UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RANDALL NAGEL and KAREN NAGEL, *Plaintiffs*, v. SMITH & NEPHEW, INC., *Defendant*.	No. 3:15-cv-00927 (JAM)

RULING GRANTING MOTION TO DISMISS

This is a products liability case involving an artificial hip-replacement device that was implanted in plaintiff Randall Nagel and manufactured by defendant Smith & Nephew, Inc. The device included a metal liner that allegedly harmed plaintiff. Because of severe medical complications stemming from the failure of the metal liner, plaintiff had to undergo surgery to have the metal liner removed.

The legal issue before me is whether plaintiff and his spouse may seek state law tort relief against the defendant device manufacturer. I conclude that federal law largely preempts plaintiff's state law claims and that to the extent his claims are not preempted by federal law, plaintiff has failed to plausibly allege sufficient facts that would give rise to grounds for relief. Accordingly, I will grant defendant's motion to dismiss.

BACKGROUND

The following facts are taken from those alleged in the complaint. In 2010, plaintiff Randall Nagel underwent surgery to have an artificial hip implanted in his body. The hip device and its components were manufactured by defendant Smith & Nephew, Inc. Plaintiff's hip socket and ball joint were replaced by a titanium alloy ball-and-socket prosthetic known as the REFLECTION 3 Acetabular System ("R3 System"). Part of the system required the use of a

liner component. With plaintiff's consent, plaintiff's surgeon chose to use a metal liner (the "R3 metal liner") rather than a polymer plastic liner that was part of the original R3 system.

Plaintiff developed severe medical complications from the hip replacement device, including the growth of a pseudotumor and significant pain. Blood testing indicated abnormal amount of metal content in his blood, consistent with failure of the metal liner. In early 2015, plaintiff underwent surgery to have the metal liner removed.

Medical devices like those implanted in plaintiff are subject to federal regulatory requirements as overseen by the Food and Drug Administration (FDA). A company that seeks regulatory approval for a medical device may ordinarily seek approval in one of two ways. First, the company may pursue a rigorous premarket approval (PMA) process that entails scrupulous evaluation of the device's safety and effectiveness. Alternatively (and far more commonly), if the device in question is substantially similar to another PMA-approved product that is already in use, then the company may instead pursue a more streamlined approval process known as § 510(k) clearance that involves premarket notification to the FDA. *See Medtronic v. Lohr*, 518 U.S. 470, 477–79 (1996); Phillip G. Palmer, Jr., *Medical Device Immunity: Should Promotion of Off-Label Uses Leave Medical Device Manufacturers Vulnerable to Unlimited Liability?*, 35 J. Legal Med. 553, 558–60 (2014).

The R3 system that plaintiff received was approved by the FDA in 2006 using the streamlined § 510(k) clearance process. But it was approved with the use of a plastic polymer liner, not the metal liner that was eventually implanted in plaintiff. The R3 metal liner was originally approved by the FDA in 2008 as part of a *different* hip replacement system known as the Birmingham Hip Resurfacing (BHR) system, which contained all-metal components. In contrast to the streamlined § 510(k) clearance process by which the R3 system (with its use of a

polymer liner) was approved, the BHR system (with its use of the R3 metal liner) was subject to the demanding PMA approval process.

Several months after the approval of the R3 metal liner with the BHR system, defendant issued a press release in 2009 indicating that the R3 metal liner could be used by hip replacement surgeons in conjunction with the R3 system. But beginning in 2008, studies showed that "metal-on-metal" hip replacement systems with metal liners similar to the R3 metal liner had higher revision rates (meaning that the patient had to have the implant removed) than with plastic liners. In 2010, two unrelated metal-on-metal hip replacement systems underwent voluntary recalls by the manufacturers. In May 2011, the FDA instructed manufacturers of metal-on-metal systems to conduct postmarket surveillance. From January 2008 through May 2014, the FDA received 317 adverse event reports regarding the R3 system and the R3 metal liner.[1] In June 2012, defendant voluntarily recalled all R3 metal liners from the market after finding a higher than expected number of revision surgeries on patients with those liners. After 2012, studies across the world continued to show higher revision rates for metal-on-metal systems.

In 2014, plaintiff began having discomfort in his implanted hip. Examination showed that the implant was failing, that plaintiff had developed a pseudotumor, and that plaintiff had elevated metal levels in his blood. In February 2015, plaintiff had surgery to remove the R3 metal liner and the pseudotumor.

Plaintiff now brings a number of claims based on the harm caused to him by the R3 metal liner used with his R3 system. According to plaintiff, "[t]he Liner was in an unsafe and unreasonably dangerous condition, was inherently unsafe, and could not be used without subjecting [him] to an unreasonable risk of injury" because the "R3 metal acetabular liner has

[1] The complaint is not clear if these 317 complaints were about each component individually, or both in combination with each other.

been linked to the accelerated release of metal debris and ions into the body and/or blood stream from articular abrasion with the femoral head, excessive liner wear, liner breakage, corrosion, or a combination of these elements," which he himself experienced. Doc. #17 at 6.

Through the PMA process, plaintiff claims, the FDA approved the R3 metal liner "for use only with Smith & Nephew's [BHR] System" and "did not receive FDA approval to be used with the R3 System or with any other total hip replacement system." Doc. #17 at 5. Any commercial marketing or sale of the R3 metal liner that did not conform to the conditions described by the FDA in its PMA approval was a violation of the Food, Drug, and Cosmetics Act (FDCA), plaintiff contends. At the time plaintiff received his hip replacement, defendant was marketing the R3 metal liner for use with the R3 system.

Plaintiff alleges that defendant failed to warn him of the R3 metal liner's defects, because it did not test the R3 metal liners, report adverse events, or warn the FDA often or well enough to comply with FDA requirements for devices that have received premarket approval, and it also failed to comply with the FDA's postmarket surveillance obligations. Plaintiff further alleges that defendant was negligent in not testing the R3 metal liners with enough sufficiency and care as required by the FDA, and that defendant misrepresented information to the FDA that resulted in inadequate warnings being approved by the FDA for the R3 metal liner.

Plaintiff now brings this lawsuit alleging one count with multiple theories of liability.[2] He alleges strict liability for the product's manufacture, design, and inadequate warning; negligence in manufacture, design, and warning; and breach of implied warranty. Plaintiff also complains that defendant negligently misrepresented the safe use of the R3 metal liner with the R3 system in violation of state and federal law. Defendant has moved to dismiss the complaint in its

[2] The complaint includes a second count by co-plaintiff Karen Nagel for loss of consortium that is wholly derivative of the first count.

entirety, contending that plaintiff's claims are either preempted by federal law or that plaintiff has failed to allege sufficient facts to establish plausible grounds for relief. Doc. #21.

DISCUSSION

The principles governing this Court's consideration of a Rule 12(b)(6) motion are well established. First, the Court must accept as true all factual matter alleged in a complaint and draw all reasonable inferences in the plaintiff's favor. *See Johnson v. Priceline.com, Inc.*, 711 F.3d 271, 275 (2d Cir. 2013). But, "'[t]o 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.'" *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Preemption

It is well established that Congress may preempt state law, whether expressly or impliedly, if state law is in conflict or otherwise inconsistent with federal law in a manner that defeats the federal purpose. *See Arizona v. United States*, 132 S. Ct. 2492, 2500–01 (2012). But a federal statute will not be found to preempt claims arising under state law unless the express or implied intent of Congress to do so is "clear and manifest." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Federal law regulates medical devices of the type at issue in this case pursuant to the Medical Device Amendments (MDA) to the FDCA. *See* 21 U.S.C. § 360c *et seq.*; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008) (describing MDA's "regime of detailed federal oversight"). Under the MDA, medical devices are grouped into three classes based on the risks that the type of device presents; a Class III device of the type at issue in this case is subject to the

most stringent review and oversight protections. *See id.* at 317; *Simoneau v. Stryker Corp*., 2014 WL 1289426, at *1 (D. Conn. 2014).

Apart from its detailed regulatory oversight requirements, the MDA largely insulates manufacturers of approved medical devices from state law tort claims if the manufacturer has complied with federal regulatory requirements. The MDA has an express preemption clause that bars the application of any state law that would impose any requirement which is "different from, or in addition to" any federal MDA requirement. *See* 21 U.S.C. § 360k(a); *see also Riegel*, 552 U.S. at 316. Moreover, in addition to the MDA's express preemption clause, the Supreme Court has otherwise held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA rather than on some independent state law duty. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (state law claim alleging fraud-on-the-FDA preempted because dependent entirely on federal law obligations of disclosure to the FDA).

Importantly, the scope of federal preemption may vary depending on whether a medical device has been subject to approval by means of the rigorous PMA process or if it has been subject to approval by means of the streamlined § 510(k) clearance process. A plaintiff who wishes to pursue state law claims involving a PMA-approved medical device must carefully frame his claim to avoid either express preemption or implied preemption under the MDA. On the one hand, the plaintiff must allege a state law claim that runs parallel to a federal law claim (or else the state law claim is expressly preempted under § 360k(a), because it would rely on a requirement that is "different from" or "in addition to" the FDCA requirements). Yet on the other hand, the plaintiff's claim must not rely solely on a requirement that is already imposed under the FDCA (or else the claim is impliedly preempted under *Buckman*).

Thus, a plaintiff must navigate a "narrow gap" to advance a parallel state law claim involving conduct that amounts to a violation of federal regulatory requirements but which claim is not wholly derivative of federal law. *See In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "It's no wonder," as Judge Gorsuch has suggested, "that the difficulty of crafting a complaint sufficient to satisfy all these demands has been compared to the task of navigating between Scylla and Charybdis." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1334, 1340 (10th Cir. 2015).

Such is the daunting preemption hurdle for any state law claims involving medical devices that have been subject to rigorous PMA approval. By contrast, preemption looms less likely for state law claims involving devices that have gained federal approval by means of the streamlined § 510(k) clearance process. Because the § 510(k) clearance process does not involve the same type of federal safety-and-effectiveness review as the PMA approval process, the Supreme Court has made clear that claims involving such § 510(k)-cleared devices are *not* subject to the MDA's express preemption provision under § 360k(a). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Accordingly, a far less demanding standard of only implied preemption applies for state law claims involving devices that have been approved by means of the § 510(k) clearance process.

All that said, a further question remains about what level of preemption should apply in the context of a device subject to mixed levels of approval. For example, what level of preemption should apply where a plaintiff's claim involves a component of a device (here, the R3 metal liner) that was initially approved within a device (here, the BHR system) that gained the FDA's approval by way of the rigorous PMA process, but which component (here, the R3

metal liner) is later used with a *different* device (here, the R3 system) that the FDA has approved only by means of the streamlined § 510(k) clearance process?

Courts that have previously considered claims like plaintiff's claim have reached differing conclusions. Several courts have concluded that a state law claim that challenges the safety and effectiveness of the R3 metal liner—which was subject to rigorous PMA approval as part of the BHR system—will be preempted by the MDA's express preemption clause typically associated with PMA-approved devices, notwithstanding that the R3 metal liner has been incorporated into the § 510(k)-approved R3 system. *See Shuker v. Smith & Nephew, Inc.*, 2015 WL 1475368, at *8–10 (E.D. Pa. 2015); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 254, 255 (E.D.N.Y. 2014); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 404–06 (S.D.N.Y. 2013).

But other courts have disagreed and concluded that a claim involving a § 510(k)-cleared device should not be subject to the MDA's express preemption clause merely because a component material of a PMA-approved device has been incorporated into the § 510(k)-cleared device. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 751–52 (S.D.W. Va. 2014). One of my colleagues on this Court has also recently declined to recognize express preemption of a very similar claim alleging failure of a § 510(k)-approved hip replacement system in combination with a PMA-approved liner "because the combination of component parts . . . had not undergone the premarket approval process." *Lafountain v. Smith & Nephew, Inc.*, 2016 WL 3919796, at *6 (D. Conn. 2016).

I am persuaded by the initial line of cases that applies the MDA's express preemption clause to claims involving device components subject to mixed levels of approval, particularly in the context of the allegations that are present in this case, which focus on harm allegedly caused

either independently by the PMA-approved R3 metal liner, or by the R3 metal liner's interaction with the R3 system (and as distinct from any harm stemming from the § 510(k)-approved R3 system not related to the PMA-approved R3 metal liner).[3] Because the FDCA does not prohibit off-label use of a component within a PMA-approved device in another medical device, I conclude that a manufacturer should not lose the protections of express preemption under § 360k(a) because of a surgeon's permissible choice to use the PMA-approved component in a § 510(k)-approved device, even if the interaction of the two components causes problems. *See* 21 U.S.C. § 396 (off-label use or promotion not prohibited).

Indeed, the term "device" under the FDCA includes "any component, part, or accessory," 21 U.S.C. § 321(h), and once a device—including its components—is approved, then the manufacturer is required to produce and market the device—including its components—in accordance with the specifications approved by the FDA. *See Shuker*, 2015 WL 1475368, at *9. A physician may then take approved devices, or parts of devices, and use them "off label"—or in a manner inconsistent with the manufacturer's label or FDA approval—and such use by a physician does not mean that the *manufacturer* somehow violated federal law. *See ibid* (noting that "[a] physician's decision to use a PMA-approved device off-label does not change the manufacturer's obligation to produce and market the device with almost no deviations from the

[3] *See* Doc. #17 at 6 ("R3 metal acetabular liner has been linked to the accelerated release of metal debris and ions into the body and/or blood stream" and "recalled all batches of R3 metal liners from the market"); *id.* at 7 ("the failure and revision rates for total hip replacements with the defective R3 metal liner have been significantly higher than the standard revision rates"); *id.* at 11 (describing that the plaintiff had the "recalled R3 Acetebular Metal Liner" removed surgically) and ("At all times mentioned herein, the R3 metal acetabular liner, both by itself and in articulation with the R3 Acetabular System, generated an adverse reaction in the Plaintiff Randall Nagel including the accelerated release of metal debris and ions into his body."); *id.* at 13 ("Had Plaintiff Randall Nagel known that the R3 System had an increased rate of failure due to the defects set forth herein, Plaintiff would not have elected to use the R3 metal liner for his total hip replacement."); *id.* at 13–14 ("The Plaintiff's injuries and damages were caused as a result of Defendant Smith & Nephew's violations of the Connecticut Product Liability Act . . . related to the design, testing, fabrication, assembly, manufacturing, construction, repair, packaging, composition of instructions, compositions of warnings, labeling, marketing, and sale of the R3 acetabular metal liner in one or more of the following respects"). The complaint's main count includes dozens of paragraphs and subparagraphs describing the various harms.

specifications in its approval application," and "[h]ence, the mere fact a device is used off-label does not render [express preemption under] § 360k(a) inapplicable"); *see also Caplinger*, 784 F.3d at 1344–47 (rejecting argument that express preemption does not apply to off-label use of a device); *Otis-Wisher v. Medtronic, Inc.*, 616 Fed Appx. 433, 435 & n.2 (2d Cir. 2015) (noting that the "weight of authority both in this Circuit and elsewhere casts doubt on the viability of such claims" based on allegedly fraudulent off-label promotion).

Accordingly, based on my conclusion that the MDA's high standard of both express and implied preemption should apply in this case, I will evaluate each of plaintiff's state law claims to consider whether it alleges a sufficiently "parallel" state law claim that navigates the "narrow gap" to escape preemption. Then, to the extent that any aspect of the complaint may allege such a claim, I will consider in turn whether the facts alleged in support of such a claim otherwise afford plausible grounds for relief.

Plaintiff's Claims

All of plaintiff's state claims are governed by the Connecticut Product Liability Act, 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 Gerrity v. R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 126 (2003) ("[T]he legislature clearly intended to make our products liability act an exclusive remedy for claims falling within its scope."). A plaintiff may nonetheless assert various common law theories of liability under the statute. *See Simoneau*, 2014 WL 1289426, at *5); *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."). Plaintiff here has asserted claims for strict product liability, failure to warn, misrepresentation, negligence, and breach of implied warranty of merchantability.

Strict Products Liability

In order to prevail on a strict products liability claim under Connecticut law, plaintiff must prove, *inter alia*, that the product was in a defective condition that was unreasonably dangerous to the plaintiff, and further that the defect caused the injury for which compensation is sought. *See D'Ascanio v. Toyota Indus. Corp*., 309 Conn. 663, 673–74 (2013). "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); *see also Simoneau*, 2014 WL 1289426, at *5 (same).

The gravamen of plaintiff's complaint is that he was harmed by the release of metal in his body from the R3 metal liner when used off-label. The complaint does not allege facts that are based on defendant's violation of any FDA manufacturing requirements, or deviation from the FDA-approved design, in the manufacture or design of the R3 metal liner implanted in plaintiff. Plaintiff's claim, then, seems to be simply that the FDA-approved design—despite the FDA's approval—still caused him harm.[4] Such state-law claims, if allowed, would "cast doubt on the FDA's findings concerning the safety of that device's design and, thus, are categorically preempted by the MDA." *Simoneau*, 2014 WL 1289426, at *9 (citing *Riegel*, 552 U.S. at 330). Recalls and FDA sanctions may constitute evidence of a defect if the facts underlying those actions support a claim that the manufacturer or designer deviated from the FDA-approved standards, s*ee id.* at *7–8, but here plaintiff has alleged only facts that indicate a higher-than-wished revision rate, not that defendant violated FDA standards. There are no allegations that the

[4] As noted above, the FDCA does not regulate off-label use, and so no state-law claim may lie for harm resulting from off-label use of an FDA-approved device. *See* 21 U.S.C. § 396 (off-label use or promotion not prohibited).

R3 metal liner was not designed and manufactured in accordance with the FDA-approved design and manufacturing specifications. *See, e.g.*, *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 106 (D. Conn. 2014) (state law claim not preempted where 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"). Because plaintiff fails to state facts alleging that the R3 metal liner was defective in its FDA-regulated manufacture or design, the complaint does not sufficiently allege a parallel state law claim and, therefore, is preempted.

Failure-to-warn

Under Connecticut law, a manufacturer is liable for failure to warn if the plaintiff "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. Ann. § 52-572q. The duty to warn of such defects exists both before and after the sale of a product. *See Densberger v. United Techs. Corp.*, 297 F.3d 66, 71 (2d Cir. 2002). To determine whether warnings were required or adequate, courts must consider

> (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. Ann. § 52-572q(b).

Plaintiff alleges facts insufficient to indicate that defendant failed to comply with FDA requirements regarding reporting adverse events that would provide the basis for a parallel state law claim. *See Simoneau*, 2014 WL 1289426, at *10 ("To be parallel, Simoneau's theory of strict liability for inadequate warnings or instructions must be premised on a violation of FDA

requirements.") While plaintiff alleges that defendant failed "to comply with the FDA's premarket approval monitoring and reporting requirements," to "discover and report to the FDA" any adverse events, and to "warn the FDA . . . that the R3 acetabular metal liners had been released by the Defendant into the stream of commerce with significant safety concerns," these claims are wholly conclusory. Plaintiff does not allege facts indicating that defendant knew of adverse events and did not report them to the FDA, nor that defendant avoided doing testing required by the FDA and that it was this non-reporting that caused the injury to plaintiff in this case. Accordingly, plaintiff's failure-to-warn claim is preempted as it fails to plead facts that would state a claim for a parallel federal violation.

Misrepresentation

Under Connecticut law, a claim for negligent misrepresentation lies when a defendant "made a misrepresentation of fact . . . that the defendant knew or should have known was false, [and] that the plaintiff reasonably relied upon the misrepresentation, and . . . suffered pecuniary harm as a result thereof." *Glazer v. Dress Barn, Inc*., 274 Conn. 33, 73 (2005); *see also McConologue*, 8 F. Supp. 3d at 112 (upholding a misrepresentation claim when the product had a manufacturing defect). Plaintiff alleges that defendants violated federal law by "marketing the R3 metal acetabular liner for use in applications other than the [BHR] System" and in so doing, also violated state law.

Federal law does not explicitly ban off-label promotion unless it is false or misleading. *See United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) (finding that "the FDCA itself does not expressly prohibit or criminalize off-label promotion"); *see also Shuker*, 2015 WL 1475368, at *14. Because the FDCA does not prohibit off-label use or promotion, off-label state-law misrepresentation claims are preempted under § 360k. *See Bertini*, 8 F. Supp. 3d at 255; *Caplinger*, 784 F.3d at 1345 (noting that *Riegel* preempted "any state safety requirement

differing from or adding to the body of federal regulations . . . even if that requirement comes in the guise of a general tort suit addressing only safety issues relating to off-label uses"). *But see Ramirez v. Medtronic Inc*., 961 F. Supp. 2d 977, 990 (D. Ariz. 2013) (allowing a federal and parallel state-law misbranding medical device claim). Courts have thus found that there is no parallel claim under federal law that may be pled alongside a state law misrepresentation claim based on off-label use alone that would allow such a claim to survive. *See Caplinger,* 784 F.3d at 1341–42; *cf. McConologue,* 8 F. Supp. 3d at 112.

There is no parallel claim pled here. Plaintiff's claim of misrepresentation is based on defendant's press release that states that the R3 metal liner may be used with the R3 system, which plaintiff claims constitutes "marketing" the R3 metal liner for off-label use. There is no federal claim for off-label marketing, so no state-law claim can survive. And insofar as there is a viable federal claim for false or misleading off-label marketing, plaintiff has alleged no facts in support of such a claim. Plaintiff has not sufficiently alleged that the marketing was false or misleading to constitute a parallel federal claim, and therefore the claim of misrepresentation is preempted.

Negligence

Plaintiff alleges that defendant "knew or should have known in the exercise of reasonable care that it should inspect, test, and monitor the R3 acetabular liners, and the process of manufacturing the metal liners, as required under the FDA's premarket approval monitoring and reporting requirements." Doc. #17 at 14. But again, plaintiff has pled no facts that would show that defendant did not do the necessary testing or did not follow the FDA specifications for manufacture and therefore was in violation of FDA requirements. Allowing a plaintiff to claim that a particular testing or manufacturing regime was negligently inadequate, despite being

required or allowed by the FDA, would establish an additional requirement beyond federal law and is subject to express preemption under § 360k. To the extent that plaintiff's negligence claims are not subject to express preemption, these claims—the "building/manufacturing [of] the R3 acetabular metal liners in a defective manner" and "that the defendant should have known . . . that the liners . . . failed to work as well" as other liners used in hip replacement systems—lack any plausible factual allegations to give rise to any grounds for relief.

Implied warranty of merchantability

Under Connecticut law, an implied warranty of merchantability arises from the Connecticut Uniform Commercial Code. *See* Conn. Gen. Stat. § 42a-2-314(a). To be merchantable, the goods must be "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." *Simoneau*, 2014 WL 1289426, at *13. Plaintiff claims that defendant violated the implied warranty of merchantability of the R3 metal liner based on factual allegations that the R3 metal liner did not work as well as other liners, that it had a high likelihood of causing complications, and that defendant knew the R3 metal liner was being used off-label.

Construing all of the plaintiff's federal violation pleadings liberally, it is difficult to find a parallel claim that does not add new requirements to the existing FDA testing, reporting, and approval regime that the R3 metal liner was subject to as a PMA-approved device. As far as plaintiff's claims would demand a more safely-designed liner or more reporting to the FDA to conform to the implied warranty, those state law claims add requirements that are preempted. *See Bertini*, 8 F. Supp. 3d at 260. And as far as plaintiff's claims rely on off-label use, such claims are preempted for the reasons stated above.

Leave to Amend

Finally, plaintiff has sought leave to file a second amended complaint in the event I grant defendant's motion to dismiss. Federal Rule of Civil Procedure 15(a)(2) provides that leave to amend a complaint shall be "freely" given when "justice so requires." "It is within the sound discretion of the district court to grant or deny leave to amend." *WC Capital Mgmt., LLC v. UBS Sec., LLC*, 711 F.3d 322, 334 (2d Cir. 2013).

A court may deny leave to amend as futile if "a proposed claim could not withstand a motion to dismiss pursuant to Rule 12(b)(6)." *Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002). In requesting leave to amend in his opposition to the pending motion to dismiss, plaintiff has not indicated what changes he would make to survive a future challenge under Rule 12(b)(6), but rather steadfastly asserts that his first amended complaint is sufficient. *See* Doc. #31 at 40.

While I understand that plaintiff filed his original complaint in state court, plaintiff has already attempted one amended complaint in federal court. That amended complaint failed to allege any facts that would plausibly support the contention that defendant violated requirements established by the FDA for the R3 metal liner. Plaintiff's underlying theory of the case—that the PMA-approved R3 metal liner, in conjunction with the R3 system, caused harm—is otherwise expressly preempted under §360k. *See Shuker*, 2015 WL 1475368, at *17; *Simon v. Smith & Nephew, Inc.*, 18 F. Supp. 3d 423, 429 (S.D.N.Y. 2014) (denying leave to amend for similar claim involving R3 metal liner). Plaintiff has not suggested that he is missing discovery on vital facts about how the defendant deviated from the FDA requirements in the design, manufacture, or testing of the R3 metal liner, nor has he suggested what facts he would add to bolster the claim that defendant's representations regarding the R3 metal liner were misleading or false. Therefore,

I will not allow leave to file a second amended complaint on the grounds that such pleading would be futile.

CONCLUSION

I conclude that the complaint does not allege claims that are not either preempted or that give rise to plausible grounds for relief. Accordingly, I GRANT defendant's motion to dismiss (Doc. #21) with prejudice. The Clerk is ordered to close this case.

It is so ordered.

Dated at New Haven this 28th day of July 2016.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge