UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA WARREN, et al.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:10 CV 1346 DDN
	)	
HOWMEDICA OSTEONICS CORP. and STRYKER CORP.	)	
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This action is before the court on the motion of defendants Howmedica Osteonics Corp. and Stryker Corporation to dismiss. (Doc. 2.) All of the parties have consented to the exercise of plenary authority by the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(c). (Doc. 16.) Oral arguments were heard on September 20, 2010.

I. BACKGROUND

On June 7, 2010, plaintiffs Pamela and David Warren commenced this action against defendant Howmedica Osteonics Corp. (Howmedica) in the Circuit Court of St. Louis County. (Doc. 1-1 at 4.) Howmedica Osteonics Corp. and Stryker Corporation[1] removed the action to this court under 28 U.S.C. § 1441, on the bases of federal question, diversity, and supplemental jurisdiction. (Doc. 1 at ¶¶ 10-12.)

[1]In the Missouri circuit court plaintiffs sued only defendant Howmedica Osteonics Corp., which was alleged to be doing business as or was formerly known as Stryker, Stryker Corporation, and/or Stryker Orthopaedics. (Doc. 1-1.) The removal petition was filed by Howmedica and Stryker Corporation. (Doc. 1.) Until clarified by the parties and ordered otherwise by the court, both Howmedica Osteonics Corp. and Stryker Corporation will be shown as the named defendants. Both are referred to in this Memorandum and Order jointly either as "Howmedica" or in the singular as "defendant".

Plaintiffs allege the following facts in their complaint:

Surgeries and Malfunction

On July 13, 2004, Pamela Warren underwent a right hip arthroplasty at Des Peres Hospital. (Doc. 1-1 at ¶ 7.) As part of the procedure, a Stryker Trident Ceramic Acetabular System ("Trident System") was implanted in her body. (Id. at ¶¶ 6-7.) The Trident System is an artificial hip replacement device that includes a metal Trident PSL Acetabular Shell ("PSL Shell"), an alumina ceramic insert, and a ceramic femoral head. (Id. at ¶ 7.) The PSL Shell was manufactured, packaged, labeled, marketed, and sold by defendant. (Id. at ¶¶ 6.)

On January 18, 2005, Pamela Warren underwent a left hip arthroplasty at Des Peres Hospital, and a second Trident System, including a PSL Shell, was implanted in her body. (Id. at ¶ 8.)

On July 24, 2007, the PSL Shell in Pamela Warren's right hip malfunctioned, such that "the ceramic lining of the PSL Shell prosthesis fractured, with migration of several of the fragments inferiorly." (Doc. 1-1 at ¶ 9.) As a result, the PSL Shell caused Pamela Warren bodily injuries and made clicking and squeaking sounds. (Id. at ¶ 10.)

Pamela Warren underwent additional surgery to repair the malfunctioning PSL Shell in her right hip. (Doc. 1 at ¶ 12.)

FDA Regulations and Reporting

On February 3, 2003, defendant received approval from the Food and Drug Administration ("FDA") to sell its Trident System in the United States. (Id. at ¶ 15.) As reported through FDA modification submissions, on May 25, 2004, defendant increased the wall thickness of Trident "T" Acetabular Shells. (Id. at ¶ 16.) On March 14, 2006, defendant changed the manufacturing process for ceramic femoral heads and inserts. (Id.) On July 7, 2006, defendant implemented two geometrical modifications to the Trident Constrained Acetabular Insert. (Doc. 1-1 at ¶ 16.)

Recalls

On March 13, 2006, after an inspection by the FDA, defendants recalled a batch of Trident PSL HA Solid Black Acetabular Shells (United

States FDA Recall Z-1261-2007). (Id. at ¶ 18.) The stated reason for the recall was that defendant discovered dimensional anomalies caused by a machine operator's failure to inspect product dimensional features prior to release. (Id.) These defects caused the PSL Shells to be out of tolerance. (Id.)

On August 30, 2007, defendant recalled another batch of Trident PSL HA Solid Black Acetabular Shells (United States FDA Recall Z-0073-2006). (Id. at ¶ 19.) The stated reason for the recall was that defendant found that "specific lots of Trident PSL Acetabular shells may have [had] dimensional discrepanc[ies]. The deviation regarding the difference in wall thickness [would] increase the gap between the shell and liner on one side and [would] decrease the gap between shell and liner on the opposing side, resulting in interference." (Id.)

On January 22, 2007, defendant recalled a batch of Trident PSL and Hemispherical Cups that were manufactured from January, 2000 through December, 2007 in defendant's facilities in Cork, Ireland. (Doc. 1-1 at ¶ 20.) The recall stemmed from an investigation into the existence of "manufacturing residuals" within the defective Trident devices. (Id.)

The FDA classified defendant's recalls and other corrective actions as Class II recalls under federal regulations.[2] (Id. at ¶ 21.)

On March 15, 2007, the FDA issued a warning letter to defendant regarding defendant's facilities in Cork, Ireland. (Id. at ¶ 28.) The FDA inspected defendant's Cork, Ireland facilities, and discovered that defendant's Trident Acetabular hip replacement systems were "adulterated"[3] as defined in 21 U.S.C. § 351(h).[4] (Id.)

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[2]In their state court petition, plaintiffs do not provide additional information regarding Class II recalls or these specific recalls.

[3]Plaintiffs allege that defendant's Trident Acetabular hip replacement systems were "adulterated" because "the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device, were not in conformity with the Current Good Manufacturing Practice [] requirements of the Quality Systems [] regulation found at 21 C.F.R. § 820." (Doc. 1 at ¶ 28.)

[4]With both the March 15, 2007 and November 28, 2007 warning letters, plaintiffs restate in full the violations listed by the FDA. (Doc. 1 at (continued...)

On November 28, 2007, the FDA issued a warning letter to defendant regarding defendant's facilities in Mahwah, New Jersey. (Id. at ¶ 30.) The FDA inspected these facilities between June 1, 2007 and July 12, 2007, and discovered that defendant's Trident PSL Acetabular Shells were adulterated. (Doc. 1-1 at ¶ 30.)

Plaintiffs' Claims

Plaintiffs allege that defendant failed to comply with: the Medical Device Reporting procedures set forth in 21 C.F.R. § 803; the failure and quality assurance procedures set forth in 21 C.F.R. § 820; and the recall and notification procedures set forth in 21 C.F.R. § 806. (Id. at ¶ 32.) Plaintiffs also allege that defendant failed to develop practices and procedures to assure compliance with: federal requirements for reporting adverse events, in accordance with 21 U.S.C. § 360; federal requirements for device modifications, instructions for use, and pre-market approval condition, in accordance with 21 C.F.R. § 814; and its duty to maintain Medical Device Reporting procedures, implementing device removals and corrections, and establishing quality systems, in accordance with 21 C.F.R. §§ 803, 806, and 820. (Id. at ¶ 33.)

Plaintiffs also allege that defendant failed to: timely report adverse events; conduct failure investigations and analysis; timely report any and all information concerning product failures and corrections; inform the FDA of adverse effects or device failures which would require a labeling, manufacturing, or device modification; and conduct necessary design validation. (Id. at ¶ 35.)

Regarding the specific device at issue, plaintiffs allege that it was defective and unreasonably dangerous. (Id. at ¶ 37.) Plaintiffs allege that defendant's manufacturing process for the device and its components did not satisfy the FDA's Pre-Market Approval standards, resulting in unreasonably dangerous manufacturing defects, and that defendant failed to warn of those unreasonable risks. (Id.) Plaintiffs

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[4](...continued)
¶¶ 29(a)-(k), 31(a)-(s).)

further allege that defendant was negligent and careless in the manufacturing process. (Doc. 1-1 at ¶ 38.)

According to plaintiffs, as a result of these failures, deficiencies, and negligence, Pamela Warren's right hip implant failed and fractured, necessitating revision surgery, and that the remaining device clicks, squeaks, grinds, and functions poorly. (Id. at ¶ 39.)

In Count I, plaintiffs assert a strict product liability claim against defendant, as defendant was the manufacturer, distributer, and seller of Pamela Warren's defective hip device. (Id. at ¶¶ 41-50.) In Count II, plaintiffs assert a negligence claim against defendant as designer, manufacturer, distributor, and seller of Pamela Warren's defective hip device. (Id. at ¶¶ 51-60.) In Count III, plaintiffs assert a breach of express warranty of fitness for a particular purpose claim. (Id. at ¶¶ 61-69.) In Count IV, plaintiffs seek punitive damages. (Id. at ¶¶ 70-73.) In Count V, David Warren seeks damages for loss of consortium. (Doc. 1-1 at ¶¶ 74-77.)

II. MOTION TO DISMISS

Defendant moves to dismiss plaintiffs' complaint. Fed. R. Civ. P. 12(b)(6); (Doc. 2.) Defendant argues that: plaintiffs' claims are expressly preempted; plaintiffs' express warranty claim does not allege a violation of federal law; plaintiffs' claims are impliedly preempted; plaintiffs' complaint fails to state plausible claims; and David Warren's loss of consortium claim fails for lack of a valid underlying claim. (Doc. 3.)

Plaintiffs respond that their claims may proceed through a "narrow gap" under which their state law claims escape express and implied preemption, and that their complaint sufficiently alleges breaches of federal law and regulations. (Doc. 10.)

In reply, defendant reasserts its arguments of express and implied preemption and lack of sufficiency of the pleadings. (Doc. 14.)

III. MOTION TO DISMISS STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the legal sufficiency of the complaint. See Carton v. General Motor Acceptance

Corp., 611 F.3d 451, 454 (8th Cir 2010); Young v. City of St. Charles, 244 F.3d 623, 627 (8th Cir. 2001). To survive a motion to dismiss, the complaint must include "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). To meet the plausibility standard, the complaint must contain "more than labels and conclusions." Id. at 555. Rather, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009).

The Federal Rules of Civil Procedure demand only that a complaint present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). And in this regard, the court must be mindful of Federal Rule of Civil Procedure 84 and its requirement that the attached Forms 10 to 21 be considered as examples of the "simplicity and brevity that [Rule 8] contemplate[s]." Fed. R. Civ. P. 84. See Hamilton v. Palm, 621 F.3d 816, 818 (8th Cir. 2010). That said, the allegations must still be enough to "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

A complaint must be liberally construed in the light most favorable to the plaintiff. Eckert v. Titan Tire Corp., 514 F.3d 801, 806 (8th Cir. 2008). Moreover, a court must accept the facts alleged as true, even if doubtful. Twombly, 550 U.S. at 555. Thus, a well-pleaded complaint may proceed even if it appears that recovery is very remote or unlikely. Id.; Young, 244 F.3d at 627.

IV. DISCUSSION

In the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), "Congress authorized the Food and Drug Administration to regulate the safety and effectiveness of medical devices." In re Medtronic Sprint Fidelis Leads Products Liability Litigation, No. 08-1905, 2010 WL 4026802, at *1 (8th Cir. Oct. 15, 2010). The MDA employed a new regulatory scheme, under which devices were classified based on their levels of risk. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). A Class III device receives the most oversight because it "presents a potentially unreasonable risk of injuring patients

or [] is used to sustain life." In re Medtronic, 2010 WL 4026802, at *1.

A new Class III device must go through a rigorous FDA Pre-Market Approval ("PMA") process to nsure its safety and efficacy before it can be marketed and sold to the public. Id. Once the device passes the PMA process, "the manufacturer may not change its design, manufacturing process, labeling, or other attributes that would affect safety or effectiveness without filing a PMA Supplement." Id.

A. Express and Implied Preemption

Congress also included an express preemption provision in the MDA:

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

21 U.S.C. § 360k(a). Under the Supreme Court's holding in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), state law is preempted by § 360k(a) if (1) "the Federal Government has established requirements applicable to [the device]," and (2) the plaintiff's claims are based on state law requirements relating to the safety and effectiveness of the device that are "different from, or in addition to" federal requirements. Riegel, 552 U.S. at 321-22 (internal quotations omitted).

The parties do not dispute that the Trident System is a Class III device. As a Class III device, the Trident System was subject to rigorous pre-market approval, which the Riegel court held sufficient to satisfy the first prong of the preemption analysis. Id. at 322-23; In re Medtronic, 2010 WL 4026802, at *2. Therefore, plaintiffs' state law claims are preempted to the extent that the alleged state duties add to, rather than parallel, federal requirements. Riegel, 552 U.S. at 330.

The MDA also provides for implied preemption of state law claims in that it "provides that all actions to enforce FDA requirements 'shall be

by and in the name of the United States.'" In re Medtronic, 2010 WL 4026802, at *2 (quoting 21 U.S.C. § 337(a)). As the Eighth Circuit explained in In re Medtronic, the Supreme Court held in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n. 4 (2001), that § 337(a) bars suits by private litigants "for noncompliance with the medical device provisions." In re Medtronic, 2010 WL 4026802, at *2 (quoting Buckman, 531 U.S. 341 n. 4). Thus, as the Eighth Circuit explained,

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

In re Medtronic, 2010 WL 4026802, at *2 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

In In re Medtronic, the Eighth Circuit found the plaintiffs' claims expressly and impliedly preempted. The court found that the plaintiffs' claims were expressly preempted because "the FDA did not prohibit Medtronic from continuing to sell the unmodified lead, [and thus] a state requirement to that effect would be 'different from or in addition to' the federal requirement and preempted under § 360k." As for implied preemption, the court held that the plaintiffs' claims alleging "that Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations . . . [were] simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in Buckman." In re Medtronic, 2010 WL 4026802, at *3.

Unlike the plaintiffs in In re Medtronic, plaintiffs raise state law claims that are premised on defendant's alleged failure to comply with federal regulations. Thus, plaintiffs' claims are more similar to those in Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 832-33 (S.D. Ind. 2009). In Hofts, the plaintiff brought claims for, *inter alia*, defective manufacturing, negligent manufacturing, and breach of express warranty. Id. at 833. The plaintiff alleged that the defendant "failed in its obligation to meet the FDA's requirements, *not that [the*

defendant] failed to exceed those requirements or to meet different requirements." Id. at 836 (emphasis added). Put another way, because a jury verdict could enforce the allegedly violated federal requirements, which gave rise to state law tort claims, the state law duties were parallel to the federal requirements. Id. at 836-37. Therefore, the plaintiff's claims were not preempted under Riegel.

Defendant argues that under Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. Dec. 28, 2009), plaintiffs' claims are not sufficiently based on violations of federal regulations to survive preemption. In Ilarraza, the court held that the plaintiff's state law claims were preempted, despite the appearance of seemingly parallel claims. Id. at 588. Although the plaintiff alleged violations of CGMPs, the court found no parallel claim because Current Good Manufacturing Practices ("CGMP"s) only provide "general objectives [that] medical device manufacturers must seek to achieve." Id. The court reasoned that, because the CGMPs were "intentionally vague and open-ended," allowing the CGMPs to serve as the basis for a claim would subject manufacturers to multiple safety requirements (not set by federal law). Id. Also, given the nature of CGMPs, the plaintiff's general allegations of violations of CGMPs did not satisfy the pleading standard set forth in Twombly. Id. at 589.

Plaintiffs have concretely premised their state law claims on violations of federal regulations. Plaintiffs' state law claims do not impose any additional duties on defendant; plaintiffs' claims stem solely from defendant's alleged violation of federal regulations. Therefore, plaintiffs' claims are not preempted. Hofts, 597 F. Supp. 2d at 836-37. Cf. Bausch v. Stryker Corp., No. 08 C 4248, 2008 WL 5157940, at *4 (dismissing the plaintiff's claims because the plaintiff failed to premise his claim "in any way" to alleged FDA regulation violations).

B. Sufficiency of the Pleadings and Additional Discovery

Defendant argues that plaintiffs failed to plead "concrete allegations" that the Trident System at issue did not comply with the federal pleading requirements, as articulated by the Eighth Circuit in In re Medtronic, 2010 WL 4026802, at *3.

The Hofts court noted that the district court in In re Medtronic held that those plaintiffs failed to plead their manufacturing claims with sufficient specificity. As the Hofts court explained, the In re Medtronic district court found that those plaintiffs' tort claims "were premised on alleged violations of the FDA's CGMPs and Quality System Regulations ("QSR"s)," and that the CGMPs and QSRs "were generic, generally applicable requirements . . . [that] lacked any specific requirement applicable to the device at issue." As such, those "plaintiffs' manufacturing defect claims would impose requirements different from or in addition to those under federal law." Hofts, 597 F. Supp. 2d at 837 (discussing In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d, 1147, 1158 (D. Minn. 2009)).

The Hofts plaintiff, like plaintiffs here, "brought claims premised on Howmedica's alleged failure to manufacture the Trident in accordance with the PMA issued by the FDA." Hofts, 597 F. Supp. 2d at 838. Thus, plaintiffs' claims survive dismissal.

As for additional discovery, the Hofts court discussed the application of strict pleading requirements in this scenario:

> This court respectfully suggests that this is an unusually stringent application of Twombly and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage. Manufacturing defect claims are not subject, for example, to the "particularity" pleading requirement of Rule 9. By way of comparison, in Lohr[5], the Supreme Court reversed dismissal of similar claims, even though "the precise contours of their theory of recovery have not yet been defined," because it was claims that the plaintiffs[']allegations "may include claims that Medtronic has, to the extent that they exist, violated FDA regulations."

Hofts, 597 F. Supp. 2d at 838. The court further noted that "[w]ith discovery, [the plaintiff] may or may not be able to prove those claims, but his claims are premised on requirements that are parallel to the federal requirements." Id.

Therefore, plaintiffs are entitled to proceed with their suit and obtain information through discovery. Hofts, 597 F. Supp. 2d at 838.

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[5]Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

See also In re Medtronic, 2010 WL 4026802, at *9 (Melloy, J., concurring in part and dissenting in part) (adopting the reasoning of Hofts regarding additional discovery "because its pragmatic approach does not turn Twombly into an insurmountable hurdle for plaintiffs"); Phillips, 2010 WL 2270683, at *7 (holding that the plaintiff's state law claims "contain[ed] sufficient factual matter, accepted as true, to state a plausible claim for relief"). Cf. In re Medtronic, 592 F. Supp. 2d 1159 n. 14 (noting that plaintiffs' counsel stated that no additional discovery was needed).

V. CONCLUSION

For the reasons set forth above,

IT IS HEREBY ORDERED that the motion of defendants to dismiss (Doc. 2) is denied.

/S/ David D. Noce
UNITED STATES MAGISTRATE JUDGE

Signed on December 8, 2010.