UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

DENISE SIMONEAU,	:	
Plaintiff,	:	CIVIL ACTION NO.
	:	3:13-CV-1200 (JCH)
v.	:	
	:	
STRYKER CORP. et al.,	:	MARCH 31, 2014
Defendants.	:	

RULING RE: STRYKER CORPORATION AND HOWMEDICA OSTEONICS CORPORATION'S MOTION TO DISMISS (Doc. Nos. 14 & 15)[1]

I. INTRODUCTION

Plaintiff Denise Simoneau brings this action in connection with components of the "Trident Acetabular System" ("Trident Hip Implant") used in a total left hip replacement surgery that she underwent in December 2003. The Complaint (Doc. No. 1) alleges two counts against Stryker Corporation and Howmedica Osteonics Corporation (collectively, the "Stryker defendants").[2] Count One alleges violations of the Connecticut Product Liability Act ("CPLA"), Conn. Gen. Stat. § 52-572m et seq. Count Two alleges negligence in the design, production, manufacture, marketing, sale, and/or distribution of the Trident Hip Implant and its components.[3] The Stryker defendants move to dismiss both counts for failure to state a claim, arguing, inter alia, that Simoneau's state

[1] Albeit docketed as two separate motions, the instant Motion is a single motion filed jointly by two defendants, and the court treats it as such, referring to the Motion in the singular throughout this Ruling.

[2] Count Three alleges a claim against Windham Community Memorial Hospital ("Windham"), who is not a party to this Motion to Dismiss. Windham filed a separate Motion to Dismiss (Doc. No. 16), which the court has addressed in a separate Ruling.

[3] Although Simoneau's Complaint alleges two counts against the Stryker defendants, "[t]he CPLA creates a consolidated cause of action for all product liability claims." Lamontagne v. E.I. Du Pont de Nemours & Co., Inc., 834 F. Supp. 576, 587 (D. Conn. 1993), aff'd, 41 F.3d 846 (2d Cir. 1994). Because "an action alleging harm from a product due to negligence . . . may not be pleaded as a separate common law claim but may only be asserted as a part of the CPLA," id., the court reads the Complaint as alleging several theories of products liability within one CPLA claim against the Stryker defendants.

law claims are preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 360c et seq.

For the reasons stated below, the Stryker defendants' Motion to Dismiss (Doc. Nos. 14 & 15) is **GRANTED in part and DENIED in part**.

II. BACKGROUND

A. Simoneau's Surgical Procedures

Simoneau underwent a left total hip arthroplasty in December 2003. Compl. (Doc. No. 1), Count One ¶ 6. During that procedure, she received components of the Trident Hip Implant designed, manufactured, and marketed by the Stryker defendants. Id. In August 2011, Simoneau began experiencing pain in her left hip and was advised that she had developed a hematoma. Id. ¶ 20. In September 2011 and October 2012, respectively, she underwent two hip aspirations, see id., Count Three ¶ 6, which revealed infection and metallosis from metal debris in and around her left hip, id., Count One ¶ 20. As a result of continuing pain, in November 2012, Simoneau underwent a "complete revision Left Total Hip Arthoplasty, which involved completely replacing the liner of her original Left Hip Implant with a polyethylene liner and the head of her original Left Hip Implant with a Cobalt chrome head." Id. ¶ 21.

B. Regulatory Framework

The FDCA has long required approval by the U.S. Food and Drug Administration ("FDA") of new drugs prior to their introduction into the market. Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). Until Congress enacted the MDA, however, oversight of the introduction of new medical devices was left largely to the states. Id. The development of medical devices using new technology—such as "kidney dialysis units, artificial heart valves, and heart pacemakers"—prompted concern among policymakers

and the public "about the increasingly severe injuries that resulted from the failure of such devices." Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-76 (1996). In response, Congress enacted the MDA, "which swept back some state obligations and imposed a regime of detailed federal oversight.'' Riegel, 552 U.S. at 316.

The MDA classifies medical devices into three categories based upon the "risks they present." Id. Medical devices in Class III receive the greatest federal oversight. Id. at 317. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented 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,' or 'presents a potential unreasonable risk of illness or injury.'" Id. (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). The product at issue in this case is a Class III medical device. See Compl., Count One, ¶ 3.

A new Class III device must undergo a rigorous premarket approval ("PMA") process, unless "the FDA finds it is 'substantially equivalent' to another device exempt from premarket approval." Riegel, 552 U.S. at 317 (quoting 21 U.S.C. § 360c(f)(1)(A)). The FDA also reviews the medical device's proposed label to establish that it is "neither false nor misleading." Id. at 318 (citing 21 U.S.C. § 360e(d)(1)(A)). Most new Class III devices enter the market through the FDA's less stringent review of "substantial equivalence" known as the section 510(k) process. Id. at 317. Only a small percentage of new Class III devices (roughly 1% in 2005) are approved annually by the FDA through the PMA process. Id.

Once the FDA has approved a medical device for sale under the PMA process, the MDA prohibits the manufacturer from making "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without filing a supplementary premarket approval application and obtaining permission from the FDA to make such changes. Id. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)); 21 C.F.R. § 814.39(a). Furthermore, following approval, the manufacturer must report to the FDA any adverse results it has become aware of in patients using the medical device. Id. (citing 21 U.S.C. § 360i). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Id. at 319-20 (citing 21 U.S.C. §§ 360e(e)(1); 360h(e)).

Medical device manufacturers in general must comply with the FDA's current good manufacturing practice requirements ("CGMPs"), which set forth a "quality system regulation" and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). The CGMPs serve "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." Id. "They do not specifically address the design, production and marketing requirements for each and every type of medical device. The CGMP requirements, therefore, leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and

effective." Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009) (citation omitted).

C. History of the Trident Hip Implant

1. FDA Approval

The FDA approved the Trident Hip Implant for sale in the United States in February 2003. Compl., Count One ¶ 3. The parties agree that the Trident Hip Implant received FDA approval pursuant to the PMA process and is classified as a Class III medical device. Id. ¶ 3. Simoneau alleges that the Stryker defendants modified the Trident Hip Implant subsequent to the FDA's initial approval and obtained FDA approval of these modifications pursuant to section 510(k) submissions. Id. ¶ 4.

2. FDA Warning Letters

In 2007, the FDA issued two warning letters to the Stryker defendants regarding certain of their facilities. Id., Count One ¶ 12. After inspecting these facilities, the FDA concluded that the Stryker defendants' Trident Hip Implant components were "adulterated" as defined in 21 U.S.C. § 351(h). Id.

3. Stryker Defendants' Voluntary Recalls

The Stryker defendants initiated several recalls relating to the Trident Hip Implant. Id. ¶¶ 13-16. In June 2008, they recalled the "Trident Hemispherical Acetabular Cluster Shells." Id. ¶ 13. Simoneau alleges that this recall stemmed from an investigation revealing the existence of "manufacturing residuals" and included the specific Acetabular Shell implanted into her in 2003. Id. In August 2009, the Stryker defendants recalled the "Trident Acetabular System Surgical Protocol instructions for use of hip prosthesis, Literature Number LSP55." Id. ¶ 14. They then issued new surgical protocol instructions creating "separate and distinct surgical protocols, one for

the Trident PSL Shell and one for the Trident Hemispherical Shell," to clarify "the differences in reaming technique required depending on the type of shell used." Id. In September 2009, the Stryker defendants recalled the "Stryker Cancellous Bone Screw" due to non-compliance with certain metallurgical standards. Id. ¶ 15. Simoneau alleges that such bone screws had been implanted into her in 2003. Id.

All three recalls were classified by the FDA under federal regulation—the June 2008 and August 2009 recalls as Class II recalls, the September 2009 as a Class III recall. Id. ¶ 13-15. Simoneau was never advised of any of these recalls. Id.

III. STANDARD OF REVIEW

A case is properly dismissed under Rule 12(b)(6) if the complaint fails to allege facts sufficient "to state a claim for relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 547 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678, (2009). As articulated by the Supreme Court in Iqbal and Twombly, the standard for dismissal on a Rule 12(b)(6) motion reflects two working principles. See Pension Ben. Guar. Corp. ex rel. St. Vincent Catholic Med. Centers Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc., 712 F.3d 705, 717 (2d Cir. 2013). First, the court's customary acceptance of all allegations in a complaint does not apply to legal conclusions. Iqbal, 556 U.S. at 678. Hence, to survive a motion to dismiss, a complaint must provide more than "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." Id. Second, assuming the truth of all well-pleaded factual allegations, and drawing all reasonable inferences in the plaintiff's favor, the court must determine whether these allegations and inferences plausibly entitle the plaintiff to

relief—that is, whether the complaint shows "more than a sheer possibility that a defendant has acted unlawfully." Id. This second task is context-specific and "requires the reviewing court to draw on its judicial experience and common sense." Id. at 679.

The plausibility standard does not impose an across-the-board, heightened fact pleading standard. Boykin v. KeyCorp, 521 F .3d 202, 213 (2d Cir. 2008). Rather, the standard is "flexible," obliging the plaintiff "to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim plausible." Id. (citation omitted); accord Arista Records, LLC v. Doe 3, 604 F.3d 110, 119 (2d Cir. 2010).

IV. DISCUSSION

The Stryker defendants argue that the MDA preempts all claims against them in the Complaint and that, in addition or in the alternative, Simoneau has not plausibly pled breach of express warranty. Having reviewed the Complaint, the parties' submissions, and the expansive and conflicting case law in this area, the court holds that Simoneau's CPLA claim is not preempted under theories of strict liability, negligence, and breach of implied warranties to the extent that these theories are premised on a violation of federal requirements. All other theories of Connecticut products liability are dismissed as preempted—with the exception of express breach of warranty, which is dismissed for failure to state a claim, independent of the preemption issue.

A. Scope of Federal Preemption Under the MDA

The MDA includes an express preemption provision:

> [N]o 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.

21 U.S.C. § 360k(a).[4]

In Riegel, the Supreme Court held that the "requirement[s]" covered by section 360k(a) include common law products liability claims. 552 U.S. at 323-25 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect."). The Riegel Court noted, however, that section 360k does not prohibit states "from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330 (quoting Lohr, 518 U.S. at 495). While the MDA does not create a private right of action for a violation of the federal requirements applicable to a medical device, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001),[5] neither does it preempt state tort claims that do not differ from or add to such requirements, Riegel, 552 U.S. at 330.

B. Application to Simoneau's State Claims

Riegel dictates a two-step inquiry in determining whether a state claim is preempted by the MDA pursuant to section 360k(a). Id. at 321-322. First, the court

[4] While section 360k excepts certain state requirements from being preempted by the MDA, see 21 U.S.C. § 360k(b), Simoneau does not assert any such exception here.

[5] In Buckman, the Supreme Court held that state "fraud on the FDA" claims are impliedly preempted because such claims conflict with the FDCA scheme. 531 U.S. at 348. Central to the Court's reasoning in that case was the fact that policing fraud against federal agencies is not a field traditionally occupied by the states, such that the presumption against preemption rooted in federalism concerns does not apply. Id. at 347-48. Although the Stryker defendants have pressed implied preemption, in the court's view, Buckman is wholly inapposite to this case. Simoneau is not seeking merely or even primarily to enforce FDA requirements but, rather, to secure relief for her injury by recourse to traditional state tort law. Indeed, her claims are the very type distinguished by Buckman and with respect to which the presumption against implied preemption is strongest due to "the historic primacy of state regulation of matters of health and safety." Id. at 348, 352-53 (citation and internal quotation marks omitted).

must find that the federal government has imposed requirements on the medical device at issue. Id. at 321. If so, then the court must determine whether the plaintiff's claims are based on state requirements that are "'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." Id. at 321-22 (quoting 21 U.S.C. § 360k(a)). Because there is no question either that the Trident Hip Implant is a Class III medical device approved by the FDA through the PMA process, or that Simoneau's state claims relate to safety and effectiveness, preemption in this case turns on whether the state claims are "parallel"—that is, whether they are premised on violations of federal requirements applicable to this device, and neither differ from nor add to such requirements.

All of Simoneau's state claims are governed by the CPLA, which provides the exclusive vehicle in this state for actions premised on "harm caused by a product." Conn. Gen. Stat. § 52-572n(a); see also Winslow v. Lewis-Shepard, Inc., 212 Conn. 462, 471 (1989) ("The legislature clearly intended to make our products liability act an exclusive remedy for claims falling within its scope."). While all products liability claims have thus been consolidated into "a single form of action," LaMontagne v. E.I. Du Pont De Nemours & Co., Inc., 41 F.3d 846, 855 (2d Cir. 1994), the CPLA permits a plaintiff to assert various common law theories of liability, Rosenthal v. Ford Motor Co., Inc., 462 F. Supp. 2d 296, 307 n.11 (D. Conn. 2006). See also Conn. Gen. Stat. § 52-572m(b) ("'Product liability claim' shall include, but is not limited to, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent.").

As the court has already observed, see supra note 3, despite Simoneau's having separately pled two counts against the Stryker defendants, her Complaint presents a single CPLA cause of action premised on multiple theories within each count. Liberally construed, the Complaint asserts the following four theories altogether: (1) strict liability; (2) negligence; (3) breach of the implied warranties of merchantability and fitness for a particular purpose; and (4) breach of express warranty. See Compl., Count One ¶¶ 26-29; id., Count Two ¶¶ 26-29.

Taking all factual allegations in the Complaint as true, and drawing all reasonable inferences in Simoneau's favor, the court finds that the Complaint pleads a plausible parallel CPLA claim under some, but not all, of these theories. Specifically, a CPLA claim under strict liability, negligence, and breach of implied warranties is not preempted to the extent that these pertain to manufacturing defects and are premised on a violation of federal requirements. All other theories are preempted—except breach of express warranty, under which Simoneau has failed to state a claim, parallel or otherwise.

1. Strict Liability

To recover on a theory of strict liability under the CPLA, Simoneau must prove, inter alia, that the Trident Hip Implant was in a defective condition unreasonably dangerous to her and that this defect caused the injury for which she seeks damages. D'Ascanio v. Toyota Indus. Corp., 309 Conn. 663, 674 (2013); Izzarelli v. R.J. Reynolds Tobacco Co., 731 F.3d 164, 167 (2d Cir. 2013) (applying strict liability doctrine in CPLA action). "A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." Vitanza v. Upjohn Co., 257 Conn. 365, 373 (2001). Simoneau has alleged all three types of defect, but

only her CPLA claim based on strict liability for defective manufacturing is not preempted by the MDA.

a. Manufacturing Defect

Simoneau alleges, in pertinent part, that the Stryker defendants' manufacture of the Trident Hip Implant did not meet FDA regulations and PMA specifications, Compl., Count One ¶¶ 25(b), 26(e); that this device was in an unreasonably dangerous and defective condition as a result, id. ¶ 25; and that its defective condition was the actual and proximate cause of her injury, id. ¶ 24.

In particular, Simoneau alleges that, in 2007, the FDA issued two warning letters relating to the Stryker defendants' facilities and that the resulting FDA investigation revealed components of the Trident Hip Implant to be "adulterated" as defined by federal law. Id. ¶ 12. A device is deemed "adulterated" if, inter alia, "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable [CGMPs]." 21 U.S.C. § 351(h).

Simoneau further alleges that two recalls by the Stryker defendants—one in June 2008, the other in September 2009—directly relate to the manufacture of the Trident Hip Implant she received in 2003. Compl., Count One ¶¶ 13, 15. The June 2008 and September 2009 recalls were allegedly intended to address, respectively, foreign material that exceeded internal acceptance criteria for manufacturing residuals in the Acetabular Shell, id. ¶ 13, and non-compliance with metallurgical standards applicable to cancellous bone screws, id. ¶ 15.

On the court's liberal reading of the Complaint, such factual allegations, together with all reasonable inferences drawn from them, suffice to state a parallel CPLA claim. Indeed, the Stryker defendants do not explain how a strict liability theory of defective

manufacturing imposes duties different from or additional to the federal ones. Rather, they argue that Simoneau's allegations lack the requisite specificity to be parallel, because they do not rest on any PMA specification referring to the Trident Hip Implant itself and rely instead on broad swaths of the Code of Federal Regulations and generalized CGMPs applicable to all devices and device manufacturers. See Stryker Defs.' Mem. in Supp. of Mot. to Dismiss ("Stryker Defs.' Mem.") (Doc. No. 15-1) at 15-19; Stryker Defs.' Reply (Doc. No. 57) at 4-6.

While Simoneau's Complaint doubtless would benefit from the type of specificity suggested by the Stryker defendants, the court rejects the need for medical device-related CPLA claims to be pled with that level of detail in order to defeat a Rule 12(b)(6) motion. In so doing, the court is mindful that "much of the critical information," including PMA specifications for a particular device, "is kept confidential as a matter of federal law" and will, therefore, be unavailable to a plaintiff without discovery. Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010) (citing 21 C.F.R. § 814.9).[6]

To evade preemption, Simoneau's CPLA claim need only be plausibly premised on a violation of "any requirement" applicable to the Trident Hip Implant under the FDCA. 21 U.S.C. § 360k(a)(1); see Riegel, 552 U.S. at 330. The predicate violation of

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[6] With respect to the appropriate pleading standard, the court finds the Seventh Circuit's reasoning in Bausch persuasive and faithful to the Supreme Court's direction to lower courts to make "context-specific" determinations rooted in "judicial experience and common sense." Iqbal, 556 U.S. at 679. The court notes, however, that the issue is scarcely settled and that, in the absence of direction from the Second Circuit, district courts have not uniformly agreed on the level of specificity required to meet the plausibility standard articulated in Iqbal and Twombly. See, e.g., Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (requiring "a particular federal specification referring to the device"); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) (requiring plaintiff to show link between specific federal violation and plaintiff's injury); Gelber v. Stryker Corp., 788 F. Supp. 2d 145, 157 (S.D.N.Y. 2011) (rejecting heightened pleading requirement).

In this court's opinion, to adopt the Stryker defendants' view of what must be pled to survive a Rule 12(b)(6) motion would, in effect, be to heighten the pleading standard for medical device torts—a path that the court declines to follow for the reasons set forth in Bausch. 630 F.3d at 558-61.

a federal requirement has been sufficiently pled in the instant case in two ways: by reference to violations of the CGMPs and by the Stryker defendants' two recalls in June 2008 and September 2009.[7]

i. CGMPs. In the court's view, Simoneau's reliance on generally applicable CGMPs is permissible at this stage and suffices to state a parallel CPLA claim based on strict liability for a manufacturing defect alleged to have personally injured her. The Second Circuit, however, has not yet spoken to the issue of plaintiffs' reliance on CGMPs, which impose general requirements applicable to all medical devices and device manufacturers rather than device-specific requirements like those found in PMA documents. Courts are split on this issue, see Bausch,630 F.3d at 554, including in this Circuit, compare Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (disallowing reliance on CGMPs), and Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (same), with Gelber v. Stryker Corp., 788 F. Supp. 2d 145, 159 (S.D.N.Y. 2011) (permitting reliance on CGMPs).

The court agrees with the reasoning in Gelber and Bausch that there is no "sound legal basis" for limiting the phrase "any requirement" in section 360k to device-specific requirements contained in PMA documents. Bausch, 630 F.3d at 555. Such a limitation "would leave injured patients without any remedy for a wide range of harmful violations of federal law." Id. Even assuming a plaintiff may recover only for claims premised on a violation of device-specific requirements (a conclusion with which the

[7] The predicate violation might also have been pled in a third way: by the two FDA warning letters and related investigation in 2007. Simoneau fails, however, to connect these to the specific Trident Hip Implant she received in 2003—for example, by alleging that the investigation was of the particular facilities where her device was manufactured. Absent some such connection, the alleged FDA warning letters and investigation do not plausibly state a parallel CPLA claim. Horowitz, 613 F. Supp. 2d at 282 (rejecting reliance on warning letters that lack "such a tie").

court disagrees), policing that limitation at the pleadings stage would work especial hardship for plaintiffs in this context, who, prior to discovery, have access to generally applicable CGMPs, but not to confidential PMA specifications. Id. at 560.

As emphasized in Gelber, the CGMPs govern manufacturing controls and methods for "all finished devices intended for human use," including devices approved through the PMA process. 788 F. Supp. 2d at 158 (quoting 21 C.F.R. § 820.1(a)(1)). The concern that CGMPs are too generic to be enforced by juries is also mitigated, if not obviated, by the fact that "the meaning of the FDA's requirements will present questions of law for the court to decide, not questions of fact for a jury." Bausch, 630 F.3d at 556. Such "questions of federal law [are] subject to the usual process for reconciling conflicting views." Id.

The Fifth Circuit, which has followed the Seventh in permitting reliance on CGMPs, has indicated a further reason that this concern about jury enforcement may well be misplaced in trials of Class III medical devices such as the Trident Hip Implant:

> [B]y the time the case is tried, the jury will have before it the PMA application that was approved by the FDA. To the extent a plaintiff can show that the FDA-approved processes and procedures were not followed, and that the injury was caused by this deviation, the plaintiff's claim will be parallel. However, if the plaintiff challenges the suitability of the precise processes or procedures chosen by the maker, and approved by the FDA, to achieve the broader regulatory goals, such a claim could not proceed.

Bass v. Stryker Corp., 669 F.3d 501, 512 (5th Cir. 2012). In the face of disagreement among courts as to which complaints are sufficient to withstand a motion to dismiss, the Bass decision advises that the dispositive factor "is not [a plaintiff's] reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal

regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." Id. 511-12.

While Simoneau did not allege a violation of any particular CGMP in the Complaint, her citation to the CGMPs generally, taken together with her pleading as to the specific conduct which violated these requirements and her description of evidence such as FDA-classified recalls, gives the Stryker defendants "more than ample notice of the alleged violation of federal law." Gelber, 788 F. Supp. 2d at 156 (finding this combination sufficient on similar facts). Indeed, one CGMP in particular—the requirement "to ensure that [manufacturing material which could reasonably be expected to have an adverse effect on product quality] is removed or limited," 21 C.F.R. § 820.70(h)—is clearly as applicable to Simoneau's claim as it was to the plaintiff's similar claim in Gelber.

The court concludes that where, as here, defective manufacturing is pled based on a violation of the CGMPs, and the complaint contains factual allegations that are plausible on their face and sufficient to put the defendant unquestionably on notice as to the violation alleged to have resulted in the defect that caused the plaintiff's injury, dismissal for lack of other device-specific allegations is improper and would unduly focus the litigation on technicalities of pleading rather than the merits of the claims brought. Cf. Foman v. Davis, 371 U.S. 178 (1962).

ii. Recalls. Simoneau's pleadings regarding the Stryker defendants' two recalls in June 2008 and September 2009 plausibly suggest an additional link between a violation of the federal requirements applicable to the Trident Hip Implant and the manufacturing defect which allegedly caused her injuries. Indeed, unlike the plaintiff in

Horowitz, whose defective manufacturing claim was dismissed for failure to allege any such link, 613 F. Supp. 2d at 283, Simoneau alleges that these recalls were of components specifically implanted into her body in 2003, Compl., Count ¶¶ 13, 15.

According to the Complaint, the purpose of the two recalls was to address, respectively, foreign material in the Acetabular Shell that exceeded internal acceptance criteria for manufacturing residuals and non-compliance with specific metallurgical standards in the manufacture of cancellous bone screws. Id. A reasonable inference is that the Stryker defendants' manufacture of these components violated PMA specifications as well. Gelber, 788 F. Supp. 2d at 157 ("It is certainly plausible that by violating internal acceptance criteria, this conduct also violated manufacturing specifications set forth in the premarket approval application.").

In sum, the court concludes that a strict liability theory is not preempted to the extent that the theory pertains to defective manufacturing and is premised on a violation of FDA requirements. Given the unavailability of PMA documents prior to discovery, Simoneau's reliance on CGMPs is permissible at this stage and, together with her factual allegations regarding the Stryker defendants' particular conduct, is sufficient to state a parallel CPLA claim. Moreover, the alleged recalls of specific components implanted into her hip give rise to a reasonable inference of related violations of PMA specifications and supply another ground for the court's conclusion.

b. Design Defect

Simoneau alleges that the Stryker Defendants failed to design the Trident Hip Implant "in a manner which was safe for its intended users." Compl., Count One ¶ 26(f). However, with respect to a Class III medical device, which is subject to the rigorous PMA process, state law claims for defective design cast doubt on the FDA's findings

concerning the safety of that device's design and, thus, are categorically preempted by the MDA. See Riegel, 552 U.S. at 330; Bausch, 630 F.3d at 560 ("If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer."); Horowitz, 613 F. Supp. 2d at 284 ("Plaintiff's defective design claim, which challenges the FDA's findings concerning the safety of the Trident System's design, necessarily imposes requirements that are different from, or in addition to, federal regulations."); Simon v. Smith & Nephew, Inc., No. 13 CIV. 1909 PAE, 2013 WL 6244525, at *7 (S.D.N.Y. Dec. 3, 2013) ("[D]esign defect claims regarding a PMA-approved device are squarely preempted by the MDA.").

Simoneau points the court to no contrary authority, nor does she suggest any FDA requirement on which a strict liability theory for defective design of a Class III medical device might conceivably be based. Accordingly, this theory is dismissed as preempted.

c. Labeling Defect / Failure to Warn

To prevail on a strict liability theory of defective labeling under the CPLA, Simoneau must prove "by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided." Conn. Gen. Stat. § 52-572q(a); see LaMontagne v. E.I. Du Pont De Nemours & Co., Inc., 41 F.3d 846, 859 (2d Cir. 1994).

Statutory factors to be considered by the trier of fact "[i]n determining whether instructions or warnings were required and, if required, whether they were adequate," include:

> (1) [t]he likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the

> product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions

Conn. Gen. Stat. § 52-572q(b). Simoneau's Complaint pleads strict liability for defective labeling or warning based on overlapping allegations of misbranding, failure to warn, and failure to report.

First, Simoneau alleges that the Trident Hip Implant was "misbranded" within the meaning of 21 U.S.C. § 352. Compl., Count One ¶ 11. A device is "misbranded" if, inter alia, "its labeling is false or misleading in any particular," 21 U.S.C. § 352(a), or it is "dangerous to health when used in the . . . manner . . . prescribed, recommended, or suggested in the labeling," id. § 352(j).

Second, Simoneau alleges that the Stryker defendants failed to warn her and others, including hospitals and doctors performing hip replacement surgery, of the hazards posed by the Trident Hip Implant, including the risk posed by the presence of manufacturing residuals. Compl., Count One ¶¶ 25(c), 26(c)-(d); id., Count Two ¶¶ 26(e)-(g). She also claims that they failed to advise her of three recalls relating to her Trident Hip Implant in June 2008, August 2009, and September 2009, respectively. Id., Count One ¶¶ 13-15. Of particular relevance to her CPLA claim for inadequate warnings or instructions, the August 2009 recall was of the "Trident Acetabular System Surgical Protocol instructions for use of hip prosthesis, Literature Number LSP55." Id. ¶ 14.

Lastly, Simoneau alleges that the Stryker defendants failed to comply with "FDA requirements for records and reports," id. ¶¶ 7-8, 17, including by failing "to timely report any and all information concerning product failures and corrections," id. at ¶ 19. As the maker of a device intended for human use, the Stryker defendants have a continuing

obligation under the FDCA to report, inter alia, adverse events of which they become aware that reasonably suggest the device "may have caused or contributed to a death or serious injury, or has malfunctioned and . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 U.S.C. § 360i(a)(1). In the case of a Class III device like the Trident Hip Implant, the FDA must withdraw premarket approval if it finds the applicant "has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports." 21 U.S.C. § 360e(e)(1)(E)(i).

To be parallel, Simoneau's theory of strict liability for inadequate warnings or instructions must be premised on a violation of FDA requirements. See Riegel, 552 U.S. at 330; 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, . . . such a claim is not expressly preempted."); Gelber, 788 F. Supp. 2d at 160 (dismissing plainitiff's failure to warn claim for lack of a plausible connection to a violation of FDA requirements). Although Simoneau alleges that the Stryker defendants violated FDA requirements, she does not link her injury to a violation, nor can the court reasonably infer such a link from the pleadings regarding misbranding, failure to warn, and failure to report in the Complaint.

With respect to misbranding, state claims based on labeling defects such as false or missing information about health risks are similar to claims based on design defects in general. Both are preempted in the case of Class III medical devices, because these claims necessarily impose requirements different from or additional to the FDA's requirements. See Riegel v. Medtronic, Inc., 451 F.3d 104, 120 (2d Cir. 2006)

(discussing the Riegels' labeling claims), aff'd, 552 U.S. 312. Indeed, like design specifications, "proposed labeling" is subject to the PMA process, 21 U.S.C. § 360e(c)(1)(F), and the applicant cannot change it without FDA permission, id. § 360e(d)(6)(A)(i)); 21 C.F.R. § 814.39(a)(2); Riegel, 552 U.S. at 318-19. Simoneau cites no authority permitting a misbranding claim against the manufacturer of a Class III medical device, nor is such a claim plausibly parallel based on the scant pleadings regarding misbranding in Simoneau's Complaint.[8]

With respect to Simoneau's other grounds—that the Styker defendants failed to advise her of their recalls or to report adverse incidents to the FDA—preemption is not so clearly categorical.[9] However, in the instant case, these other grounds have not been sufficiently pled to permit a careful preemption analysis. As to the first ground, Simoneau identifies no federal requirement that the Stryker defendants warn an implant recipient like her directly of their recalls. Cf. Bertini v. Smith & Nephew, Inc., No. 13 CIV. 79 BMC, 2014 WL 1028950, at *7-8 (E.D.N.Y. Mar. 17, 2014). As to the second ground, she identifies no separate state law duty to warn the FDA.[10]

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[8] Simoneau did not brief failure to warn in connection with the Stryker defendants' August 2009 recall of the Trident Acetabular System Surgical Protocol instructions. Compl., Count One ¶ 14. Although, at the motion to dismiss stage, the court may reasonably infer from the alleged recall that the instructions were defective, a CPLA claim based on strict liability for such a defect is still preempted to the extent that the instructions were submitted to the FDA pursuant to the PMA process.

[9] The court notes that these two grounds presuppose a continuing duty to warn. While such a duty does not fall within strict liability for inadequate warnings or instructions, as set forth in section 52-572q of the Connecticut General Statutes, the Second Circuit has held that "the post-sale duty to warn exists in negligence, and is cognizable under the CPLA." Densberger v. United Technologies Corp., 297 F.3d 66, 71 (2d Cir. 2002). Rather than address failure to warn under strict liability and negligence separately, the court has grouped all related allegations together here and incorporated this analysis into the discussion of negligence in Part IV.B.2, infra.

[10] At least two Circuits have held that failure to warn claims based on the manufacturer's failure to report adverse events to the FDA may be permissible in some instances. Stengel v. Medtronic Inc., 704 F.3d 1224, 1233-34 (9th Cir. 2013) (en banc), petition for cert. filed, 2013 WL 1963892 (U.S. May 10, 2013) (No. 12-1351); Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011). In both

While the court is mindful that Simoneau has not had the benefit of discovery, the Complaint does not plausibly plead a parallel CPLA claim based on strict liability for failure to advise her of recalls or to report adverse events to the FDA . This theory is, therefore, dismissed as preempted, but without prejudice to replead.

2. Negligence

To prevail on her CPLA claim based on a negligence theory, Simoneau must show, inter alia, that the Stryker defendants owed her a duty a care. See LaMontagne v. E.I. Du Pont De Nemours & Co., Inc., 41 F.3d 846, 856 (2d Cir. 1994). The existence of a cognizable duty is a legal question, although "the answer in a given case depends in part on the factual circumstances." Id. Under Connecticut law,

> the test for the existence of a legal duty of care entails (1) a determination of whether an ordinary person in the defendant's position, knowing what the defendant knew or should have known, would anticipate that harm of the general nature of that suffered was likely to result, and (2) a determination, on the basis of a public policy analysis, of whether the defendant's responsibility for its negligent conduct should extend to the particular consequences or particular plaintiff in the case

Gazo v. City of Stamford, 255 Conn. 245, 250 (2001) (citation and internal quotation marks omitted).

Although negligence is pled separately as Count Two of the Complaint, Count One likewise pleads negligent conduct by the Stryker defendants. Compl., Count One ¶ 27 ("Said acts constituting the negligence and careless conduct as aforesaid . . . ."). In fact, the underlying factual allegations for both counts are identical. Id., Count Two ¶¶

Stengel and Hughes, however, a continuing state law duty to warn of known risks was found to encompass (or assumed to encompass) a duty to warn the FDA. Stengel, 704 F.3d at 1233 ("Arizona law contemplates a warning to a third party such as the FDA."); Hughes, 631 F.3d at 769 ("Assuming that a failure to warn claim may be pursued under Mississippi law as Hughes argues . . . ."). Given that Simoneau has not sufficiently pled such a theory or alleged any link to her injury, the court declines to reach the issue—one of first impression in this jurisdiction—of whether Connecticut law recognizes a duty to warn that encompasses warning a federal agency like the FDA.

1-25 (incorporating by reference paragraphs 1-25 of Count One). The Complaint can reasonably be read to assert a negligence theory of Connecticut products liability based on state common law duties to exercise due care in the manufacture and design of a medical device intended for human use and to provide adequate warnings and instructions for such use.

Simoneau alleges, in pertinent part, that:

(1) the Stryker defendants negligently manufactured the Trident Hip Implant by failing to comply with federal regulations and PMA specifications, id. Count One ¶¶ 17-19, 25(a)-(b), 26(e); id., Count Two ¶¶ 26(c)-(d), as evidenced by FDA warning letters and recalls of specific components implanted into Simoneau, id., Count One ¶¶ 12-13, 15, with the result that the device she received contained excess debris and was adulterated within the meaning of 21 U.S.C. § 351, id. ¶¶ 19-20;

(2) the Stryker defendants negligently designed the Trident Hip Implant, id., Count One ¶¶ 26(f), 27;

(3) the Stryker defendants negligently failed to warn Simoneau and others, including doctors and hospitals performing hip replacement surgery, of the risk of excess manufacturing residuals in the Trident Hip Implant, id., Count One ¶¶ 25(c), 26(c)-(d); id., Count Two ¶¶ 26(e)-(g)—including by putting into the stream of commerce a device that was misbranded within the meaning of 21 U.S.C. § 352(a), id., Count One ¶¶ 11, 19, not informing recipients like her of device recalls, id. ¶¶ 13-15, and not complying with FDA reporting requirements, id. ¶¶ 7-8, 17, 19.

With respect to these allegations, the court reaches the same conclusions regarding preemption that it reached with respect to the related allegations under strict liability, and for the same reasons outlined in Part IV.B.1, supra. First, negligent manufacturing is not preempted, because to the extent such negligence is premised on a violation of FDA requirements, the state common law duty parallels the federal requirement. Bass, 669 F.3d at 515 (negligent manufacturing claim not preempted); Bausch, 630 F.3d at 553 (same); Gelber, 788 F. Supp. 2d at 155-60 (same); see discussion supra Part IV.B.1.a. Second, in contrast, negligent design is preempted, as is negligent failure to warn where based on labels or instructions submitted to the FDA pursuant to the PMA process. Riegel, 552 U.S. at 330; Bausch, 630 F.3d at 560; Simon, 2013 WL 6244525, at *7; see discussion supra Part IV.B.1.b & c. Simoneau's negligent design and negligent labeling theories are, therefore, dismissed.

Third, as to the remaining two grounds of negligent failure to warn—that the Stryker defendants did not advise Simoneau of recalls and did not report adverse events to the FDA—the court concludes that the Complaint does not plausibly plead a parallel CPLA claim based on these allegations for the respective reasons given in Part IV.B.1.c, supra: (1) Simoneau fails to identify a federal requirement that the Stryker defendants directly notify implant recipients of recalls; and (2) she fails to identify a state law duty requiring the Stryker defendants to warn the FDA.[11] The dismissal of these two grounds of negligent failure to warn is without prejudice to replead.

[11] It bears reiterating that, while the court has grouped together all allegations of failure to warn, not all allegations are cognizable under both strict liability and negligence. In particular, the failure to advise Simoneau of recalls and to report adverse events to the FDA are predicated on a post-sale duty to warn that the Second Circuit has held to exist only in negligence. See Densberger, 297 F.3d at 71.

3. Breach of the Implied Warranties of Merchantability and Fitness for a Particular Purpose

The CPLA incorporates breach of warranty theories. Conn. Gen. Stat. § 52-572m(b) ("'Product liability claim' shall include . . . breach of warranty, express or implied."). The elements of the theories, however, derive from a different statutory source—namely, the Connecticut Uniform Commercial Code ("CUCC"), title 42 of the Connecticut General Statutes. Walters v. Howmedica Osteonics Corp., 676 F. Supp. 2d 44, 55 (D. Conn. 2009). While the CPLA provides, then, the statutory vehicle for Simoneau's action, the CUCC provides the substantive legal basis for her theories here of breach of the implied warranties of merchantability and fitness for a particular purpose, Conn. Gen. Stat. §§ 42a-2-314 & 42-2-315, as well as her theory of breach of express warranty, id. § 42a-2-313, discussed in Part IV.B.4, infra.

Under the CUCC, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Conn. Gen. Stat. § 42a-2-314(1). To be merchantable, the goods must be, inter alia, "fit for the ordinary purposes for which such goods are used" and "conform to the promises or affirmations of fact made on the container or label." Id. §§ 42a-2-314(2). In addition, "there is an implied warranty that the goods shall be fit for [any particular purpose for which the goods are required]" if, at the time of contracting, the seller has reason to know of such purpose and of the buyer's reliance "on the seller's skill or judgment to select or furnish suitable goods." Id. § 42a-2-315.

Simoneau pleads breach of these implied warranties based on factual allegations regarding defective manufacture, which the court has already detailed in Part IV.B.1.a, supra. The gravamen of this theory is that the Stryker defendants' failure to comply with

federal regulations and PMA specifications caused components of the Trident Hip Implant received by Simoneau in 2003 to be unfit for their ordinary and intended purposes. See Compl., Count One ¶ 26(g); id., Count Two ¶ 26(h). To the extent that this theory relates to manufacturing defects and is premised on a violation of FDA requirements, the state and federal requirements are parallel, and the theory is not preempted. Bass, 669 F.3d at 517 (breach of implied warranty claim not preempted); Gelber, 788 F. Supp. 2d at 166 (same); McConologue v. Smith & Nephew, Inc., No. 3:13-CV-00880 VLB, 2014 WL 1246834, at *16 (D. Conn. Mar. 24, 2014) (same). Hence, for the reasons stated in Part IV.B.1.a, supra, the court concludes that the Complaint plausibly pleads a theory of Connecticut products liability based on breach of the implied warranties of merchantability and fitness for a particular purpose.

4. Breach of Express Warranty

To prevail on a breach of express warranty theory, Simoneau must prove, inter alia, "the existence of an express warranty." Web Press Servs. Corp. v. New London Motors, Inc., 203 Conn. 342, 351 (1987). Under the CUCC,

> Express warranties by the seller are created as follows: (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Conn. Gen. Stat. § 42a-2-313(1). Although the seller need not use specific words or even intend to make such a warranty, "some statements of sellers are merely 'puffing' and do not create express warranties." Web Press Servs., 203 Conn. at 351; see Conn. Gen. Stat. § 42a-2-313(2).

Simoneau alleges that the Stryker defendants breached their express warranty that the Trident Hip Implant was "safe [and] effective for its intended use." Compl., Count One ¶ 26(h). The underlying warranty of safety and effectiveness, however, is not specifically pled, nor is the identity of the party to whom it was made "as part of the basis of the bargain." Conn. Gen. Stat. § 42a-2-313. Nor are there any factual allegations from which the court could reasonably infer these prerequisites of a breach of express warranty theory.

Such a theory is by no means categorically preempted in the case of Class III medical devices.[12] But the theory has not been sufficiently pled to state a CPLA claim, parallel or otherwise. The court, therefore, dismisses it for that reason alone.

To analyze preemption, the court must have before it allegations in the Complaint plausibly indicating a basis for breach of an express warranty. Such allegations are entirely lacking at present. In her Opposition brief, Simoneau asserts that the basis is not "labeling" submitted to the FDA but "commitments voluntarily undertaken, resulting

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[12] Although Riegel does not address whether courts should analyze breach of express warranty claims like other state products liability claims, the Supreme Court has explained in a different preemption context:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirement[s]" imposed by an express warranty claim are not "imposed under State law," but rather imposed by the warrantor. . . . While the general duty not to breach warranties arises under state law, the particular [requirement] in an express warranty claim arises from the manufacturer's statements in its advertisements. In short, a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement . . . imposed under State law."

Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 525-26 (1992).

So long as the representation at issue is volunteered outside the PMA process, a breach of warranty theory appears not to trigger express preemption. Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997); Gelber, 788 F. Supp. 2d at 165; Horowitz, 613 F. Supp. 2d at 285. The MDA prohibits states from imposing different or additional requirements. 21 U.S.C. § 360k(a). It does not, however, prohibit the manufacturer from imposing such requirements on itself and being held to them by state law. It would be strange indeed to read section 360k to preempt breach of an express warranty that neither federal nor state law required the manufacturer to make in the first place.

from Stryker's marketing efforts." Pl.'s Mem. in Opp'n to Stryker Defs. Mot. to Dismiss ("Pl.'s Opp'n") (Doc. No. 51) at 24 (citing Compl., Count One ¶ 6). Paragraph 6 of the Complaint alleges that Simoneau received components that were marketed (as well as designed and manufactured) by the Stryker defendants. The hospital record referenced in Paragraph 6 and attached as Exhibit A to the Complaint lists, inter alia, such components, with serial and lot numbers. None of this, however, suffices to indicate a plausible factual basis for Connecticut products liability based on breach of an express warranty.

While Simoneau need not prove the existence of the warranty at this stage, the Complaint must at least indicate the representation that the Stryker defendants are alleged to have made and breached. Otherwise, Simoneau has not given them "fair notice" of the nature and basis of her claim. Twombly, 550 U.S. at 556 n.3 ("Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of, but also 'grounds' on which the claim rests." (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957))). Indeed, while the Complaint need not plead every element of the prima facie case, Swierkiewicz v. Sorema N. A., 534 U.S. 506, 511 (2002), a breach of express warranty claim without any reference to the underlying representation lacks plausibility.

Accordingly, Simoneau's breach of express warranty theory is dismissed for failure to state a claim, with the right to replead.

V. CONCLUSION

For the reasons set forth above, the Stryker Defendants' Motion to Dismiss (Doc. Nos. 14 &15) is **GRANTED in part and DENIED in part.** The Motion is **denied** as to the strict liability, negligence, and breach of implied warranties theories of Simoneau's

CPLA claim to the extent that these relate to defective manufacturing of the Trident Hip Implant and are premised on a violation of the FDA's requirements. The Motion is **granted** as to all other theories of products liability.

With respect to all of the theories dismissed, Simoneau's request for leave to amend her Complaint is **granted**. An amended complaint, if any, shall be filed no later than **April 21, 2014**.

SO ORDERED.

Dated at New Haven, Connecticut this 31st day of March, 2014.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge