UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

THE KINETIC CO., INC., on behalf of itself and others similarly situated,	Case No. 08-CV-6062 (PJS/AJB)
Plaintiff,	ORDER
v.	
MEDTRONIC, INC.,	
Defendant.	

Lauren Guth Barnes, Thomas M. Sobol, HAGENS BERMAN SOBOL SHAPIRO LLP; Thomas I. Hara; Vernon J. Vander Weide, HEAD, SIEFERT & VANDER WEIDE; Joseph H. Meltzer, Terence S. Ziegler, Casandra A. Murphy, BARROWAY TOPAZ KESSLER MELTZER & CHECK, LLP, for plaintiff.

David M. Gossett, MAYER BROWN LLP; Michael T. Nilan, Andrew J. Sveen, NILAN JOHNSON LEWIS PA; Stephen J. Immelt, Steven F. Barley, Lauren S. Colton, HOGAN LOVELLS US LLP, for defendant.

Plaintiff The Kinetic Co., Inc. ("Kinetic") brings this putative class action asserting numerous state-law claims on behalf of itself and other similarly situated third-party payors of health-care expenses against defendant Medtronic, Inc. ("Medtronic"). Medtronic moves for judgment on the pleadings on the ground that Kinetic's state-law claims are preempted by federal law. For the reasons explained below, the Court largely agrees with Medtronic and therefore dismisses Kinetic's claims, with only a couple of exceptions.

I. BACKGROUND

Medtronic is a manufacturer of medical devices, including implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices ("CRT-Ds"). Am. Compl. ¶ 6. ICDs and CRT-Ds are used to treat cardiovascular and peripheral disease, cardiac arrhythmias, heart failure, and slow heartbeats. *Id.* ¶ 10. ICDs monitor, regulate, and stabilize

the heart in the event of sudden heart failure or a change in the heart's rhythm. *Id.* ¶ 11. CRT-Ds supply mild electrical impulses to the lower chambers of the heart to treat heart-failure symptoms and allow the heart to beat in a normal sequence. *Id.* ¶ 14.

In April 2004, the FDA announced a Class I recall of two models of Medtronic ICDs.[1] *Id.* ¶ 19. In February 2005, Medtronic initiated a recall of four additional models of ICDs and four models of CRT-Ds. *Id.* ¶¶ 22-23. All of these devices experienced a problem with their batteries that could cause the devices to fail. *Id.* ¶ 25. Kinetic alleges that Medtronic knew of this battery problem as early as January 2003, but failed to immediately advise the FDA or the public about it. *Id.* ¶ 29. Instead, in fall 2003, Medtronic sought and received the FDA's permission to make a change in the batteries. *Id.* But Medtronic continued to sell its existing stock of defective devices at least until February 2005.[2] *Id.* ¶ 30.

Kinetic brings nine claims against Medtronic based on Medtronic's sales of these defective ICDs and CRT-Ds: (1) violation of Minnesota's False Statement in Advertising statute, Minn. Stat. § 325F.67; (2) violation of Minnesota's Deceptive Trade Practices Act, Minn. Stat. § 325D.44; (3) violation of Minnesota's Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69; (4) unfair and deceptive trade practices under the laws of the other 49 states and the District of Columbia; (5) unjust enrichment; (6) breach of express warranty; (7) breach of

---

[1]A Class I recall is instituted when there exists a reasonable probability that use of the product will cause serious injury or death. Am. Compl. ¶ 19.

[2]Kinetic does not allege that Medtronic's continued sale of these devices violated the terms of the recalls. According to Medtronic, neither the Class I recall nor Medtronic's later recall (which Medtronic characterizes as nothing more than a voluntary letter to physicians recommending certain patient-management options) required Medtronic to replace the devices or withdraw them from the market.

implied warranty; (8) breach of assumed contractual warranty obligations; and (9) misrepresentation by omission.

II. ANALYSIS

A. Standard of Review

In reviewing a motion for judgment on the pleadings under Fed. R. Civ. P. 12(c), a court applies the same standard used in reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6). *Ashley Cnty. v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009). Under this standard, the court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *Id.* Although the factual allegations in the complaint need not be detailed, they must be sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

B. Preemption

Medtronic moves for judgment on the pleadings on the ground that all of Kinetic's claims are preempted under the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.[3] The Eighth

[3]Medtronic previously litigated and lost the preemption issue in a related case. *See In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006). Kinetic contends that, under the doctrine of offensive nonmutual collateral estoppel, Medtronic should be precluded from relitigating the preemption issue in this case. The Court disagrees. There are a host of reasons why offensive nonmutual collateral estoppel should not apply here, the most important of which is that the decision of a judge of this Court in *Implantable Defibrillators* predated both the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and the Eighth Circuit's decision in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010). Both of those decisions significantly changed and clarified the law of preemption. Under these circumstances, giving preclusive effect to the *Implantable Defibrillators* decision would be unjust. *See Berger Transfer & Storage v. Cent. States, Se. & Sw. Areas Pension Fund*, 85 F.3d 1374, 1377 (8th Cir. 1996) ("If application of (continued...)

Circuit recently summarized the law regarding federal preemption of state-law claims concerning Class III medical devices:[4]

> In the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("MDA"), Congress authorized the Food and Drug Administration ("FDA") to regulate the safety and effectiveness of medical devices. . . . Before a new Class III device may be marketed, the manufacturer must assure the FDA through a rigorous Pre-Market Approval ("PMA") process that the device is safe and effective. Once the product is approved, the manufacturer may not change its design, manufacturing process, labeling, or other attributes that would affect safety or effectiveness without filing a PMA Supplement. 21 C.F.R. § 814.39(a). The PMA Supplement is reviewed using the same standard as the original PMA. *See generally* [*Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-19 (2008)] . . . .
>
> The MDA contains an express preemption provision: no State "may establish or continue in effect with respect to a device . . . 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." 21 U.S.C. § 360k(a). In *Riegel*, the Court held that, for § 360k(a) preemption purposes, (i) FDA pre-market approval is "federal safety review" that results in federal "requirements" specific to the approved device, and (ii) common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by PMA approval. 552 U.S. at 322-24, 128 S. Ct. 999. However, the Court noted, § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of

---

[3](...continued)
offensive issue preclusion would be unfair to a defendant, a trial judge should not allow the use of offensive issue preclusion.").

[4]A Class III device is "one that presents a potentially unreasonable risk of injuring patients or that is used to sustain life." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010); *see* 21 U.S.C. § 360c(a)(1)(C).

> FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330, 128 S. Ct. 999.
>
> The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), the Court construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." Read together —
>
> > *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, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1203-04 (8th Cir. 2010) [hereinafter *Sprint Fidelis*] (footnotes omitted) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

With respect to all of the medical devices at issue in this case save one (the Model 7285[5]), there is no dispute that they are Class III devices that were approved by the FDA pursuant to the PMA process and that, as a result, the FDA has established federal requirements applicable to these devices. Under the MDA, then, Kinetic's claims are preempted to the extent

[5]Medtronic does not move for judgment on preemption grounds with respect to the Model 7285, which Medtronic believes is a CRT-D that was never sold in the United States and was thus not subject to FDA approval. *See* Docket No. 93 at 10 n.1. At oral argument, Kinetic agreed that, if the Model 7285 was never sold in the United States and no members of the class paid for a Model 7285, Kinetic would voluntarily dismiss its claims with respect to that device. But Kinetic is not yet willing to concede that the Model 7285 was never sold in the United States. For the time being, therefore, Kinetic's claims survive insofar as they relate to the Model 7285.

that they would impose requirements that relate to the safety or effectiveness of these devices and that are either different from or in addition to the requirements imposed under the FDCA.

All but two of Kinetic's claims are based on allegations that Medtronic failed to disclose the defects in the devices and that Medtronic affirmatively misrepresented the safety and effectiveness of the devices. At times in its complaint, Kinetic seems to focus on misrepresentations and omissions allegedly made to doctors and patients. At other times, Kinetic seems to focus on misrepresentations and omissions allegedly made to the FDA. Under either theory, though, Kinetic's claims are squarely preempted under § 360k, *Riegel*, and *Sprint Fidelis*.

With respect to Medtronic's communications to doctors and patients, Kinetic does not claim that Medtronic failed to include FDA-approved warnings and disclosures with the devices. Rather, Kinetic seeks to hold Medtronic liable for failing to include *additional* warnings — specifically, a warning about the devices' battery problems and resulting high risk of failure. But Kinetic admits that there is no federal requirement that Medtronic disclose this information to doctors or patients. Because there is no such requirement under the FDCA, Kinetic is seeking to use state law to impose requirements on Medtronic that are "different from, or in addition to," the requirements imposed by the FDCA. 21 U.S.C. § 360k(a)(1); *see Sprint Fidelis*, 623 F.3d at 1205. Kinetic cannot do this under § 360k.

With respect to Medtronic's communications to the FDA, Kinetic alleges that Medtronic violated federal regulations that required Medtronic to disclose the battery problems to the FDA. *See, e.g.*, 21 C.F.R. § 803.50. But to avoid being impliedly preempted under *Buckman*, a claim must "rely[] on traditional state tort law which had predated the federal enactments in

question[]." *Buckman Co.*, 531 U.S. at 353. "In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law — and that would give rise to liability under state law even if the FDCA had never been enacted." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). Obviously, a claim premised on a defendant's violation of an FDA regulation requiring that information be reported to the FDA is not a claim "that would give rise to liability under state law even if the FDCA had never been enacted." *Id.* It is, instead, "simply an attempt by private parties to enforce the MDA" — an attempt that is preempted under *Buckman*. *See Sprint Fidelis*, 623 F.3d at 1205-06.

Kinetic's claims that Medtronic falsely represented and warranted the safety of the devices are likewise preempted. The amended complaint relies entirely on general warranties and representations by Medtronic that the devices were "safe," Am. Compl. ¶¶ 31, 35, 45(*l*), 55, 59, 67, 93,109, "sound," *id.* ¶¶ 36, 49, 55, 59, 107, "reliable," *id.* ¶¶ 36, 49, 61, 107, 109, "effective," *id.* ¶¶ 67, 93, "non-defective," *id.* ¶ 60, and "fit and proper for [their] intended use," *id.* ¶ 93. These allegations are materially indistinguishable from the allegations in *Sprint Fidelis* that Medtronic had warranted and represented the Sprint Fidelis leads as "safe, effective, fit and proper for their intended use."[6] *Sprint Fidelis*, 623 F.3d at 1207. The Eighth Circuit held that claims based on such representations are preempted: "To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement."

[6]To be sure, Kinetic sometimes uses the adverb "mechanically" to modify these adjectives. *See, e.g.*, Am. Compl. ¶¶ 36, 55. But representations about the soundness and reliability of mechanical devices necessarily include their mechanical qualities; adding the qualifier "mechanically" does not change the nature of the representation.

Sprint Fidelis, 623 F.3d at 1208. Similarly, to succeed on their consumer-protection, express-warranty, and unjust-enrichment claims in this case, Kinetic would have to persuade a jury that the devices were not "safe," "sound," "reliable," "effective," "non-defective," and "fit and proper for [their] intended use" — which is no different than persuading a jury that the devices are not "safe and effective." These claims are therefore preempted under *Sprint Fidelis*.

Kinetic suggests that it should be allowed to take discovery to determine whether Medtronic made any warranties or representations beyond the general ones regarding safety and effectiveness alleged in the amended complaint. Kinetic misunderstands the purpose of discovery. A plaintiff is permitted to take discovery to find evidence to support a properly pleaded claim for relief; a plaintiff is not permitted to take discovery to fish for claims of which it is not aware. Because the misrepresentation, express-warranty, and unjust-enrichment claims pleaded by Kinetic are clearly preempted (with the exception of the claims related to the Model 7285 device), Kinetic is not entitled to take discovery on those claims.

As noted, two of Kinetic's claims are *not* based on Medtronic's alleged misrepresentations and omissions about the safety and effectiveness of the devices. Those claims are for breach of implied warranty (Count VII) and "breach of assumed contractual warranty obligations" (Count VIII).

Count VII alleges that, in breach of the implied warranty of merchantability, the devices were unsafe and defective. As Kinetic more or less conceded at oral argument, this claim is clearly preempted by § 360k. If a jury were to agree with Kinetic that the devices were unsafe and defective, then state law would impose liability on Medtronic for selling devices that Medtronic is authorized to sell under federal law — a result that would obviously impose state-

law requirements "different from, or in addition to" the requirements imposed under the FDCA. *See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (rejecting implied-warranty claim), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

In Count VIII, Kinetic claims that Medtronic breached certain "assumed contractual warranty obligations." The amended complaint leaves unclear the exact basis of this claim. At oral argument, however, Kinetic clarified that it is alleging that Medtronic promised patients in whom the devices had been implanted that Medtronic would pay certain costs associated with removing and replacing the devices. Kinetic apparently alleges that, by not making such payments to third-party payors (such as Kinetic), Medtronic breached the promise that it made to patients. At oral argument, Medtronic conceded that, as clarified by Kinetic, Count VIII has nothing to do with the safety or effectiveness of the devices and thus is not preempted by § 360k. The Court therefore denies Medtronic's motion with respect to Count VIII.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Defendant's motion for judgment on the pleadings [Docket No. 91] is GRANTED IN PART and DENIED IN PART.
2. Defendant's motion is GRANTED as to Counts I, II, III, IV, V, VI, VII and IX in plaintiff's amended complaint [Docket No. 57] with respect to all devices at issue except the Model 7285 device, and those claims are DISMISSED WITH PREJUDICE AND ON THE MERITS.

3. Defendant's motion is DENIED in all other respects.

Dated: April 19, 2011

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge