NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRACY HUBER, individually and on behalf of others similarly situated, Plaintiff, v. HOWMEDICA OSTEONICS CORP., a New Jersey corporation doing business as Stryker Orthopaedics, Defendant.	CIVIL ACTION NO. 07-2400 (JLL) **OPINION AND ORDER**

LINARES, District Judge.

On December 5, 2008, this Court heard oral argument regarding Defendant Howmedica Osteonics Corporation's ("Defendant" or "Howmedica") motion to dismiss Plaintiff's complaint pursuant to Fed. R. Civ. P. 12(b)(6).[1] The Court granted Defendant's motion to dismiss Count I of the Second Amended Complaint ("SAC"), alleging violations of the New Jersey Consumer Fraud Act, but the Court reserved decision on Defendant's motion to dismiss Count II, a claim alleging breach of express warranty. (Docket Entry No. 54.) For the reasons set forth below, Defendant's motion to dismiss Count II is **DENIED.**

[1] On September 12, 2008, this Court granted Plaintiff Jama Parker's request to dismiss her claims only. (Docket Entry No. 46.) Thus, the only remaining named plaintiff is Tracy Huber.

I. Facts

The facts giving rise to this class action complaint are set forth at length in this Court's January 14, 2008 opinion addressing Defendant's first motion to dismiss. (Docket Entry No. 20.) Thus, the Court discusses the facts at a high level and specifically focuses on those relevant to Plaintiff's one remaining claim – breach of express warranty.

This case arises out of Plaintiff's experiences with the Trident Ceramic Acetabular System ("Trident System") a device implanted in patients requiring a total hip replacement. In 2005, Plaintiff Huber underwent total hip replacement surgery ("arthroplasty") and received implants of the Trident System. She now brings a breach of express warranty claim alleging that Howmedica's product label contained deficient and inaccurate affirmations of fact. (Second Amended Compl. ("SAC") ¶ 101.) Specifically, Huber alleges that the label represented a .5% rate of defect in which the device would emit an audible sound. (Id.) After her implantation, Huber heard audible "clicking, squeaking, and/or squealing sounds emanating from the implanted [Trident System]." (Id. ¶ 20.) Moreover, evidence shows that the .5% defect rate is inaccurate and that the actual rate is much higher. (Id. ¶¶ 33-40.) Huber now claims that the inaccurate .5% rate of defect represented a basis for the bargain and substantiates a claim against Defendant for breach of an express warranty.[2]

[2] Plaintiff also makes other allegations with respect to the claim of breach of express warrant, including Defendant's alleged public statements that the Trident System was "efficacious and safe for its intended use." (SAC ¶ 100.) However, in its Jan. 14, 2008 Opinion, this Court found that such bald assertions failed to give Howmedica fair notice of the claim against it. (Docket Entry No. 20 at 13.) In its SAC, Plaintiff has only added a specific factual allegation of breach of express warranty with respect to the product label, while leaving all other assertions unchanged. Thus, the Court focuses only on the claim as it relates to the product label and finds that all other factual allegations fail to sufficiently allege a claim for breach of express warranty for the same reasons as set forth in the Jan. 14, 2008 Opinion.

The question before the Court is whether Plaintiff's claim for breach of an express warranty based upon affirmations made on the product label is pre-empted by the Medical Device Amendments of 1976 ("MDA"). If the claim is not preempted, then the Court must review Plaintiff's allegations to ensure that they sufficiently plead a claim for breach of express warranty.

I. Preemption

A. Premarket Approval Process

In Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008), the Supreme Court held that the MDA pre-empted Plaintiff's common law claims of negligence, strict liability, and implied warranty against the manufacturer of a device approved pursuant to the FDA's premarket approval ("PMA") process. The PMA process is mandatory for a device listed as Class III under the MDA's three-tiered system of oversight for medical devices. Id. at 1004. Class III devices are those that either (1) "present[ ] a potential unreasonable risk of illness or injury," or are (2) "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health [.]" 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II).

The premarket approval process is rigorous. Riegel, 128 S. Ct. at 1004; Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996). It requires a manufacturer to submit all information concerning investigations which have been made to show whether or not the device is safe and effective, a statement of the product's intended use, a description of the anticipated manufacturing processes for the device, and any other information requested by the FDA. 21 U.S.C. § 360e(c)(1)(A)-(G). Of particular importance to the present motion, the FDA

also requires a sample of the proposed labeling for the device. Id. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and makes a determination that the proposed label is neither false nor misleading. § 360e(d)(1)(A). After spending an average of 1200 hours reviewing each Class III application, the FDA chooses whether to grant or deny premarket approval. § 360e(d).

If appproval is granted, the manufacturer is forbidden from making any changes in "design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness." Riegel, 128 S. Ct. at 1005; § 360e(d)(6)(A)(I). The manufacturer also retains the obligation to inform the FDA of new clinical investigations and studies concerning the device, and the FDA has the continuing power to withdraw premarket approval. Id.

There is no dispute that the device at issue in this litigation – the Trident System – was approved pursuant to the FDA's PMA process for Class III devices.

B. Analysis

The MDA expressly pre-empts state requirements "different from, or in addition to, any requirement applicable ... to the device" under federal law. Riegel, 128 S.Ct. at 1006. In Lohr, the Supreme Court held that federal manufacturing and labeling requirements that applied to all medical devices, rather than specifically to the device in question, did not pre-empt state common-law claims. Lohr, 518 U.S. at 501. The Lohr Court, however, had before it a Class III device that had been approved pursuant to substantial-equivalence review under § 510(k).[3] In

[3] Devices sold prior to the MDA's effective date may remain on the market, under a grandfather clause, until the FDA promulgates a regulation requiring premarket approval. §§ 360c(f)(1); 360e(b)(1). Section 510(k) review is the name given to the FDA's analysis of "substantially equivalent" devices. Under this procedure, new devices that are "substantially equivalent" to grandfathered devices are exempt from the PMA process. The Lohr Court addressed the issue of preemption in the context of this exemption to the PMA process.

Riegel, however, the Court found that premarket approval – as opposed to § 510(k) review -- imposes requirements specific to individual devices. Finding that a state's requirements include its common-law duties, the Supreme Court therefore held that the tort causes of action brought by Plaintiff Riegel were preempted by the MDA. 128 S.Ct. at 1009.

The Riegel decision, however, did not specifically address the preemption issue with regard to a claim for breach of express warranty. 128 S. Ct. at 1006 n.2. The district court in Riegel found that the MDA did not preempt a breach of express warranty allegation and later granted summary judgment to Medtronic on that claim. Id. The Court of Appeals affirmed the grant of summary judgment without needing to address the issue of preemption, and therefore the issue of whether or not the MDA preempts a breach of warranty claim with respect to a Class III device never made it up to the Supreme Court. Id.

Thus, this Court turns to Third Circuit law to guide its analysis. In Michael v. Shiley, 46 F.3d 1316 (3d Cir. 1995) (overruled on other grounds), the Third Circuit held that the MDA did not preempt a breach of express warranty claim based on a statement made on the defendant's product packaging. Id. at 1325. Rather, the Shiley Court found that express warranties arise from voluntary representations of the parties and not from the independent operation of state law. Id. The fact that the FDA approves the label does not undermine "the doctrine that contractual duties arise from the mutual assent of parties to agreed upon language." Id. at 1327. Furthermore, the manufacturer itself drafted the initial language of the label and "participated actively and meaningfully in the FDA regulatory process." Id. at 1328. Finally, the enforcement of an express warranty arising from FDA-approved packaging does not establish a requirement that is different from, or in addition to, a federally-imposed requirement. Id. Rather, the Shiley

Court held that plaintiff sought to enforce the very language which the FDA had approved. Id. Thus, though the MDA preempted other common law claims, the Third Circuit found that a claim for breach of express warranty related to statements made on a product's label and packaging is not preempted. Id.

Subsequent to Shiley, other courts have divided on the issue of whether or not the MDA preempts express warranty claims. The Seventh Circuit similarly held that express warranty claims arise from representations of the parties made as part of the basis of the bargain and therefore do not interfere with operation of the PMA. Mitchell v. Collagen, 126 F.3d 902, 915 (7th Cir. 1997), cert. denied, 118 S. Ct. 1300 (1998). Judge Kugler, in Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 455-56 (D.N.J. 2003), applied Shiley to deny defendant's motion for summary judgment as to a breach of express warranty claim. See also Brown v. DePuy Spine, Inc., 2007 WL 1089337, at *16-17 (Mass. Super. April 9, 2007) (unpublished) (agreeing with view that "claims for breach of an express warranty based upon words approved by the FDA are not preempted by the MDA"); but see Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919, 928 (5th Cir. 2006) (finding that duties arising under the Louisiana breach of warranty statute are potentially inconsistent with the federal regulatory scheme); Enlow v. St. Jude Med., Inc., 210 F. Supp. 2d 853, 861-62 (W.D.Ky. 2001) (finding Third Circuit's reasoning "unpersuasive" and holding MDA preempted claim for express warranty). Prior to Riegel, therefore, courts were effectively divided on the propriety of a breach of warranty claim with respect to a product approved via the MDA's PMA process.

Since the Riegel decision, Defendant points to several courts that have found such a claim preempted. In the District of Colorado, Judge Blackburn had occasion to decide the issue on

nearly the same factual scenario presented in this case. Parker v. Stryker Corp., No. 08-1093, 2008 WL 4716879, at *4 (D.Colo. Oct. 22, 2008). The Parker court analyzed the approach taken in Shiley and found that in light of Riegel, the "better-reasoned approach would find plaintiff's breach of express warranty claims based on the labeling of the Trident System preempted." Id. According to Judge Blackburn, Plaintiff's express warranty claim "would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements." Id. The Court therefore dismissed Parker's claim for breach of express warranty as preempted by the MDA. As Defendant has noted, other courts have also disallowed post-Riegel breach of express warranty claims. See, e.g., Lake v. Kardjian, No. 03-1267, 2008 WL 5244823, at *2 (N.Y. Sup. Ct. Dec. 17, 2008). Based upon Parker and Lake, as well as the general language in Riegel, Defendant urges this Court to reach a similar conclusion.

This Court, however, unlike the Parker and Lake courts, is bound by the decisions of the Third Circuit. While the Riegel decision has generally clarified the law with respect to MDA preemption, it is unclear whether Riegel in fact has changed the law with respect to preemption of breach of express warranty claims. The Third Circuit's rationale for allowing breach of express warranty claims actually appears to survive the Riegel decision. The Third Circuit found that a breach of express warranty does not implicate a state action (but is rather a voluntary commitment between two contracting parties) and does not seek to enforce a requirement different from, or in addition to, federal requirements. Nothing in Riegel explicitly undermines this rationale for not preempting breach of express warranty claims. Regardless of how this Court would hold were it an open issue, it is constrained to follow the law as set forth by the

Third Circuit. See, e.g., Sheet Metal Workers' Intern. Ass'n Local Union No. 19 v. U.S. Dep't of Veterans Affairs, No. 96-4120, 1997 WL 34681, at *6 (E.D.Pa. Jan. 28, 19997) (disagreeing with Third Circuit's analysis but finding that Supreme Court had not clearly overruled the case and therefore district court was bound by Third Circuit law). This court, therefore, denies Defendant's motion to dismiss.

II. Sufficiency of Pleading

Defendant makes the alternative argument that Plaintiff's breach of express warranty allegation contains "bald assertions" that do not suffice to state a claim. In its Jan. 14, 2008 Opinion, the Court dismissed similar allegations for failure to state claim. (Docket Entry No. 20 at 13.) Plaintiff's SAC adds a new, factually-specific allegation regarding the .5% defect rate printed on the product's label. Plaintiff alleges that her product malfunctioned, that evidence shows the rate of defect to be much higher than .5% (SAC ¶¶ 33-40), and that the failure of the Trident System to adhere to the published defect rate gives rise to a claim for breach of express warranty. Under the heightened pleading standard set forth by the Supreme Court in Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1959 (2007), this allegation raises the right to relief above the speculative level and gives the defendant fair notice of the claim and of the grounds upon which it rests.

Defendant argues that simply because Plaintiff finds herself within the .5% of people expected to experience a product defect does not allow her to bring a breach of express warranty claim. If Defendant's argument held true, then it would be under no restrictions in terms of what it could post as its defect rate. Any rate greater than zero could be printed on the label, and under no circumstance would an affected plaintiff have a right of action, because that plaintiff would

simply be the lone individual with the misfortune to fall within the affected rate. Here, Plaintiff has adequately alleged that Defendant's express warranty of a .5% defect became a basis of the bargain and that evidence shows that rate to be much higher than claimed. Regardless of whether the FDA approved the .5% figure, the Third Circuit allows for Plaintiff to bring a claim against the manufacturer for independently warranting to the buyer that the product in question would only malfunction .5% of the time. The Court allows Plaintiff's claim to proceed to the discovery stage.

III. Conclusion

Because this Court is bound by the Third Circuit's decision in Shiley and because Plaintiff has pleaded a claim for breach of express warranty that withstands Twombly scrutiny, Defendant's motion to dismiss is denied.

It is, therefore, on this 30th day of December, 2008,

ORDERED that Defendant's motion to dismiss Plaintiff's claim for breach of express warranty is **DENIED.**

Dated: December 30, 2008

/s/ Jose L. Linares
United States District Judge