Buckman Co. v. Plaintiffs' Legal

[2] Among other information, an application must include all known reports pertaining to the device's safety and efficacy; a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples of the device (when practicable); and specimens of the labeling proposed to be used for such device. The PMA process is ordinarily quite time

Committee, 531 U.S. 341, 344, 121 S.Ct. 1012, 1015 (2001).

Medtronic submitted an application for the Infuse/LT-Cage device to the FDA on January 12, 2001. The device received approval under PMA Number P000058 on July 2, 2002. The Infuse device's description states, in part:

> The InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device consists of two components containing three parts-a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. The InFUSE™ Bone Graft component is inserted into the LT-CAGE™ Lumbar Tapered Fusion Device component to form the complete InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. **These components must be used as a system. The InFUSETM Bone Graft component must not be used without the LT-CAGETM Lumbar Tapered Fusion Device component.**
>
> ...
>
> LT-CAGE™ Lumbar Tapered Fusion Device component is sold separately from the InFUSE™ Bone Graft component, however, these two componenets must be used together. The package labeling for the LT-CAGE™ Lumbar Tapered Fusion Device contains complete product information for this component.

(Emphasis in original).

> consuming because the FDA's review requires an average of 1,200 hours [for] each submission.

Buckman, 531 U.S. at 344-45 (internal quotes and citations omitted).

Although the parties agree that the device is a Class III device that received PMA, the parties disagree on whether federal law preempts plaintiff's state law claims.

C. Federal Preemption

Given the extensive regulation by the FDA over medical devices, certain state law claims are preempted by federal law. What state law claims are preempted, and under what conditions, has been the subject of much debate by the courts.

In Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240 (1996), the Supreme Court found that certain state law claims were not preempted if those claims imposed duties that paralleled federal requirements. The medical device in Lohr, a pacemaker, received premarket approval as a "substantial equivalent" of a device already on the market. 518 U.S. at 479 (contrasting the more limited " § 510(k) process," for devices that are substantially equivalent with devices already on the market, with the more rigorous PMA process).

In Reigel, the Supreme Court ruled that state common law claims against manufacturers of medical devices that are approved through §360k premarket approval are subject to federal preemption. 552 U.S. at 322–25. The MDA contains an express preemption clause that "bars common-law claims challenging the safety and effectiveness of a medical device

given premarket approval by the [FDA]." Id. at 315. This express preemption provision is generally applied in a two-step process in which it must be determined: (1) "whether the Federal Government has established requirements applicable to" a medical device; and if so, (2) whether the state law claim asserted against the manufacturer is based on requirements with respect to the device that are different from or in addition to federal requirements, and that relate to safety and effectiveness. Riegel, 552 U.S. at 321-22; 21 U.S.C. § 360k(a).[3]

If the state law claim is expressly preempted, then the claim is dismissed. If not expressly preempted, the state law claim may be still be barred under implied preemption. See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 350,

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3 Section 360k(a) states, in part:

> (a) General rule
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> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

121 S.Ct. 1012 (2001) (finding that the FCDA impliedly preempted state law fraud claims because claims conflicted with federal law). The holding in Buckman, however, is often limited to "fraud-on-the-agency" claims and not extended to claims based on state law tort principles. See Bausch v. Stryker Corp., 630 F.3d 546, 557 (7th Cir. 2010) (finding no implied preemption where state law claims were based on manufacturing defects, not fraud on a federal agency).

Courts have understood that the general rule that has emerged from this trio of cases, Lohr, Buckman, and Reigel, is that "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1117 (9th Cir. 2013) (citing Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc)); compare Lohr, 518 U.S. at 495 (finding common-law claims were not preempted under § 360k because allegations included claims that Medtronic had violated FDA regulations) with Riegel, 552 U.S. at 322-23 (finding that § 360k preempted common-law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA).

In order to determine if plaintiff's claims are expressly preempted, first, it must be determined whether the

Federal Government established requirements applicable to Medtronic's medical device. There is no dispute that the Infuse/LT-Cage device is a Class III device that obtained PMA approval, and, therefore, is subject to the MDA express preemption provision.[4]

Secondly, it must be determined whether plaintiff's state claims are based on requirements that relate to safety and effectiveness with respect to the Infuse/LT-Cage device that are different from or in addition to federal requirements. Plaintiff argues that she was harmed by defendants' illegal promotion and sale of a component of the Infuse/LT-Cage device, the Infuse Bone Graft, for uses not approved by the FDA and, therefore, her "parallel" claims are not preempted by federal law. Particularly, she argues that the PMA was for the Infuse Bone Graft to be used in combination with the LT-Cage Lumbar Tapered Fusion Device ("LT-Cage"), employing an anterior approach. She argues that the use of the Infuse Bone Graft with the Capstone Cage employing a posterior approach violated federal law. Although plaintiff concedes that a doctor may prescribe an FDA approved device for non-approved used, she

4 The parties do not address whether any of the other products listed obtained PMA, or other FDA approval, so the preemption discussion is limited to the Infuse/LT-Cage device.

argues that a manufacturer is barred from marketing or promoting "off-label" uses.

Plaintiff also argues that the Medtronic defendants, in order to increase sales, promoted the use of the Infuse Bone Graft without the LT-Cage, in violation of the FDA approval. She states that the Infuse Bone Graft was sold separately to facilitate off-label use and that sales representatives were placed in operating rooms to promote the separate use.

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 from using the Infuse Bone Graft without the LT-Cage, or not using an anterior approach, 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.[5] See Horn v. Thoratec Corp., 376 F.3d 163, 168 (3d Cir. 2004) ("[W]hen a state law neither imposes requirements nor differs from or adds to an FDA requirement nor relates to the safety or effectiveness of the device or to any other matter included in an FDA requirement, the state law is not pre-empted

5 The Medtronic defendants would be prohibited by federal law from changing any of the language approved by the FDA in the PMA. Any change in the label would require the defendants to submit a supplemental request for approval.

by § 360k.").

What plaintiff is arguing, however, is that defendants engaged in off-label promotion that was false or misleading. Plaintiff has argued that defendants through their marketing and sales representatives promoted the use of the Infuse Bone Graft in a manner that was contrary to the labeling approved on the device, and harmful to patients. Defendants argue that off-label promotion is not expressly banned by federal law. They rely on Buckman in which the Supreme Court noted that "off-label" usage of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." 531 U.S. at 350. However, the Court was referring to off-label use by physicians, not manufacturers. See id. (noting an amendment to the FDCA that expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a *health care practitioner* to prescribe or administer any legally marketed device to a patient for any condition or disease within *a legitimate health care practitioner-patient relationship*.")(citing 21 U.S.C. § 396 (1994 ed., Supp. V) (emphasis added).

Certain courts have noted the murkiness of federal preemption law with regard to medical devices and off-label use.

See Schouest v. Medtronic, Inc., --- F.Supp.2d ----, 2014 WL 1213243, at *6 (S.D.Tex. 2014) (noting that federal law does not expressly ban off-label promotion, but noting the FDA views off-label promotion to be misbranding and concluding that "federal law bars off-label promotion when it is false or misleading."). Thus, although there is no express provision banning off-label promotion, it is clear that such practices are not in keeping with FDA directions and allowing such practices would encourage manufacturers to promote their products in ways not approved by the FDA and possibly provide inaccurate or misleading information to patients.

Therefore, plaintiff's claims based on a theory of off-label promotion of the Infuse/LT-Bone Graft device is not different from or in addition to federal requirements, and therefore are not preempted by federal law. See id. at *8 ("[M]aking false or misleading statements about medical devices is prohibited by federal law[; therefore,]... state law fraud claims based on false off-label promotion would, if proven, also amount to a violation of federal law, and thus such claims could survive preemption."). 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.

Further, the Infuse/LT-Cage device received PMA as a system, not as separate parts. In plaintiff's case, the Infuse Bone Graft was used without the LT-Cage. The FDA did not give PMA to the Infuse Bone Graft alone, or to the Infuse Bone Graft with devices other than the LT-Cage. Thus, to the extent Medtronic's argument is that its Infuse Bone Graft by itself enjoys PMA, such argument is on shaky ground, particularly here, where plaintiff has alleged that not only did Medtronic know about the off-label use, but encouraged it.[6]

Having determined generally that claims based on a theory of off-label marketing and promotion by the manufacturer would not necessarily be preempted by federal law, we now turn to the specific state law claims brought by plaintiff to determine whether they are subject to dismissal.[7]

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6 The Court does not determine at this early stage in the proceeding whether there is Federal preemption for a device knowingly sold and marketed as separate device where the PMA was for the device to be part of a system. Health care practitioners use devices off-label. We do not suggest that such off-label use strips a manufacturer of its PMA status for the device, particularly if the usage is not promoted by the manufacturer.

7 In assessing each state law claim, the first inquiry is whether a state law claim exists. If it does not, then it will be dismissed pursuant to Fed.R.Civ.P. 12(b)(6). If there is a valid state law claim, then the inquiry is whether it is barred by the doctrine of federal preemption.

D. Breach of Implied Warranty – Count V

Medtronic seeks dismissal of plaintiff's breach of implied warranty claim on grounds that the claim is subsumed under the PLA and, therefore should be dismissed pursuant to FedR.Civ.P. 12(b)(6). Plaintiff responds that her claim is pursuant to the Uniform Commercial Code (UCC) and that the warranty of fitness in this case is "express" not "implied" based on the conduct, representations, and circumstances surrounding the sale of the Medtronic medical devices to plaintiff's surgeon, including the presence of a Medtronic sales representative in the operating room.

The section of the UCC relied upon by plaintiff, 12A:2-315, pertains to the implied warranty for fitness for particular purpose. It states that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose." See N.J.S.A. 12A:2-315.

New Jersey law is clear that the PLA provides one unified, statutorily defined theory of recovery for harm caused by a product. See Calender v. NVR, Inc., No. 10–4277, 2012 WL

4482009, at *3–4 (D.N.J. Sept. 26, 2012) (granting summary judgment to defendant on negligence and implied breach of warranty claims because they were subsumed by the PLA); Gupta v. Asha Enterprises, LLC, 422 N.J.Super. 136, 144-45, 27 A.3d 953 (App.Div. 2011) (affirming dismissal of claims for negligence, violations of the CFA and breach of implied warranty insofar as they were based upon product defect); Koruba v. Am. Honda Motor Co., 396 N.J.Super. 517, 935 A.2d 787, 795 (2007) (explaining that "the PLA 'no longer recognizes negligence or breach of warranty (with the exception of an express warranty) as a viable separate claim for "harm[,]" [including personal injury,] caused by a defective product' or an inadequate warning.") (citation omitted).

New Jersey courts have not made any exception to this rule and have adhered strictly to the parameters set out in the PLA. See Cornett v. Johnson & Johnson, 998 A.2d 543, 566 (N.J.Super.A.D. 2010) ("This preclusion of breach of implied warranty 'as a viable separate claim' is 'definitive.'") (citing Tirrell v. Navistar Int'l, Inc., 248 N.J.Super. 390, 398, 591 A.2d 643 (App.Div.); Koruba, 935 A.2d at 787). Plaintiff has not demonstrated how her claim brought under a statute for implied warranty could be translated into an express warranty, and even if it could, plaintiff has not shown why her express

warranty claim in Count V is different from the express warranty claim raised in Count VII. Further, there is nothing in the UCC language to suggest that it encompasses express warranties. Accordingly, plaintiff's claim for implied warranty is subsumed under the PLA and not cognizable as a state law claim under New Jersey law. Therefore it shall be dismissed.

E. Breach of Express Warranty – Count VII

Medtronic also seeks to dismiss plaintiff's claim for breach of express warranty pursuant to Fed.R.Civ.P 12(b)(6). "Under New Jersey law, in order to state a claim for breach of express warranty, Plaintiffs must properly allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Companies, Inc., 792 F.Supp.2d 712, 721 (D.N.J. 2011) (citing N.J. Stat. Ann. § 12A:2–313). "However, 'an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.'" Id. (citing N.J. Stat. Ann. § 12A:2–313(2)). "Additionally, statements that are nothing more than mere puffery are not considered specific enough to create an express

warranty." Id. (citations omitted). A plaintiff in a warranty action "need not establish the existence of a defect; the failure of the goods to perform as warranted is sufficient." Spring Motors Distributors, Inc. v. Ford Motor Co., 489 A.2d 660 (N.J. 1985). However, "[p]roof of causation must still be shown in a case based on breach of an express warranty". Ford Motor Credit Company, LLC v. Mendola, 48 A.3d 366, 375 (N.J.Super.A.D. 2012) (citing Realmuto v. Straub Motors, Inc., 65 N.J. 336, 343, 322 A.2d 440 (1974)).

Plaintiff responds generally that Medtronic provided an express warranty in their conduct and representations concerning the use of Infuse separately from the "system" approved by the FDA, and in the aggressive marketing campaign including incentive payments, kickbacks, and falsifying clinical trial results. Plaintiff also argues that the Medtronic defendants separately packaged and sold the Infuse device and trained physicians to use it in ways the FDA did not approve and in direct conflict with the restrictions on the FDA approval received for the 3-component Infuse system with the LT-cage. Plaintiff states that in her case Infuse was used with a different cage and other materials, in a posterior approach, which was contraindicated.

It not clear, however, what Medtronic expressly

warranted. Even a review of the allegations in plaintiff's second amended complaint do not shed any additional light on what express warranties Medtronic allegedly made. In her second amended complaint, plaintiff alleges that the Medtronic defendants expressly warranted that their product would help and cure her. Plaintiff also alleges that statements made by Medtronic's sale and marketing personnel in "literature, on-line and in television or other advertising" constituted express warranties. Plaintiff states that Medtronic promoted off-label experimental uses in public advertising, as well as to physicians, hospitals or surgical centers. Plaintiff alleges that the Medtronic defendants breached the express warranties by using off-label experimental use of their "spinal surgery products" in plaintiff's back without her consent which caused aggravation of her existing condition, new nerve and muscular damage and "drop foot."

Plaintiff's statements are general averments and do not allege the specific affirmation, promise or guarantee made by Medtronic regarding the Infuse device. See Synder, 792 F.Supp.2d at 722 ("Plaintiffs have pointed to specific affirmations or promises by Defendants regarding the safety of the use of their Products on pets, and therefore their breach of warranty claim survives a motion to dismiss."); Hemy v. Perdue

Farms, Inc., 2013 WL 1338199, at *10 (D.N.J. Mar. 31 2013) (denying motion to dismiss express warranty claim where plaintiffs sufficiently pled that a reasonable consumer may have interpreted the Humanely Raised label to include the processes to which the chicken is exposed throughout its life, including slaughter, and fulfilled their obligations under the contract by paying the purchase price and have alleged damages derived therefrom).

Although plaintiff refers to advertising and marketing of Medtronic products off-label, she does not specifically state what Medtronic expressly warranted. See Fidelity and Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc., 936 F.Supp.2d 441, 452 (D.N.J. 2013) (dismissing breach of express warranty claim because plaintiff asserted only that its insured relied on the skill and judgment of defendant and its representations and warranties in the purchase and/or use of product, but failed to identify any actual representations regarding the product); Schraeder v. Demilec (USA) LLC, 2013 WL 3654093, at *5 (D.N.J. July 12, 2013) ("Courts dismiss claims for breach of an express warranty where plaintiffs fail to specify any factual support as to the specific language or source of the alleged warranty."); Walters v. Carson, 2012 WL 6595732, at *3 (D.N.J. Dec. 17, 2012) (dismissing express warranty claim because plaintiff did not

state how the claims allegedly made by Tylenol that its product was merchantable, free from defects, and reasonably fit for the foreseeable use and intended purposes for which it was sold formed any part of the basis of his decision to purchase the product).

If plaintiff is alleging that Medtronic made statements during its promotion and marketing campaigns that deviated from the device's labeling and instructions, then plaintiff must provide a more definite statement regarding what those statements were regarding which specific devices. Therefore, plaintiff's express warranty claims will be dismissed without prejudice. Plaintiff is granted leave to amend her complaint to provide more detail as to what was expressly warranted by Medtronic and for what device. [8]

8 Pursuant to Fed.R.Civ.P. 15(a), "The court should freely give leave [to amend] when justice so requires." See Snyder v. Baxter Healthcare, Inc., 393 Fed.Appx. 905, 909-10 (3d Cir. 2010) (noting the conflict between Phillips v. County of Allegheny, 515 F.3d 224, 236 (3d Cir. 2008) which held that "[i]f a complaint is vulnerable to 12(b)(6), a district court must permit a curative amendment, unless an amendment would be inequitable or futile[]" and the long standing rule that, to request leave to amend a complaint, the plaintiff must submit a draft amended complaint to the court so that it can determine whether amendment would be futile). Here, the conflict is not implicated because the Court is not permitting plaintiff to plead new claims, only permitting plaintiff to provide a clearer statement of her claims. See Island Green, LLC v. Querrard, 429 Fed.Appx. 90, 92-93 (3d Cir. 2011) (instructing that the district court should give plaintiff the opportunity to amend

F. New Jersey Product Liability Act

The Medtronic defendants also seek to dismiss plaintiff's PLA claims pursuant to Fed.R.Civ.P. 12(b)(6).

Under the New Jersey Product Liability Act (PLA),

> 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.

Three causes of action are established under the PLA, namely, claims for design defect, manufacturing defect, or warnings defect. Roberts v. Rich Foods, Inc., 139 N.J. 365, 375, 654 A.2d 1365 (N.J. 1995); Dziewiecki v. Bakula, 361 N.J.Super. 90, 97-98, 824 A.2d 241 (App.Div. 2003). The standard of liability is that the product "was not reasonably fit, suitable or safe for its intended purpose." Cornett v. Johnson & Johnson, 414 N.J.Super. 365, 998 A.2d 543 (App.Div.

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and re-plead specifically what wrongful conduct was committed and by whom). Plaintiff has requested leave to amend the complaint if her allegations concerning violations of Federal prove insufficient. See Pl. Opp. at 33 n. 8.

2010).

To prove a defect, a plaintiff must be able to show that: (1) the product was defective; (2) the defect existed when product left the hands of the defendant; and (3) the defect caused the injury to a reasonably foreseeable user.'" McGarvey v. G.I. Joe Septic Service, Inc., 293 N.J.Super. 129, 142, 679 A.2d 733 (App.Div. 1996)(citing Jurado v. Western Gear Works, 131 N.J. 375, 385, 619 A.2d 1312 (1993)). "To prove both the existence of a defect and that the defect existed while the product was in the control of the manufacturer, a plaintiff may resort to direct evidence, such as the testimony of an expert who has examined the product, or, in the absence of such evidence, to circumstantial proof." Myrlak v. Port Authority of New York and New Jersey, 157 N.J. 84, 723 A.2d 45, 52 (N.J. 1999) (citing Scanlon v. General Motors Corp., 65 N.J. 582, 591, 326 A.2d 673 (1974); Manieri v. Volkswagenwerk A.G., 151 N.J.Super. 422, 430-31, 376 A.2d 1317 (App.Div. 1977)). A plaintiff may also establish a defect by "negat[ing] other causes of the failure of the product for which the defendant would not be responsible, in order to make it reasonable to infer that a dangerous condition existed at the time the defendant had control [of the product]." Id. at 53 (citing Scanlon, 65 N.J. at 593-94).

Under New Jersey product liability law, “the injured plaintiff is not required to prove a specific manufacturer’s defect.” Id. at 52 (citing Moraca v. Ford Motor Co., 66 N.J. 454, 458, 332 A.2d 599 (1975)). “Proof that a product is not fit for its intended purposes ‘requires only proof ... that ‘something was wrong’ with the product.’” Id. (citing Scanlon, 65 N.J. at 591, 326 A.2d 673). However, the “mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect.” Id.

Plaintiff asserts manufacturing and design defect claims, as well as failure to warn claims against Medtronic. Plaintiff identifies the defective products as the Infuse bone graft material, Capstone spinal cage, various screws and other material as listed in the operative reports. Plaintiff also points to the operative reports which lists "hardware failure" as the diagnosis. Plaintiff has stated that a manufacturing defect caused overgrowth of bone graft material resulting in migration of the cages out of position described as "hardware failure" in the medical records; identified as a design defect the design of separate packaging for marketing and sale of the Infuse product without the other components of the "system" approved by the FDA; and has alleged that the Medtronic

defendants failed to include truthful and adequate warnings and instructions. Plaintiff does not allege that the FDA warnings are somehow inadequate on the Infuse itself, but that the conduct of the Medtronic defendants mitigated or nullified the warnings in their marketing and distribution scheme and created inadequate warnings. Plaintiff also states that the Medtronic sales representative may have removed or otherwise mitigated the warnings to encourage the surgeon to use the product in an ill-advised, contraindicated, and experimental way in plaintiff's surgery. Plaintiff further alleges that these defects were all significant causative factors in the harm that plaintiff sustained.

Although plaintiff jumbled together her analysis of all three theories of defect under the PLA, the standards of proof for each theory are not exactly the same and therefore, are addressed separately.

1. Design Defect

For a design defect, plaintiff must assert that the product could have been designed more safely and present under a risk-utility analysis the existence of an alternative design that is both practical and feasible. Lewis v. American Cyanamid Co., 715 A.2d 967, 980 (N.J. 1998). A plaintiff may pursue a

design defect claim by contending that its risk outweighs its harm, or that an alternate design exists. See Schraeder v. Demilec (USA) LLC, No. 12–cv–6074, 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013). Though there is no "per se rule that Plaintiffs must, under all circumstances, provide a reasonable alternative design," a plaintiff must plead either that the product's risk outweighs its harm, or that an alternate design exists, in order to state a claim for a design defect under the Product Liability–Act. Id.

Plaintiff has stated that the separate packaging of the Infuse Bone Graft product without the other components of the "system" approved by the FDA constituted a design defect. Presumably, plaintiff is suggesting that the alternative design would be to package the components together. Plaintiff has failed, however, to present a risk-utility analysis on the group packaging. Medtronic has stated that the Infuse Bone Graft is supplied in three kit sizes containing different amounts of rhBMP protein and that the LT-Cage Lumbar Tapered Fusion Device component is supplied in seven sizes which must be properly selected based on a specific patient's anatomy. The components are sold separately to allow physicians to select the

appropriate combination based on each patient's needs.[9]

Plaintiff has not presented any allegations to refute this. Thus, plaintiff has not sufficiently alleged a design defect claim under New Jersey law and this claim will be dismissed pursuant to Fed.R.Civ.P. 12(b)(6). Moreover, even if plaintiff properly plead the design defect claim, it would be preempted under federal law. The packaging of the components separately was approved by the FDA during the PMA process. Allowing a state law claim to proceed that would challenge the safety and effectiveness of the packaging would run afoul of the MDA's express preemption clause barring such claims brought against a medical device with PMA. See Reigel, 552 U.S. at 315.

2. Manufacturing Defect

To determine whether a product contains a manufacturing defect, the "product may be measured against the same product as manufactured according to the manufacturer's

9 In general, when ruling on a motion to dismiss pursuant to 12(b)(6), a court may only consider the contents of the pleadings. Pryor v. Nat'l Collegiate Athletic Ass'n, 288 F.3d 548, 560 (3d Cir. 2002) (quoting 62 Fed. Proc. L.Ed. § 62:508). However, "[d]ocuments that the defendant attaches to the motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to the claim...." Id. Here, the information regarding the device is from documents submitted for its PMA and, therefore, directly related to plaintiff's claim.

standards. Mickens v. Ford Motor Co., No. 10–cv–05842, 2011 WL 3444055, at *3 (D.N.J. 2011) (citing Navarro v. George Koch & Sons, Inc., 512 A.2d 507, 517 (N.J.Super. App. Div. 1986)). "If the particular product used by the plaintiff fails to conform to those standards or other units of the same kind, it is a manufacturing defect." Id. (internal marks omitted).

Plaintiff has stated that a manufacturing defect caused overgrowth of bone graft material resulting in migration of the cages out of position, that the defect was "hardware failure" in the medical records, and that she was injured as a result of the product failing.

Although rather sparse, plaintiff has pleaded the minimum needed to survive a 12(b)(6) challenge. By alleging that the medical records indicate that the device had a "hardware failure" this could suggest a plausible claim that the device as manufactured did not conform to standards of other units of the same kind.

Having determined that plaintiff plead a state law claim for manufacturing defect, it must be determined whether her claim is preempted by federal law. To the extent that the claim is a hardware failure because the device did not conform to the standards of other units, and also violated federal

regulations and procedures in manufacturing, then it would be parallel claim and would not be preempted. See Bass v. Stryker Corp., 669 F.3d 501, 515 (5th Cir. 2012) (finding that plaintiff's manufacturing defect claims could proceed because they were premised on violations of FDA regulations and therefore parallel claims that were not preempted); Williams v. Cyberonics, Inc., 654 F.Supp.2d 301, 306 (E.D.Pa. 2009) ("To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards."), aff'd 388 Fed.Appx. 169 (3d Cir. 2010). However, if the Infuse device was manufactured in compliance with its PMA, then any claim of manufacturing defect would not parallel a federal claim and would be preempted. See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1207 (8th Cir. 2010) (finding district court properly concluded manufacturing claim preempted because "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.").

Although plaintiff's claim of manufacturing defect may be enough to survive a 12(b)(6) challenge, in order to determine

whether the claim is preempted by federal law, additional facts must be alleged. It is not clear on the basis of plaintiff's complaint or opposition to the motion to dismiss the exact nature of plaintiff's manufacturing claim. Therefore, the claim will be dismissed without prejudice and plaintiff granted leave to amend her complaint. To avoid preemption, plaintiff must be able to demonstrate that her state law manufacturing defect claim is parallel to federal law with regard to any PMA approved device. With regard to other devices, plaintiff must allege that the device failed to conform to standards or other units of the same kind.

3. Failure to Warn

In 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 product can potentially cause injury.'" Clark v. Safety–Kleen Corp., 179 N.J. 318, 336, 845 A.2d 587 (2004) (quoting Coffman v. Keene Corp., 628 A.2d 710 (N.J. 1993)). The plaintiff must establish that the defendant had a duty to warn, and then establish that an adequate warning was not provided. James v. Bessemer Processing Co., 714 A.2d 898, 907 (N.J. 1998). Plaintiff must then prove the breach of duty (the absence of a warning) was a

proximate cause of the accident. Coffman, 628 A.2d at 716.

There is no question Medtronic had a duty to warn or that a warning was placed on the device. The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiff does not allege that Medtronic modified or failed to include FDA-approved warnings.

Rather, she alleges that defendants did not provide truthful and adequate warnings and instructions due to the conduct of the Medtronic defendants who mitigated or nullified the warnings in their marketing and distribution scheme, or in their encouragement to use the product separately. Plaintiff has alleged that the "nullification" of the warnings caused her injury in how the product was used during her surgery.

Given the early procedural posture of the case, this claim will be allowed to proceed. If defendants had physically removed the warning label from the device, then it would be clear that the warnings were no longer adequate since they would no longer be on the device. However, if the defendants by their actions nullified the warning, it could be plausible that the warning would have been inadequate as if it had been physically removed.

In addition, plaintiff's failure to warn claim is not

preempted. Plaintiff's theory is based on the idea that Medtronic's actions modified the warning label so that the prohibition against using the Infuse Bone Graft with any other component other than the LT-Cage was nullified. Plaintiff is not arguing that Medtronic should have given warnings that were different from or in addition to the warning provided. See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1205 (8th Cir. 2010) ("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."). Rather, plaintiff is arguing that Medtronic's actions resulted in the warning label being ignored. What is not clear, however, is whether plaintiff is asserting that Medtronic's actions is a failure to comply with FDA regulations. See Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011) ("To the extent that Hughes asserts a failure to warn claim based only on Boston Scientific's failure to comply with FDA regulations, however, such a claim is not expressly preempted.").

Thus, plaintiff's failure to warn claim will be dismissed without prejudice. Plaintiff must clearly state the federal regulation that parallels her state law claim.

G. Third Party Beneficiary

The Federal government and Medtronic (formerly known as Kyphon, Inc.) entered into a "Corporate Integrity Agreement" (CIA) to "promote Kyphon's compliance with … Medicare, Medicaid, and all other Federal health care programs." This agreement was entered into, along with a settlement agreement, to resolve a lawsuit brought against Medtronic based on the Federal government's investigation of Medtronic's submission of false claims to Medicare. Plaintiff asserts that as a Medicare beneficiary, she is also a third party beneficiary to the CIA.

Under New Jersey law, plaintiff lacks standing to be a third party beneficiary to the CIA. See Rieder Communities, Inc. v. Township of North Brunswick, 546 A.2d 563, 567 (N.J.Super.A.D. 1988). "The essence of contract liability to a third party is that the contract be made for the benefit of said third party within the intent and contemplation of the contracting parties." Id. (quoting Gold Mills, Inc. v. Orbit Processing Corp., 121 N.J.Super. 370, 373, 297 A.2d 203 (Law Div. 1972)). "Unless such a conclusion can be derived from the

contract or surrounding facts, a third party has no right of action under that contract despite the fact that he may derive an incidental benefit from its performance." Id. Rather, plaintiff is an "incidental beneficiary." See id.

Plaintiff failed to demonstrate that the parties to the CIA intended Medicare beneficiaries to also be beneficiaries of the contract, or that they intended Medicare beneficiaries to enforce such a benefit in a court of law. A review of the CIA shows that it was meant to provide terms within which Medtronic must comply, including reporting and training, and terms for breach of any of the terms of the agreement by Medtronic. There is no indication that the parties contemplated, much less intended, that third parties be granted a right of action under the CIA. Therefore, plaintiff's claim as a third party beneficiary will be dismissed.

H. Fraud and Misrepresentation

Plaintiff alleges, in the alternative, that Medtronic engaged in a false and misleading campaign for advertising, marketing and promoting the use of Infuse. Plaintiff states that her claims are separate from any issue of product defect and are based entirely upon the improper course of conduct by Medtronic. Specifically, plaintiff alleges:

- Defendants made material misrepresentations of past and presently existing facts including but not limited to: misrepresenting the use of InFuse® as safe and effective when it was not; misrepresenting the causation of side effects when InFuse® was used in spinal surgeries (whether used in FDA approved ways or not); misrepresenting its financial arrangements including but not limited to contracts with researchers, paid consultants, recipients of royalties, sham study payments, promotional payments to surgeons and facilities; and other misrepresentations.

- Defendants knew and believed that such misrepresentations were false because it had actual and/or constructive knowledge of the side effects at the very highest levels of management and (i) designed and conducted the nationwide and global advertising campaign of falsified data and studies as a means to satisfy its greed and profit motive with skyrocketing sales of InFuse® and (ii) "agreed" in a Corporate Integrity Agreement entered into in July 2008 for a period of five years as part of its settlement with DOJ to implement a monitoring program of payments to physicians and surgeons and other parts of its marketing campaign and (iii) continues to this day to downplay, minimize, and deny the catastrophic side effects of InFuse® in spinal surgeries despite growing reports and disclosures of adverse events which Medtronic paid handsomely to suppress from the first trials forward.

- Defendants specifically intended that surgeons and the medical community generally would rely on their misrepresentations so that their sales of InFuse would increase, as they did—sometimes to the extent of becoming highly paid Medtronic consultants or "opinion leaders" who would then convince other surgeons to recommend and use InFuse®.

- Defendants specifically intended that patients rely on the misrepresentations of Medtronic delivered by and through their physicians and the coercive influence of sales representatives in the operating rooms, including the operating rooms in which Plaintiff was surgically implanted with InFuse and other Medtronic products.

- Such reliance on Medtronic's misrepresentations and fraudulent statements was justifiable in the case of this Plaintiff because she trusted her doctor and had absolutely no knowledge of the truth about the surgical products used in her and, whether her doctor was complicit in this scheme or not, he failed to advise her of what was going on, even concerning the revelations in various journal articles and news sources disclosing the falsification of studies and data by Medtronic agents, servants and employees, or even the presence of a Medtronic salesman in the OR, or the fact that her surgeries would be an off-label, experimental use of InFuse and the other products.

- Even now, on Medtronic's website, they misrepresent the findings of the Yale study and have posted a false and misleading video to "spin" the true results by CEO Omar Ishrak in order to continue to perpetrate the fraud against the public, the medical community, patients, and the government.

Although plaintiff stresses the representations made by Medtronic, ultimately, the essence of her claim is that the misrepresentations resulted in physical harm from the product. See Schraeder v. Demilec (USA) LLC, 12-6074, 2013 WL 3654093, at *4 (D.N.J. 2013) (dismissing CFA claim as subsumed under PLA and concluding that while plaintiffs allege that Demilec promoted the SPF as "green" and non-toxic, the essence of plaintiffs' real claim sounds in products liability; "it asserts that Demilec failed to warn of the potential health issues that could occur if their product was not mixed correctly, which resulted in harm from the product."); Sinclair v. Merck & Co., Inc., 195 N.J. 51, 66, 948 A.2d 587 (2008) (finding that the PLA subsumed

plaintiffs' CFA claim because “the heart of plaintiffs' case is the potential for harm caused by [defendants'] drug.”).

In Indian Brand Farms v. Novartis Crop Protection, Inc., 890 F.Supp.2d 534, 547 (D.N.J. 2012), this Court was faced with a similar theory and determined that the essential nature of plaintiffs’ case was that of a traditional product liability action and therefore, found that plaintiffs' common law misrepresentation claim and statutory claim under the CFA were subsumed by the PLA. Id. (finding that although plaintiffs clearly alleged that Novartis misrepresented that product controlled certain insects without inflicting adverse effects on plants or soil, and that plaintiffs relied on these misrepresentations, the heart of plaintiffs' dissatisfaction is that the product itself caused harm to the blueberry plants).

The Court understands that plaintiff is trying to navigate her tort claims through the barriers of Federal preemption and the absorption of common law tort claims by the PLA. However, re-packaging her basic argument to argue in the alternative that Medtronic’s promotion of off-label use of Infuse, without the LT-Cage, in a posterior approach procedure, at two levels in the spine is a “conduct” claim rather than a “product” claim will not work. See Sinclair, 195 N.J. at 66

(the "language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product").

Thus, plaintiff's fraud and misrepresentation claim against Medtronic shall be dismissed as subsumed under the PLA.[10]

10 Plaintiff attempts to come under an exception to the PLA which permits a CFA claim to stand alone if the harm alleged was to the product itself. This is not applicable here since plaintiff is not alleging harm to the Infuse product itself, but rather the harm is to her physically. The PLA defines the term "product liability action" as "any claim or action ... 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. Stat. Ann. § 2A:58C–1(b)(3). Claims for "physical damage ... to the product itself" are not "product liability action[s]" because the PLA specifically excludes such damage from its definition of "harm." Estate of Edward W. Knoster v. Ford Motor Co., 200 Fed.Appx. 106, 115-16 (3d Cir. 2006) (citing N.J. Stat. Ann. § 58C–1(b)(2),(3); Alloway v. General Marine Ins. L.P., 149 N.J. 620, 695 A.2d 264 (1997)). In Knoster, the Third Circuit concluded that plaintiffs' consumer fraud claim was not subsumed by the PLA because they were seeking only to recover harm to the product, a car, itself. Id. at 116 ("The PLA cannot subsume that which it explicitly excludes from its coverage."). However, in cases where the plaintiff is seeking to recover for physical injuries caused by a defective product, such a fraud claim is subsumed by the PLA. See Rossi v. Innovation Ventures, LLC, No. 13-1870, 2014 WL 1315656, at *5 (D.N.J. 2014) (where the factual allegations in support of consumer fraud claim relate to a physical injury caused by the alleged defective product, the PLA subsumes plaintiff's cause of action under the Consumer Fraud Act).

I. Punitive Damages

The PLA provides that:

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

N.J.S.A. 2A:58C–5c.

Plaintiff has argued that Medtronic's off-label promotion was not approved by the FDA, and resulted in a "nullification" of the FDA approved labeling of the device. Such allegations would come under the exception to the PLA where the product manufacturer knowingly withheld or misrepresented information to the FDA.

A determination that plaintiff's request for punitive damages comes under an exception to the PLA does not end the inquiry. The next question is whether punitive damages are

impliedly preempted under Buckman. In Buckman, plaintiff alleged that the defendant made fraudulent representations to the FDA "in the course of obtaining approval to market the screws." 531 U.S. at 344. The defendant sought § 510(k) approval[11] for its bone screw device, indicating it for use in spinal surgery. Id. at 346. In its third application to the FDA, defendant "sought clearance to market the plates and screws for use in the long bones of the arms and legs" rather than seeking clearance for spinal applications. Id. The Supreme Court found that plaintiffs' state-law fraud-on-the-FDA claims conflicted with federal law. Id. at 348. "The conflict stems

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> An exception to the PMA requirement exists for devices that were already on the market prior to the MDA's enactment in 1976. See 21 U.S.C. § 360e(b)(1)(A). The MDA allows these "predicate" devices to remain available until the FDA initiates and completes the PMA process. In order to avoid the potentially monopolistic consequences of this predicate-device exception, the MDA allows other manufacturers to distribute (also pending completion of the predicate device's PMA review) devices that are shown to be "substantially equivalent" to a predicate device. § 360e(b)(1)(B).
>
> Demonstrating that a device qualifies for this exception is known as the "§ 510(k) process," which refers to the section of the original MDA containing this provision.

Buckman, 531 U.S. at 345.

from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." Id.[12]

Therefore, the issue in Buckman is slightly different than the issue here. In Buckman, the Supreme Court found that plaintiff's claims that defendant committed fraud on the FDA during the § 510(k) process was impliedly preempted. Here, the issue is whether plaintiff's claims that Medtronic is committing fraud, after the PMA process, permits plaintiff to seek punitive damages. While it is clear that any claim of fraud during the §510(k) process, or the more demanding PMA process, would be preempted, it is not clear whether the holding in Buckman would extend to fraud committed after the PMA process concluded.

Here, plaintiff alleges that Medtronic engaged in off-label marketing. The Supreme Court in Buckman states that "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the

12 The Court notes that the FDA has enforcement authority under the Federal Food, Drug and Cosmetic Act (FDCA). It can seek injunctive relief, 21 U.S.C. § 332, civil penalties, 21 U.S.C. § 333(f)(1)(A), seizing the device, 21 U.S.C. § 334(a)(2)(D), and criminal prosecution, 21 U.S.C. § 333(a). The FDCA does not permit a private right of action.

FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." Id. at 350. However, as previously noted, this statement only refers to off-label *usage*, not off-label *marketing*. Also, the Supreme Court clarified their intent by citing to 21 U.S.C. § 396 (1994 ed., Supp. V), which states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.". The Supreme Court cited to a statement regarding a health care practitioner's authority to engage in off label uses, not a drug company's.

Therefore there is nothing in Buckman that would clearly preempt a plaintiff seeking punitive damages for off-label marketing by a drug company after the PMA process has concluded. Nonetheless, it is important to review the policy underlying the preemption for "fraud-on-FDA" claims to determine whether Buckman should be extended in this case. In Buckman, the Supreme Court determined that if plaintiffs were to maintain their fraud-on-the-agency claims, "they would not be relying on

traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." Id. at 353. In other words, "but for petitioner's fraud, the allegedly defective orthopedic bone screws would not have reached the market." Id.

After the approval process, and after the device has reached the market, the causation element is that but for defendant's off label marketing, the medical device would not have been used in the manner contrary to the FDA approved labeling on the device. In their concurrence, Justices Stevens and Thomas noted that in Buckman, the "fact that the Food and Drug Administration (FDA) has done nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, convinces me that this essential element of the claim cannot be proved." The concurring opinion was concerned with the idea that a plaintiff should not "second guess" the FDA, and concluded that if the FDA had determined that fraud occurred during the approval process and required removal of the product from the market, then "state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme."

Thus, the underlying inquiry is whether allowing plaintiff to assert a claim would impinge upon the authority of the FDA to regulate medical devices. In McDarby v. Merck & Co., Inc., 949 A.2d 223, 275 (N.J.Super.A.D. 2008), the New Jersey appellate court concluded that the PLA's provision excluding claims for fraud "is designed to effectuate the State's interest in punishing unlawful conduct." The court determined that "a plaintiff bringing a product liability action acts in a fashion akin to a private attorney general, since any damages awarded on his punitive damage claim do not compensate him for his injury, but instead vindicate societal interests." Id. (citations omitted). The court found a distinction between a plaintiff seeking compensatory damages, and a plaintiff seeking punitive damages in which the latter "is narrowly drawn upon a defendant's act of knowingly withholding from or misrepresenting to the FDA information material to the harm alleged." Id. ("Although there are differences between the fraud-on-the-FDA claim asserted in Buckman and McDarby's punitive damage claim premised on the withholding of information regarding the incidence of myocardial infarctions demonstrated by a meta-analysis, we find the single focus upon fraud on the FDA in each to be sufficiently similar to warrant the application of Buckman

to this case.").

Based on a review of the Supreme Court's policy suspending the presumption against preemption in fraud-on-the-FDA claims, and the New Jersey courts' interpretation of their PLA statute regarding punitive claims as a vindication of societal interests, it appears that plaintiff's punitive damages claim is impliedly preempted. Whether Medtronic misrepresented to the FDA its use of the Infuse device, or whether its off label marketing actions rendered the FDA approved label a nullity, the imposition of punitive damages would act as a punishment against Medtronic. Any punishment or policing of Medtronic would fall within the purview of the FDA and encroach upon "the federal statutory scheme [to] empower[] the FDA to punish and deter fraud against the Administration... ." Buckman 531 U.S. at 348. In other words, the policing power of the FDA does not stop after a device is approved, but rather the relationship between the FDA and those subject to its regulations continues so that any behavior contrary to what was specifically approved by the FDA is subject to FDA authority. Indeed, the PMA for the Infuse/LT-Cage device required Medtronic to perform post-approval studies and provide post-approval reports. A punitive damages claim would permit plaintiff to

potentially encroach upon duties of the FDA and, therefore, plaintiff's punitive damages claim as to the Infuse device is preempted.

With regard to the other devices, the Court will permit plaintiff to amend her allegations so that it is clear what allegations pertain to the other devices that would give rise to malice or willful disregard in support of a punitive damages claim, while deleting any allegations specific to the Infuse/LT-Cage device.

IV. CONCLUSION

Medtronic's motion to dismiss shall be granted in part and denied in part. Count V (implied warranty), Count VI (design defect), Count X (third party beneficiary), and Count XII (fraud) will be dismissed. Plaintiff's request for punitive damages will be denied as to any Medtronic device that received premarket approval. Count VII (express warranty), and Count VI (manufacturing defect and failure to warn) will be dismissed without prejudice and plaintiff will be granted leave to file an amended complaint to provide a more definite statement of her claims.

An appropriate order will be entered.

s/Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

At Camden, New Jersey

Dated: June 27, 2014