

**UNITED STATES DISTRICT COURT  
DISTRICT OF CONNECTICUT**

<b>JOHN MCCONOLOGUE,</b>	:	
Plaintiff,	:	<b>CIVIL ACTION NO.</b>
	:	<b>3:13-CV-00880 (VLB)</b>
<b>v.</b>	:	
	:	
<b>SMITH &amp; NEPHEW, INC.,</b>	:	
Defendant.	:	<b>March 24, 2014</b>

**MEMORANDUM OF DECISION GRANTING IN PART AND DENYING IN PART  
DEFENDANT’S MOTION TO DISMISS [Dkt. 16]**

**I. Introduction**

The Plaintiff, John McConologue (“McConologue”), brings this action against Defendant Smith & Nephew, Inc. (“Smith & Nephew”) for injuries allegedly sustained as a result of the placement in Plaintiff’s hip of the Defendant’s allegedly defective medical device. The Plaintiff alleges one count sounding in products liability pursuant to Connecticut General Statute § 52-572m, encompassing the legal theories of strict liability in tort (itself encompassing design defect, manufacturing defect, failure to warn), negligence (also encompassing failure to warn), breach of express and implied warranty, and misrepresentation. The Defendant has moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted. For the reasons that follow, the Defendant’s Motion to Dismiss is GRANTED in part and DENIED in part.

**II. Factual Background**

**The following facts and allegations are taken from Plaintiff's complaint.**

**On or about March 22, 2010 John McConologue underwent a right total hip arthroplasty surgery, during which Dr. John M. Keggi implanted in McConologue's body an R3 Ceramic Ace Liner Biolox Forte, Ref. # 71338954, Lot # 09FT32751 (the "Liner" or "Ceramic Liner"), manufactured and marketed by Defendant Smith & Nephew. [Dkt. 1-1, Compl. ¶¶3, 4]. McConologue alleges that the Liner was expected to and did reach the Plaintiff without substantial change in condition from which it was manufactured and sold, and was not altered or modified in any way by McConologue or any third party from the condition in which it was manufactured, retailed, distributed, packaged and/or sold by Smith & Nephew. [*Id.* at ¶ 6].**

**Dr. Keggi notified McConologue by letter dated March 21, 2011 that Smith & Nephew was conducting a recall of the Liner that had been implanted in the Plaintiff. [*Id.* at ¶ 7]. A stated reason for the recall was that the Defendant failed to manufacture the Liner according to the U.S. Food and Drug Administration's ("FDA"'s) approved manufacturing process. [*Id.* at ¶ 8]. During the manufacturing process for several batches of R3 Ceramic Liners, including the Liner implanted in Mr. McConologue, titanium rings were pressed onto the ceramic component with a higher force than allowed by manufacturing specifications approved by the FDA, which had the potential to result in lower than expected strength for the liners. [*Id.* at ¶ 9]. Although the Liner implanted in the Plaintiff was subject to recall because it was manufactured outside of specifications, Dr. Keggi's letter indicated that "[t]he Smith & Nephew liners are**

expected to continue to function well and no change is recommended in your level of activity. No surgery is required to change the liner and Smith & Nephew has informed [Dr. Keggi] that the liner is expected to have the same durability as those not affected by the recall.” [*Id.* at ¶ 10].

About twenty-seven months after his hip surgery (and fifteen months after Dr. Keggi’s letter), in June 2012, Mr. McConologue began to notice squeaking and pain in his right hip. [*Id.* at ¶ 11]. Dr. Keggi saw the Plaintiff approximately one month later in connection with this squeaking and pain. [*Id.* at ¶ 12]. A follow-up CT scan on the Plaintiff’s right hip, which was ordered by Dr. Keggi and performed on August 17, 2012, indicated in an addendum to the report that the Ceramic Liner had fractured. [*Id.* at ¶ 13]. As a result of clinical findings from physical examinations of the Plaintiff, including findings that substantiated the pain, discomfort, and squeaking that McConologue reported, and the reported fracture to the Ceramic Liner reported in the addendum to the CT scan, McConologue underwent a total right hip arthroplasty revision surgery on September 11, 2012, performed by Dr. Keggi. [*Id.* at ¶ 14]. This revision surgery confirmed that the Liner was fractured. [*Id.* at ¶ 15].

The Plaintiff alleges that Smith & Nephew’s conduct in manufacturing the Liner in violation of the FDA approved process makes the Defendant liable in products liability pursuant to Conn. Gen. Stat. § 52-572m in the following ways:

- a. The Liner was in a defective and unreasonably dangerous condition, was inherently unsafe, was inherently unreliable, and could not be used without subjecting the plaintiff to an unreasonable risk of injury;

- b. The defendant failed to properly or adequately warn, disclose or instruct the plaintiff that the product was defective prior to implantation;**
- c. The defendant misrepresented to the plaintiff and third parties that the Liner was safe for use;**
- d. The defendant failed to disclose to the plaintiff and third parties that the Liner was defective and unreasonably dangerous;**
- e. The defendant was negligent:**
  - (i) in failing to properly and adequately test the Liner prior to marketing it;**
  - (ii) in designing, building and packaging the Liner in a defective manner;**
  - (iii) in that the defendant knew or should have known that the liners, including the Liner implanted in the plaintiff, were being manufactured in violation of FDA approved manufacturing specifications, yet continued their manufacture and distribution;**
  - (iv) in failing to perform a proper study to evaluate whether the press settings that were being used to press the titanium rings onto the Liner were appropriate;**
- f. The defendant breached an implied warranty of merchantability in that the Liner was not of merchantable quality and fit for its intended purpose;**
- g. The defendant breached its express warranty that the Liner was safe and effective for its intended use;**
- h. The defendant failed to employ adequate techniques in manufacturing, assembling, labeling, testing, inspecting and marketing the Liner.**

[Dkt. 1-1, Compl. ¶ 16].

### **III. Standard of Review**

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Sarmiento v. U.S.*, 678 F.3d 147 (2d Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). While Rule 8 does not require detailed factual allegations, “[a] pleading that offers ‘labels and conclusions’ or ‘formulaic recitation of the elements of a cause of action will not do.’ Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678 (citations and internal quotations omitted). “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of ‘entitlement to relief.’” *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (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.” *Id.* (internal citations omitted).

In considering a motion to dismiss for failure to state a claim, the Court should follow a “two-pronged approach” to evaluate the sufficiency of the complaint. *Hayden v. Paterson*, 594 F.3d 150, 161 (2d Cir. 2010). “A court ‘can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.’” *Id.* (quoting *Iqbal*, 556 U.S. at 679). “At the second step, a court should determine whether the ‘well-pleaded factual allegations,’ assumed to be true, ‘plausibly give rise to an entitlement to relief.’” *Id.* (quoting *Iqbal*, 556 U.S. at 679). “The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer

possibility that a defendant has acted unlawfully.” *Iqbal*, 556 U.S. at 678 (internal quotations omitted).

In general, the Court’s review on a motion to dismiss pursuant to Rule 12(b)(6) “is limited to the facts as asserted within the four corners of the complaint, the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference.” *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). The Court may also consider “matters of which judicial notice may be taken” and “documents either in plaintiffs’ possession or of which plaintiffs had knowledge and relied on in bringing suit.” *Brass v. Am. Film Techs., Inc.*, 987 F.2d 142, 150 (2d Cir.1993); *Patrowicz v. Transamerica HomeFirst, Inc.*, 359 F. Supp. 2d 140, 144 (D. Conn. 2005)(MRK). Here, the Plaintiff has attached to his complaint the letter from Dr. Keggi notifying him of the recall of certain batches of ceramic liners and the letter from Smith & Nephew to Dr. Keggi.

#### IV. Analysis

The Defendant argues that McConologue’s complaint must be dismissed for failure to state a claim because the Ceramic Liner is a Class III medical device approved by the Food and Drug Administration pursuant to a stringent premarket approval process, and thus claims involving this device are preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act. The Defendant also argues that the Plaintiff’s complaint is inadequately pled under Federal Rule of Civil Procedure 8(a) and the standards set forth in *Iqbal* and *Twombly*. The

Plaintiff counters that the Medical Device Amendments are inapplicable to the device surgically implanted in his hip and thus cannot preempt his claims, that his claims are based on a violation of federal law and are thus not preempted, and that he has sufficiently pled claims for the strict liability claims of manufacturing defect, failure to warn, and design defect; negligence; misrepresentation; and breach of both express and implied warranties.

a. Products Liability

Connecticut statutory law provides that a “product liability claim ... may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product.” Conn. Gen. Stat. § 52-572n(a). Product liability claims include those actions based on the theories of strict liability in tort; negligence; breach of express or implied warranty; failure to warn; and misrepresentation or nondisclosure. Conn. Gen. Stat. § 52-572m(b).

“Manufacturers in Connecticut are strictly liable for defective products under § 402A of the Restatement (Second) of Torts. A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions.” *Breen v. Synthes-Stratec, Inc.*, 108 Conn. App. 105, 110 (2008) (internal quotation marks and citation omitted). Strict tort liability “relieves the plaintiff from proving that the manufacturer was negligent and allows the plaintiff to establish instead the defective condition of the product as the principal basis of liability.” *Potter v. Chicago Pneumatic Tool Co.*, 241

Conn. 199, 211 (1997). To recover under the doctrine of strict liability in tort, a “plaintiff must prove that: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition.” *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 302 Conn. 123, 131 (2011) (citations omitted). For a product to be unreasonably dangerous, it “must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” *Id.* (citation omitted). “Proper warnings, however, may prevent a product from being unreasonably dangerous.” *Vitanza v. Upjohn Co.*, 257 Conn. 365, 374 (2001). In a products liability action “the plaintiff must plead and prove that the product was defective and that the defect was the proximate cause of the plaintiff's injuries.” *Haesche v. Kissner*, 229 Conn. 213, 218 (1994).

Conn. Gen. Stat. § 52-572q governs products liability actions based on a failure to warn theory. The statute provides that a “product seller may be subject to liability for harm caused to a claimant who proves 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). In determining what factors or warnings were required and whether they were adequate, a trier of fact may consider the likelihood that the product would cause the harm suffered,



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 the technological feasibility and cost of warnings and instructions. Conn. Gen. Stat. § 52-572q(b). To prevail, a claim must prove by a preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm. Conn. Gen. Stat. § 52-572q(c).

**b. MDA Preemption**

The Medical Device Amendments of 1976 (the “MDA”) to the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* require certain medical devices to undergo a lengthy and rigorous premarket approval process before such devices may be marketed to the public. 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). This premarket approval (“PMA”) process involves the submission to the Food and Drug Administration (“FDA”) of voluminous, comprehensive information including, among other things, full reports of all studies and investigations of a device’s safety and effectiveness, a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and, when relevant, the packing and installation of the device, samples or device components, and a specimen of the proposed labeling. *Riegel*, 552 U.S. at 318–19. The FDA spends an average of 1,200 hours reviewing each application. *Id.* at 318. Class III devices, which are those used “in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or those that “present[ ] a

potential unreasonable risk of illness or injury,” are subject to the highest level of government oversight. *Id.* at 316; 21 U.S.C. § 360c(a)(1)(c).

In analyzing whether a device should be granted approval, the FDA must weigh “any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” 21 U.S.C. § 360c(a)(2)(C). The FDA will grant premarket approval only if it finds that there is “reasonable assurance” of the device’s “safety and effectiveness.” 21 U.S.C. § 360e(d); *Riegel*, 552 U.S. at 319. Once approved, “all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications.” *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 119 (2d Cir. 2006) *aff’d*, 552 U.S. 312 (2008).

After approval, the MDA imposes a rigorous oversight regime and forbids the manufacturer from making, absent FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect the device’s safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i); *Riegel*, 552 U.S. at 319. Approved medical devices are also subject to continuing recording and reporting requirements, including the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device of which the manufacturer knows or reasonably should know, and the obligation to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury were it to recur. 21 U.S.C. § 360i; 21 C.F.R. §§ 814.84(b)(2), 803.50(a); *Riegel*, 552 U.S. at 319. The FDA must withdraw premarket approval of

a medical device if, inter alia, it learns that the device is unsafe or ineffective under the conditions or use prescribed, recommended, or suggested in the device's labeling; if new information demonstrates that there is a lack of reasonable assurance that the device is safe or effective, that the manufacture, processing, packaging, or installation of such device do not conform with FDA requirements, that the device's labeling is false or misleading; or if the applicant fails to establish a system for maintaining records or repeatedly or deliberately fails to maintain records or make reports. 21 U.S.C. § 360e(e)(1).

The Defendant has warranted and the Plaintiff does not deny that Smith & Nephew's Reflection Ceramic Acetabular System, encompassing the R3 Ceramic Liner, underwent and was approved as a Class III device pursuant to the FDA's premarket approval process in 2008.

Plaintiffs attempting to assert claims regarding devices approved by the FDA face two initial hurdles: potential implied and express preemption of their claims. The FDCA, of which the Medical Device Amendments are a part, provides no private right of action for violations of the Act. Section 337 dictates, in relevant part, that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has posited that, pursuant to § 337, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). See also *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997)

“no such private right of action exists [under the FDCA]. See 21 U.S.C. § 337(a) (restricting enforcement to suits by the United States)”; *Stokes v. I-Flow Corp.*, 6:12-CV-991-ORL-36, 2013 WL 1715427, at \*4-5 (M.D. Fla. Apr. 8, 2013) (noting that “only the Federal Government is authorized to enforce FDA regulations”). Thus, a private litigant may not base a claim explicitly on an alleged violation of the FDCA as the Act does not confer a private right of action, and a litigant’s common law claim may be *impliedly* preempted “when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist.” *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

Further, section 360k of the MDA contains an express pre-emption provision that applies to medical devices that have received the FDA’s premarket approval and that states:

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.

21 U.S.C. § 360k. The case at hand involves this express pre-emption provision.

Notwithstanding that the FDCA does not provide a private right of action for violations of that Act, and notwithstanding that § 360k provides for express preemption in certain instances, a private litigant *may* bring a common law claim regarding a device regulated by the FDCA in narrow circumstances where it is not impliedly preempted pursuant to § 337 or expressly preempted under § 360k. The

Supreme Court has recently attempted to refine the parameters of the MDA's express preemption provision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In *Riegel*, the Court held that where a plaintiff seeks to assert state law causes of action stemming from injuries caused by a medical device that has received the FDA's premarket approval, claims based on state tort-law duties imposing different or additional requirements than those imposed by the FDA's premarket approval process are preempted pursuant to § 360k. In so holding, the *Riegel* Court affirmed the Second Circuit's conclusion that the plaintiff's New York common law claims of negligence, strict liability, and breach of implied warranty against the manufacturer of a balloon catheter were preempted pursuant to § 360k of the MDA. The Court recognized that the FDA's premarket approval process, which is "specific to individual devices," is "in no sense an exemption from federal safety review – it *is* federal safety review" that imposes federal requirements triggering the preemption clause of § 360k. *Riegel*, 552 U.S. at 322-23. This premarket approval process requires that a device approved through it "be made with almost no deviations from the 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.* at 322-23. Thus, state law claims challenging the safety and efficacy of an FDA approved Class III device which has complied with its premarket approval requirements are preempted pursuant to § 360k of the MDA as they would be different from or in addition to federal requirements provided by the premarket approval process.

The *Riegel* Court, however, took care to point out the *exception* to the MDA's preemption provision, noting that certain claims may be asserted:

[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.

*Id.* at 330. Section 360k, then, protects manufacturers of medical devices from liability to the extent that they have complied with federal law, including the device's premarket approval standards. Where a plaintiff claims that an approved Class III device has violated its own premarket approval standards, state law claims based on such a violation are not preempted under § 360k so long as they are parallel claims. *Id.* at 330. See also *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006), *aff'd* 552 U.S. 312 (2008) ("tort claims that are based on a manufacturer's departure from the standards set forth in the device's approved [premarket approval] application ... are not preempted"); *Gale v. Smith & Nephew, Inc.*, 12 CV 3614 VB, 2013 WL 563403, at \*3 (S.D.N.Y. Feb. 13, 2013) (as to preemption pursuant to the MDA, "a plaintiff's state tort claim would be pre-empted if it alleged the device, as approved by the FDA, was unreasonably dangerous. But a plaintiff could bring a state tort claim alleging a manufacturer's device, as produced, was adulterated and therefore did not conform to that device's specific FDA premarket approval requirements."); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 280 (E.D.N.Y. 2009) ("What is clear after *Riegel* is that claims which impose liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained

premarket approval from the FDA, are preempted. However, if plaintiff's state common law claims are premised on the device's failing to comply with FDA standards, then they are parallel") (citation and internal quotation marks omitted); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4<sup>th</sup> Cir. 2012) (common law claims not preempted where state duties parallel, rather than add to, federal requirements, which occurs when claims are premised on a violation of FDA regulations); *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5<sup>th</sup> Cir. 2012) ("state common law claims are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements"); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7<sup>th</sup> Cir. 2010) (same; "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law"); *Stengel v. Medtronic Inc.*, 704 f.3d 1224, 1228 (9<sup>th</sup> Cir. 2013) ("the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA"). Thus, where state tort-law duties impose no additional or different requirements than a device's premarket approval plan, and where a plaintiff asserts that a device approved by the premarket approval process has violated that very process, such state law claims are not automatically preempted by § 360k.

Circuit courts have held that the pleading standard applicable to a Class III medical device claim alleging a violation of federal law is the same as the plausibility standard articulated in *Iqbal* and *Twombly*. See *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5<sup>th</sup> Cir. 2012) ("to plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet

the *Twombly* plausibility standard.”); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7<sup>th</sup> Cir. 2010) (“[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new ‘plausibility’ standard applied in *Iqbal* and *Twombly*”). The Eleventh Circuit has held that parallel claims must be “specifically stated in the initial pleadings,” whereby a plaintiff must set forth facts pointing to a specific premarket approval requirement that has been violated. *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11<sup>th</sup> Cir. 2011); see also *Gale v. Smith & Nephew, Inc.*, 12 CV 3614 VB, 2013 WL 563403, at \*4 (S.D.N.Y. Feb. 13, 2013) (same); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011) (same). “Plaintiffs cannot simply incant the magic words [the manufacturer] violated FDA regulations in order to avoid preemption.” *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010) (quoting *In re Medtronic*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)).

In applying the *Iqbal* and *Twombly* standard to claims for defective manufacture of a Class III in violation of federal law, the Seventh Circuit has cautioned that “district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law,” and thus plaintiffs may not be able to allege with specificity the exact federal requirement that was violated. *Bausch v. Stryker Corp.*, 630 F.3d 546, 558, 560 (7<sup>th</sup> Cir. 2010). Moreover, the Fifth Circuit has held that a finding by the FDA that a device has violated the premarket



approval standards is *not* required to successfully plead a parallel claim, nor is an enforcement action by the FDA against the manufacturer. *Bass*, 669 F.3d at 509, 511.

Here, premarket approval was a federal requirement imposed on Smith & Nephew's Ceramic Liner, and McConologue's claims relate to the safety and effectiveness of the Liner. Therefore, Plaintiff's state law claims will not be preempted by § 360k of the MDA if they are not different from or in addition to federal law, *Riegel*, 552 U.S. at 330, and will stand if they meet the pleading requirements of *Iqbal* and *Twombly*.

i. Wholesale Preemption

The Defendant's first argument that the Plaintiff's complaint is wholly and expressly preempted by the MDA because the ceramic liner at issue received approval from the FDA and because Plaintiff's claims challenge the safety and effectiveness of the device – an argument that ignores the Plaintiff's allegations that Smith & Nephew's Ceramic Liner was not manufactured according to the FDA's premarket approval process – is misinformed. The Defendant has provided no support for its proposition that the MDA expressly preempts *the entirety* of the Plaintiff's complaint simply because the Class III Liner had received premarket approval, but where the plaintiff's general claims are based on a failure to adhere to the FDA's premarket approval standards. This argument ignores the conclusions reached in *Riegel* and its progeny regarding exceptions to MDA preemption. Thus, insofar as the Defendant argues that the MDA

preempts the Plaintiff's complaint in its entirety solely because Smith & Nephew's Ceramic Liner was approved by the FDA's premarket approval process, the motion to dismiss is DENIED.

ii. "Device Intended for Human Use"

In response to each of the Defendant's preemption arguments (discussed in the prior section and in the sections to follow), the Plaintiff counters that preemption under § 360k is inapplicable to this case because the defective ceramic liner implanted in Mr. McConologue was not "a device intended for human use" within the meaning of § 360k(a). In other words, the Plaintiff argues, Smith & Nephew has failed to present any facts tending to show that the *specific* device with the *specific* alleged defect implanted in the Plaintiff's hip, which was not manufactured in accordance with FDA approved processes, was a device intended for human use such that it could come under the purview of the MDA. Rather, the specific Liner the Plaintiff received was not FDA-approved pursuant to the rigorous premarket approval process, as the device did not comport with that prescribed process. As 21 U.S.C. § 360k only preempts state law claims relating to devices intended for human use, the Plaintiff asserts that his claims cannot be preempted as to the specific Liner he received.

The Plaintiff's theory does not find footing in the case law and this Court finds no reason to depart from precedent. The *Riegel* Court explicitly noted that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case

‘parallel,’ rather than add to, federal requirements.” *Riegel*, 552 U.S. at 330. Thus, pursuant to *Riegel*, a plaintiff may assert state law claims relating to Class III devices where those devices fail to comply with their premarket approval specifications, as state law claims may merely parallel the federal requirements. Consequently, a plaintiff bringing state law claims regarding a Class III device must allege a violation of federal law or regulations in order to capitalize on a state law cause of action. In other words, because the FDA’s device-specific premarket approval process “*is* federal safety review,” a plaintiff bears the burden of alleging deviations from those safety standards in order to avoid preemption and assert state tort-law causes of action. *Id.* at 322-23. A claim which fails to allege a violation of federal regulations which a state law claim would parallel will fail. The assumption in *Riegel*, then, is *not* that the MDA is inapplicable to any suit involving an allegedly noncompliant medical device as, in order to avoid preemption, a plaintiff must still plead noncompliance with federal requirements. Plaintiff’s argument fails.

c. Products Liability: Manufacturing Defect

The Defendant argues that McConologue’s manufacturing defect theory of products liability must fail because it is preempted by the MDA, as it “relates to the safety and effectiveness of the R3 ceramic liner.” [Dkt. 16-1, MSJ p. 12]. Smith & Nephew further contends that the complaint “fails to link [plaintiff’s] alleged injury to any purported manufacturing defect noted in the letter sent by Smith & Nephew to his physician, or to any purported defect addressed by the voluntary recall” of the Ceramic Liner, and thus pleads only conclusory

allegations insufficient to comport with *Iqbal* and *Twombly*. [*Id.* at p. 13]. The Court disagrees.

The Plaintiff has sufficiently alleged that the Ceramic Liner implanted in his body was not manufactured in accordance with federal standards and that the failure to meet these standards resulted in the defect observed on the device implanted in his body; thus his manufacturing defect claim survives preemption under § 360k and meets the pleading standards set forth in *Iqbal* and *Twombly*. McConologue has pleaded that (1) he received a Ceramic Liner manufactured by Smith & Nephew; (2) after the Liner was implanted, he was notified by his doctor that the batch from which the Liner hailed was manufactured outside Smith & Nephew's specifications, and that products in these batches not yet implanted in patients were being recalled for their failure to comply with the FDA's specifications; (3) specifically, titanium rings were pressed onto the ceramic component of these Liners with a higher force than allowed by manufacturing specifications, which had the potential to result in lower than expected strength for the liners; (4) twenty-seven months after his surgery, McConologue noticed squeaking and pain in his hip; (5) a CT scan on the Plaintiff's right hip indicated that the Ceramic Liner had fractured; (6) the Plaintiff underwent total right hip arthroplasty revision surgery as a result of the pain, squeaking, and reported Liner fracture; and (7) the surgery confirmed that the Liner was fractured. McConologue has specified the defect in the Liner he received and how that defect differed from the federal standards applicable to the device, including Smith & Nephew's apparent admission that the Liner departed from its acceptable

manufacturing specifications. At the motion to dismiss stage, McConologue has pleaded sufficient facts to find that his injury plausibly resulted from a violation of FDA manufacturing standards, resulting in a fractured Liner, in connection with his manufacturing defect claims. He has thus successfully pleaded a parallel manufacturing defect claim that is not preempted by § 360k. See, e.g., *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 123 (2d Cir. 2006), aff'd 552 U.S. 312 (2008) (“Riegel’s negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel’s angioplasty had not been manufactured in accordance with the PMA-approved standards. A jury verdict in the Riegels’ favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for [the manufacturer’s] deviation from those standards.”); *Gelber*, 788 F. Supp. 2d at 156 (manufacturing defect claim not preempted where plaintiffs alleged that device was not manufactured in accordance with the FDA’s current good manufacturing practice requirements, even though plaintiffs did not expressly state which specific provision the defendants violated, but where plaintiffs pointed to FDA warning letter to manufacturer, and to manufacturer’s voluntary recall of device); *Bass*, 669 F.3d at 510 (manufacturing defect claim was plausibly pled and survived preemption where plaintiff pleaded he received implant of hip replacement shell, the FDA had warned manufacturer of noncompliance with regulations regarding an excess of bioburden and residuals on shell, shell was voluntarily recalled after implantation

in plaintiff, shell was loose due to lack of bony ingrowth, and lack of bony ingrowth was known effect of bioburden and manufacturing residuals on device); *Bausch*, 630 F.3d at 553 (manufacturing defect claim was not preempted where plaintiff alleged that hip replacement device was manufactured in violation of FDA regulations).

Smith & Nephew's motion to dismiss McConologue's products liability claim on a manufacturing defect theory is DENIED.

d. Products Liability: Failure to Warn

Smith & Nephew argues that the Plaintiff's failure to warn claim is preempted by the MDA because it relates to the safety and effectiveness of the ceramic liner, and because it seeks to hold the Defendant liable for failing to provide warnings above and beyond those specifically approved and required by the FDA as part of the premarket approval process. Smith & Nephew further argues that the Plaintiff's failure to warn claim must be dismissed because he has not identified any warnings regarding the ceramic liner that were mandated by the FDA and which Smith & Nephew did not provide to consumers.

The Defendant has cited in support of its argument for dismissal only the district court's holding in *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009), in which the court dismissed the plaintiff's claim that the defendant failed to properly warn her about the risk of an audible noise emanating from the allegedly defective artificial hip implanted in the plaintiff's body. *Id.* at 286. The court concluded that plaintiff's claim "would clearly impose requirements

different from, or in addition to, the federal regulations,” as her claim constituted an attack on the device’s federally approved label, which contained information about audible squeaking emanating from the device. *Id.* Allowing the claim to proceed, the court concluded, would permit a jury to find that the defendants were required to provide warnings above and beyond those on the device’s product label, which was specifically approved by the FDA as part of the PMA process. *Id.* at 286-87. The Defendant here does not explain how *Horowitz* is applicable to this case, given that the failure to warn claim in *Horowitz* was premised on the insufficiency of the label on a device which was manufactured as mandated by the FDA and bore the FDA approved label. The Court thus finds *Horowitz* to be inapposite.

The Plaintiff, on the other hand, contends that courts “uniformly reject the notion that defendants can dismiss failure to warn cases in the MDA preemption context where it is alleged that the specific device at issue that was placed into the stream of commerce was not an FDA approved device.” [Dkt. 19, P’s Opp. at p. 21]. This argument is not supported by the cases to which the Plaintiff cites. On the contrary, the weight of authority establishes that only parallel claims and not independent state law claims are not preempted by the MDA. For instance, in *Stengel v. Medtronic Inc.*, the Ninth Circuit held that a failure to warn claim which “rests on a state-law duty that parallels a federal-law duty under the MDA” was not preempted where the plaintiffs alleged (1) that the manufacturer violated a specific continuing duty to monitor the medical device after it had received premarket approval, (2) that the manufacturer violated a duty to discover and

report to the FDA any complaints about the product's performance and any adverse health consequences, and (3) that the manufacturer failed to warn the FDA. 704 F.3d 1224, 1232-33 (9<sup>th</sup> Cir. 2013). The Ninth Circuit did *not* presage a broad rejection of preemption wherever a plaintiff alleges a manufacturing defect but fails to allege a violation of federal law that speaks precisely to a duty to warn, nor did the Court allow the failure to warn claim to survive because, as McConologue urges, the medical device at issue was not an FDA approved device.<sup>1</sup>

Indeed, courts have dismissed as preempted pursuant to § 360k failure to warn claims that were not based on a violation of FDA requirements to warn consumers, even where plaintiffs successfully alleged other violations of FDA regulations. See *Bass*, 669 F.3d at 515 (claims for negligence as based on manufacturer's failure to warn plaintiff that Class III device was adulterated were preempted by § 360k, as plaintiff did not plead that the manufacturer "failed to include FDA-approved warnings," even where manufacturing defect and negligent manufacturing claims survived "as they are parallel claims that do not impose different or additional requirements than the FDA regulations because [plaintiff] pleaded that [the manufacturer] failed to abide by the FDA regulations in the manufacture of the [device]"); *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1205 (8<sup>th</sup> Cir. 2010) ("The FDA's PMA approval includes specific language for Class III device labels and warnings.

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<sup>1</sup> The Plaintiff also cites to the Seventh Circuit's decision in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7<sup>th</sup> Cir. 2010). *Bausch*, however, dealt only with claims alleging a manufacturing defect, not failure to warn.



Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings”); *Gale*, 2013 WL 563403, at \*5 (dismissing one of two failure to warn claims where complaint “neither specific[ed] the legal basis for any such duty [to warn], nor to whom the duty [was] allegedly owed,” and concluding that duty to warn claim was “pre-empted because the FDA's premarket approval established the information [the manufacturer] was obligated to disclose”); *Purcel v. Advanced Bionics Corp.*, 3:07-CV-1777-M, 2010 WL 2679988, at \*6 (N.D. Tex. June 30, 2010) (“Plaintiffs' fraud by nondisclosure claim asserts that Bionics owed a duty to the Plaintiffs to disclose that the devices were adulterated. Plaintiffs cite no federal requirement obligating Bionics to warn them that the devices were adulterated. These claims of fraud by nondisclosure and negligence by failure to warn impose a requirement in addition to those approved by the FDA—the duty to warn consumers if devices are adulterated—and are therefore preempted by § 360k(a).”).

Courts have also held that a failure to warn claim may be based on a violation of the FDA’s continuing reporting requirements for manufacturers of Class III devices. See *Stengel*, 704 F.3d at 1232-33 (holding that proposed failure to warn claim was not preempted and was a claim paralleling federal law where plaintiffs alleged that manufacturer violated continuing duty to monitor the product after pre-market approval, to discover and report to the FDA any complaints about the product’s performance and any adverse health consequences, and to warn the FDA; the claim “rests on a state-law duty that parallels a federal-law duty under the MDA”); *Hughes v. Boston Scientific Corp.*,

631 F.3d 762, 776 (5<sup>th</sup> Cir. 2011) (the “failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]’s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the [device].”); *Gale*, 2013 WL 563403 (second of plaintiff’s failure to warn claims was not preempted because he successfully alleged that he was injured based on manufacturer’s failure to comply with the premarket approval’s monitoring and reporting requirements; allegation was “a state-law tort claim based on an alleged violation of a specific premarket approval requirement, and it link[ed] the federal violation to plaintiff’s injuries”); *Simmons v. Boston Scientific Corp.*, CV 12-7962 PA FFMX, 2013 WL 1207421 (C.D. Cal. Mar. 25, 2013) (“where a state law failure to warn claim is premised on a defendant’s failure to report to the FDA relevant adverse health consequences of its Class III device of which it became aware after obtaining PMA, such a claim would not be preempted, because FDA regulations require (rather than allow) recipients of PMA to file an adverse event report with the FDA”).

McConologue contends that the Defendant did not warn him that the allegedly mis-manufactured Liner implanted in his hip was defective at the time it was implanted. However, McConologue has failed to allege the existence of any FDA requirements applicable to consumer warnings such that the Court may determine whether a state failure to warn claim is “different from, or in addition to” FDA requirements and thus pre-empted, or contrastly whether the state duties “parallel, rather than add to, federal requirements” such that they are organic to or derivative of the device’s premarket approval and thus not preempted. *Riegel*,

552 U.S. at 330. He has also failed to allege both that Smith & Nephew violated any duty of continuing reporting pursuant to the FDA's premarket approval process, and how the Defendant violated such a requirement. In sum, the Plaintiff has not identified a federal law or regulation that his state duty to warn claim would parallel. Absent factual support in the record as to the federal law allegedly violated in connection with the failure to warn claim, Plaintiff has failed to sufficiently plead a parallel claim.

Defendant's motion to dismiss Plaintiff's failure to warn claim is GRANTED, without prejudice to the Plaintiff re-pleading this claim.

e. Products Liability: Design Defect

Paragraph 16(e)(ii) of the Plaintiff's complaint alleges that the Defendant was negligent in "designing, building and packaging the Liner in a defective manner." The Defendant contends that this claim must be dismissed as preempted pursuant to the MDA because it relates to the safety and effectiveness of the Ceramic Liner. Defendant further correctly contends that the Plaintiff's allegations relate only to the manufacture, not to the FDA-approved design, of its Ceramic Liner and thus Plaintiff's design defect claim is inadequately pled. According to the Defendant, this amounts to the Plaintiff conflating two separate claims for a manufacturing defect and a design defect. The Plaintiff, on the other hand, argues that manufacturing a Class III device in a manner that violates the FDA approved process, as in this case, constitutes the sale of a product that is dangerous to an extent beyond that which would be contemplated by the ordinary

consumer with the ordinary knowledge common to the community as to the product's characteristics, and thus his design defect claim is not preempted.

Here, the Plaintiff does not contend that the original design of the Ceramic Liner – which was FDA-approved pursuant to the premarket approval process – was defective. Rather, McConologue alleges a products liability claim predicated on a manufacturing defect, asserting only that the Liner was manufactured *contrary to its federally approved design specifications*, thereby making it unreasonably dangerous. As noted previously, the Plaintiff has effectively pled a manufacturing defect claim pursuant to Connecticut law. Under Connecticut law, “‘[p]roduct liability claim’ includes all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product.” Conn. Gen.Stat. § 52-572m(b). A 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.” *Id.* Connecticut merges the common law products liability theories and recognizes three basic theories of products liability: (1) manufacturing defects; (2) design defects; and (3) warnings defects. *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 165-66 (D. Conn. 2012) (SRU). A manufacturing defect is a flaw in the manufacturing process which causes the product to deviate from the design standards and intended specifications. *Miller*

*v. United Technologies Corp.*, 233 Conn. 732, 779 (1995). Contrastly, a design defect claim exists where the product is “unreasonably dangerous.” *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 214-15 (1997). Connecticut derives its definition of “ ‘unreasonably dangerous’ ” from comment (i) to § 402A [of the Restatement], which provides that ‘the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.’ ” *Id.* (citing 2 Restatement (Second), § 402A, comment (i)). See also *Vaccarelli v. Ford Motor Co.*, CV990153308, 2001 WL 862643 (Conn. Super. Ct. July 6, 2001) (same). This “consumer expectation” standard, the Court noted, is well-established in Connecticut strict liability law. *Potter*, 241 Conn. at 215.

McConologue has alleged that Smith & Nephew’s Ceramic Liner differed from the federally approved premarket manufacturing design specifications under which the Liner was deemed to be safe and effective for consumer use. A design defect claim exists where a product is defectively designed, allowing recovery where the product is “unreasonably dangerous.” *Potter*, 241 Conn. at 215. A products liability claim based on a design defect is a general intent tort claim for injury resulting from the intentional manufacture of a device in conformity with flawed design specifications. McConologue has not alleged that the design of the Liner was defective; instead he alleges that Smith & Nephew failed to manufacture the Liner in accordance with its FDA approved design specifications. Thus, the facts alleged in the complaint do not support a defective design claim.

The motion to dismiss the products liability claim premised on a design defect is GRANTED without prejudice to re-pleading.

f. Products Liability: Negligence

The Defendant alleges that the Plaintiff's product liability claim sounding in negligence – including that Smith & Nephew (1) failed to properly and adequately test the Liner prior to marketing it, (2) designed, built, and packed the Liner in a defective manner, and (3) failed to perform a proper study to evaluate whether the press settings that were being used to press the titanium rings onto the Liner were appropriate – is preempted pursuant to the MDA because the allegations relate solely to the safety and effectiveness of the Ceramic Liner. The Defendant contends that these allegations are “merely an attack on the PMA process itself, as PMA and supplemental PMA applicants are required to produce ample safety information to FDA before FDA approves the device, and manufacturers are still subject to strict FDA oversight even after their device has received PMA or supplemental PMA approval.” [Dkt. 16-1, MTD, p. 14]. Smith & Nephew further contends that these allegations, along with Plaintiff's allegation that the Defendant knew or should have known that the liners were being manufactured in violation of FDA approved manufacturing specifications yet continued their manufacture and distribution, amount to nothing more than conclusory assertions devoid of further factual enhancement, and thus are not well-pled.

As explained previously, the Plaintiff has successfully pled a manufacturing defect claim that is not preempted. For the same reasons, the

Plaintiff's negligence theory based on defective manufacturing of the Ceramic Liner survives.

However, Plaintiff's claims that Smith & Nephew (1) failed to properly and adequately test the Liner prior to marketing it, (2) designed and packed the Liner in a defective manner, and (3) failed to perform a proper study to evaluate whether the press settings that were being used to press the titanium rings onto the liner were appropriate fail the *Trombly* and *Iqbal* pleading standard as the only facts alleged in support of his claims are that the Liner was defectively or negligently manufactured as described above; the additional claims amount to nothing more than conclusory allegations and "naked assertion[s] devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678.

The Defendant's motion to dismiss Plaintiff's negligence claim on a negligent or defective manufacturing theory is DENIED. The Defendant's motion to dismiss the Plaintiff's failure to test, negligent design and packaging, and failure to perform a proper study or test claims is GRANTED without prejudice to re-pleading.

**g. Products Liability: Innocent and Negligent Misrepresentation**

McConologue has pled that "the defendant misrepresented to the plaintiff and third parties that the Liner was defective and unreasonably dangerous." [Dkt. 1-1, Compl. ¶ 16(c)]. The Defendant urges the Court to dismiss this misrepresentation claim as preempted under the MDA because it relates to the safety and effectiveness of the Liner, and "takes issue with language contained in

the FDA-approved product labeling and advertising.” [Dkt. 16-1, MTD p. 14]. The Defendant also urges that this claim must be dismissed as insufficiently pled because, if the Plaintiff is alleging fraudulent misrepresentation he has not met the heightened pleading standards of Rule 9(b), and if he is alleging negligent misrepresentation, he has not alleged the elements of the claim. The Plaintiff counters that “[s]ince the defective liner allegedly at issue in this case was never FDA approved, the representations accompanying that liner were not FDA approved for that liner. Therefore, any state tort law enforcement activities with respect to the representations accompanying this defective device are necessarily parallel to the federal requirements.” [Dkt. 19, Opp. to MTD, p. 18]. Thus, the crux of Plaintiff’s claim is that, because the Liner implanted in Mr. McConologue contained an alleged manufacturing defect, the FDA-approved warnings accompanying the Liner but intended for devices manufactured in accordance with the premarket approval process misrepresented the safety and efficacy of the specific mis-manufactured Liner. The Plaintiff also counters that he has alleged sufficient facts to plausibly support claims for negligent and innocent misrepresentation. As the Plaintiff has conceded that he has not plausibly alleged a fraudulent misrepresentation claim (see Dkt. 19, P’s Opposition, p. 24), this Court will consider only his innocent and negligent misrepresentation claims.

First, the Court declines to credit the Defendant’s preemption argument as Smith & Nephew has utterly failed to explain how the Plaintiff’s misrepresentation claim imposes requirements that are different from or in addition to requirements



imposed by federal law. Although the Defendant cites to various cases for the proposition that preemption is necessary because the claim challenges the Liner's FDA-approved label, the cases to which Defendant cites are inapposite as they are not premised on violations of federal law to which parallel state claims could attach. Here, in contrast, the Plaintiff has successfully pled a manufacturing defect claim, which informs his misrepresentation claim. See *Smith v. Depuy Orthopaedics, Inc.*, CIV.A. 11-4139 JAP, 2013 WL 1108555, at \*10 (D.N.J. Mar. 18, 2013) aff'd in part, 13-2148, 2014 WL 116288 (3d Cir. Jan. 14, 2014) (finding that device was safe and effective as per FDA's premarket approval and concluding that defective manufacture and misrepresentation claims were thus preempted); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197 (W.D.N.Y. 2011) (dismissing state tort law claims as preempted where plaintiff failed to allege facts implicating a violation of federal law); *Anthony v. Stryker Corp.*, 1:09-CV-2343, 2010 WL 1387790 (N.D. Ohio Mar. 31, 2010) (state tort law claims preempted where plaintiff did not specifically mention either the FDA or its regulations and did not plead any facts such that that the court could plausibly infer that defendant's noncompliance with FDA regulations led to his injury). Thus, this Court cannot at this juncture determine – based on the Defendant's argument – that the Plaintiff's misrepresentation claim is preempted pursuant to § 360k.

Nor is the Plaintiff's misrepresentation claim insufficiently pled. To establish a claim for negligent misrepresentation, a plaintiff must establish (1) that the defendant made a misrepresentation of fact (2) that the defendant knew

or should have known was false, (3) that the plaintiff reasonably relied upon the misrepresentation, and (4) that the plaintiff suffered pecuniary harm as a result thereof. *Glazer v. Dress Barn, Inc.*, 274 Conn. 33, 73 (2005); *Coppola Const. Co., Inc. v. Hoffman Enterprises Ltd. P'ship*, 134 Conn. App. 203, 208 (2012) aff'd, 309 Conn. 342 (2013). The elements of a claim for innocent misrepresentation are “(1) a representation of material fact (2) made for the purpose of inducing the purchase [of the product], (3) the representation is untrue, and (4) there is justifiable reliance by the plaintiff on the representation by the defendant and (5) damages.” *Matyas v. Minck*, 37 Conn. App. 321, 333 (1995).

The Defendant contends that the Plaintiff has failed to allege the second and third prongs of a negligent misrepresentation claim, and has failed to allege justifiable reliance to make out an innocent misrepresentation claim. The Plaintiff counters that, “[h]aving placed into the stream of commerce a defective product that the defendant made, it is reasonable to presume that the defendant either knew or should have known it was defective,” given the FDA representations about the safety of the device for its intended use as a Class III FDA approved device, and given that the device was defective. [Dkt. 19, Opp. to MTD, p. 24-25]. McConologue also contends that there was justifiable reliance by consumers and the physicians that implant the Ceramic Liners on the representations that the devices are safe, fit, and effective for their intended purposes, which representations are made for the purpose of inducing physicians to implant the devices into their patients. The Plaintiff admits, however, that the justifiable reliance element is not explicitly stated in his complaint, but contends that it is

**“plausibly inferred from the very nature of this transaction and the purposes behind requiring that Class III devices be designed, built and sold in accordance with the purportedly stringent requirements imposed by the PMA process.” [Dkt. 19, P’s Opp. to MTD, p. 26].**

**Here, McConologue has alleged that a Ceramic Liner manufactured by Smith & Nephew was implanted in his hip, that the Defendant conducted a recall of a batch of liners which included the Plaintiff’s because titanium rings were pressed onto the ceramic component with a higher force than allowed by the FDA’s manufacturing specifications, that the Plaintiff experienced squeaking and pain, that a CT scan revealed that the Liner was fractured, and that the Plaintiff underwent revision surgery that further confirmed the fracture in the Liner. Moreover, the parties agree that an R3 Ceramic Liner manufactured to FDA specifications would be FDA compliant and therefore reasonably safe and effective for its intended purpose, and that the Ceramic Liner is subject to the stringent requirements of the FDA’s premarket approval process, which preempts liability when an approved device complies with the federal standards it imposes. Given that the premarket approval process is lengthy and rigorous, and that it imposes numerous continuing obligations on manufacturers, who are held to particular manufacturing specifications, the Plaintiff has sufficiently alleged that Smith & Nephew should have known that a representation of safety and efficacy geared toward a device fully compliant with FDA requirements would be false as to a device with a manufacturing defect. Moreover, the fact of conferring Class III status on a medical device, by its nature, means that McConologue was entitled**

to reasonably rely on the warnings and representations made to his physician acting as a learned intermediary in deciding whether to implant the Ceramic Liner into the Plaintiff's hip. See, e.g., *Vitanza v. Upjohn Co.*, 257 Conn. 365, 376 (2001) ("The learned intermediary doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment."). The Defendant's motion to dismiss the Plaintiff's misrepresentation claim is DENIED.

#### **h. Products Liability: Breach of Warranty**

Smith & Nephew urges dismissal of the Plaintiff's claims for breach of express and implied warranty as preempted by the MDA because the claims challenge the safety and effectiveness of the Ceramic Liner and, for Plaintiff to prevail, the Defendant contends that the Court would have to find that the device was *not* safe and effective. The Defendant argues that this finding would contradict the FDA's determination of safety and effectiveness when it granted approval to the Liner pursuant to the premarket approval process.

The Defendant's argument, however, again refuses to recognize the Plaintiff's sufficient allegation that the Ceramic Liner was manufactured in violation of FDA standards, which allegedly undermined the device's safety and

effectiveness. The Plaintiff has alleged a violation of federal law, and the Defendant has failed to demonstrate how the requirements of state law causes of action for breach of warranty add to or differ from these requirements. Moreover, the cases to which the Defendant cites are inapposite, as each found state tort law claims to be preempted where the plaintiff failed to sufficiently plead a violation of the FDA requirements governing the devices. That is not the case here, as McConologue has pleaded a violation of the device's manufacturing standards. See *Horowitz*, 613 F. Supp. 2d at 282 (dismissing as preempted state law tort claims – including those for breach of express and implied warranty – where plaintiff failed to allege sufficient facts substantiating her claim that hip replacement device violated federal requirements and “failed to demonstrate that the injuries she sustained resulted from the federal violations spelled out in the warning letters” attached to her complaint); *Bertini v. Smith & Nephew, Inc.*, 13 CIV. 0079 BMC, 2013 WL 6332684 (E.D.N.Y. July 15, 2013) (holding that “[b]ecause they failed to plausibly show that the R3 liner is defective, plaintiffs have also failed to plead a necessary element of their implied warranty claim;” and where plaintiffs failed to allege sufficient facts to support breach of warranty claim).

Indeed, courts have held that, where a plaintiff has pled a defective manufacturing claim, a state law claim for breach of implied warranty of merchantability is not preempted. See *Gelber*, 788 F. Supp. 2d at 166 (“Plaintiffs allege that defendants breached their implied warranty of merchantability by selling plaintiffs an adulterated device because the Trident System was unfit for its ordinary purpose. Plaintiffs’ implied warranty claims are not preempted to the

extent they allege a defective manufacturing claim.”). Several courts that have addressed whether implied warranty claims are preempted after *Riegel* have determined that, to the extent the plaintiff relies on the failure to comply with the FDA's requirements in asserting his breach of implied warranty claim, such claims may proceed. *Bass*, 669 F.3d at 517 (“Most post-*Riegel* cases that have found implied warranty claims preempted either concluded that the claims failed to rely on violations of the FDA's requirements, or the plaintiff pleaded that the defendants complied with the FDA's requirements. We agree with the courts that hold that an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements and can ultimately show a causal link between the violation and the breach of the implied warranty. If, however, the plaintiff claims that the defendant breached the implied warranty despite its compliance with FDA requirements, that claim is clearly preempted, as it would be “ ‘different from, or in addition to,’ the requirements imposed by federal law.”) (collecting cases).

The Defendant has failed to articulate how these claims are preempted. Smith & Nephew’s motion to dismiss these claims based on preemption is DENIED.

The Defendant also argues that both the express and implied warranty claims must be dismissed because they are inadequately pled, unsupported by sufficient facts, and conclusory. The elements for a claim for breach of warranty in Connecticut are: (1) existence of the warranty; (2) breach of the warranty; and, (3) damages proximately caused by the breach. *Motley v. Jaguar Land Rover N.*

*Am.*, LLC, X03CV084057552S, 2012 WL 5860477 (Conn. Super. Ct. Nov. 1, 2012);  
*Gerrity v. R.J. Reynolds Tobacco Co.*, 399 F. Supp. 2d 87, 90 (D. Conn. 2005);  
*Omega Eng'g, Inc. v. Eastman Kodak Co.*, 30 F. Supp. 2d 226, 246 (D. Conn. 1998).

An express warranty is defined under Conn. Gen. Stat. § 42a-2-313(1) as:

(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 good shall conform to the sample or model.

Conn. Gen. Stat. § 42a-2-313(1). The Defendant contends that McConologue's express warranty claim must fail because he has failed to set forth the terms of the warranty upon which he relied, and instead merely states that the Defendant "breached its express warranty that the Liner was safe and effective for its intended use," unsupported by any factual content. [Dkt. 1-1, Compl. ¶16(g)].

The Court first notes that each of the cases to which the Defendant cites is based on New York tort law, whose relevance to a case premised on Connecticut law the Defendant fails to explain. However, although the parties seem to agree that the FDA approved Smith & Nephew's Ceramic Liner pursuant to its premarket approval process for Class III devices, which itself warrants with "reasonable assurance" that the Liner was safe and effective for use, the complaint fails to state this, and thus there are no allegations in the complaint

that demonstrate the existence of an express warranty. The Plaintiff's express warranty claim is thus DISMISSED without prejudice to repleading.

As to the implied warranty of merchantability, courts have held that "because the CPLA is silent as to the elements of a cause of action for breach of warranty," plaintiffs may rely on the Connecticut Uniform Commercial Code, Title 42a of the Connecticut General Statutes. *Walters v. Howmedica Osteonics Corp.*, 676 F. Supp. 2d 44, 55 (D. Conn. 2009); *Johnson v. Sears Roebuck & Co.*, No.3:05-cv-139(JCH), 2007 WL 2491897, at \*4 (D. Conn. Aug. 29, 2007); *Kuzmech v. Werner Ladder Co.*, 3:10-CV-266 VLB, 2012 WL 6093898 (D. Conn. Dec. 7, 2012). Conn. Gen. Stat. § 42a-2-314 states that "[u]nless excluded or modified ... 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(a). Smith & Nephew does not allege that it was not a merchant, nor does it allege that an implied warranty of merchantability did not apply to its sale of the R3 Ceramic Liner. Instead, the Defendant alleges that Plaintiff's claim is inadequately pled because he has failed to factually support his claim that the Liner used in his surgery was defective. Contrary to Defendant's argument, however, McConologue has successfully alleged that the Liner was defectively manufactured. Thus, the Plaintiff has successfully pled that the Liner was not of merchantable quality at the time it was implanted in his hip. Therefore, Smith & Nephew's motion to dismiss the Plaintiff's implied warranty claim is DENIED.

## V. Conclusion



For the foregoing reasons, the Defendant's [Dkt. 16] Motion to Dismiss the Complaint is GRANTED in part and DENIED in part. The Plaintiff shall file an amended complaint within twenty-one (21) days of the date of this Order, or by April 15, 2014.

IT IS SO ORDERED.

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Hon. Vanessa L. Bryant  
United States District Judge

Dated at Hartford, Connecticut: March 24, 2014