IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

ALICE PONTIOUS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**No. 11-4069-CM-GLR**
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM AND ORDER

Plaintiff Alice Pontious originally brought this product liability action in the District Court of Shawnee County, Kansas, against a number of defendants. The action was removed on diversity grounds and is now before this court on Defendants ConvaTec, Inc., Unomedical, Unomedical Infusion Devices, and Unomedical, Inc.'s [the "ConvaTec defendants"] Motion to Dismiss Under Rule 12(b)(6) (Doc. 9). The ConvaTec defendants seek dismissal of plaintiff's Kansas Consumer Protection Act ("KCPA") claim (Count VII) on the basis that it is preempted by federal law. Also before the court is Plaintiff's Motion for Leave to Amend and Memorandum of Support (Doc. 21) and Plaintiff's Motion for Enlargement of Time to Obtain Service (Doc. 28). The ConvaTec defendants oppose plaintiff's motion to amend because Count VII is futile. For the reasons that follow, the court grants all three motions.

I. Factual and Procedural Background

Plaintiff's product liability claim is based upon her use of two medical devices: a Medtronic insulin infusion pump and a Quick-Set insulin infusion set. Plaintiff's claims against the ConvaTec defendants are based upon the failure of the insulin infusion set. Her Amended Petition, filed before

the case was removed, asserts five counts under Kansas common law and two counts under Kansas statutes. Count VII makes a claim for relief under the KCPA. The ConvaTec defendants assert that the complaint alleges defendants violated the KCPA "solely by failing to report to the Food and Drug Administration ("FDA") an alleged device malfunction, which the Amended Petition claims was required by 21 C.F.R. § 805.50(a)." (Doc. 9 at 2.) Based on this reading, they argue the claim is preempted because it arises from the violation of federal law. (*See* Doc. 9 at 4) (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)). Plaintiff, on the other hand, argues that she states a viable KCPA claim "parallel" to 21 C.F.R. § 805.50(a), and seeks leave to amend her complaint to, among other things, clarify her claim.

II. Judgment Standards

To survive a motion to dismiss, a complaint must present factual allegations that "raise a right to relief above the speculative level" and must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 555, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, __, 129 S.Ct. 1937, 1949 (2009); Fed. R. Civ. P. 8(a), 12(b)(6). The allegations must be enough that, if assumed to be true, the plaintiff plausibly, not merely speculatively, has a claim for relief. *Robbins v. Oklahoma*, 519 F.3d 1242, 1247–48 (10th Cir. 2008). The issue in reviewing the sufficiency of a complaint is not whether the plaintiff will prevail, but whether the plaintiff is entitled to offer evidence to support her claims. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) *overruled on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800 (1982). In ruling on a motion to dismiss for failure to state a claim, the court assumes as true all well-pleaded facts, as distinguished from conclusory allegations, and views those facts in the light most favorable to plaintiff. *See Shero v. City of Grove, Okla.*, 510 F.3d 1196, 1200 (10th Cir. 2007); *Zinermon v.*

Burch, 494 U.S. 113, 118 (1990); *Swanson v. Bixler*, 750 F.2d 810, 813 (10th Cir. 1984).

III. Discussion

First, plaintiff appears to suggests that preemption is an affirmative defense and is not ripe for disposition through a Rule 12(b)(6) motion to dismiss. The court is convinced that it can rule on defendant's Rule 12(b)(6) motion based on preemption. *See generally R.W. Beck, Inc. v. E3 Consulting, LLC*, 577 F.3d 1133, 1136, 1149 (10th Cir. 2009) (affirming in part the district court's dismissal, on 12(b)(6) motion treated as summary judgment motion, of plaintiff's state law claims on the basis that they are preempted by the Copyright Act); *Mowry v. United Parcel Serv.*, 415 F.3d 1149, 1157 (10th Cir. 2005) (reviewing district court's dismissal, on 12(b)(6) motion, of plaintiff's state law claims as preempted by the Labor Management Relations Act); *Blue Circle Cement, Inc., v. Bd. of Cnty. Comm'rs of Cnty. of Rogers*, 27 F.3d 1499, 1503–04 (10th Cir. 1994). A "self-defeating" complaint will be dismissed when the "allegations clearly indicate the existence of an affirmative defense." *Classic Commc'ns, Inc. v. Rural Tel. Serv. Co., Inc.*, 956 F. Supp. 896, 901 (D. Kan. 1996).

A. Count VII of the First Amended Complaint

Plaintiff's First Amended Complaint sets out its KCPA claim in part as follows:

> 99. Under the K.S.A. § 50-626, no supplier shall engage in any deceptive act or practice in connection with a consumer transaction and deceptive acts include, but are not limited to the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact. K.S.A. § 50-626(b)(3).
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> 100. Upon information and belief, Defendants violated the KCPA by engaging in deceptive acts and practices when they willfully failed and refused to timely report information that reasonably suggested that the device (1) may have caused or contributed to a death or serious injury; or (2) had malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 C.F.R. § 805.50(a).

(Doc. 1-1 at 40).

Based on this alleged violation, plaintiff seeks to recover actual damages, civil penalties, and reasonable attorney's fees.

The court agrees with defendants that, under the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Leg. Comm*., 531 U.S. 341, 348 (2001), plaintiff's KCPA claim, as set out in the complaint, is preempted. In *Buckman*, plaintiffs alleged that the defendant's fraudulent misrepresentations to the FDA in obtaining approval to market a device caused plaintiffs' injuries. 531 U.S. at 343. The Supreme Court held that the plaintiffs' product liability claim was impliedly preempted because such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id*. at 350. Here, as in *Buckman*, the federal regulation is critical to plaintiff's state-law claim. Plaintiff's KCPA claim is based on "fail[ure] and refus[al] to timely report information . . . as required by 21 C.F.R. 805.50(a)." Claims that a defendant failed to make a report to the FDA as required by the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.*, ("MDA") to the Food Drug and Cosmetic Act ("FDCA") are among those that are preempted and cannot give rise to a state law cause of action. *See Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 809–10 (W.D. Va. 2002). Viewing the allegations in the light most favorable to plaintiff, the court finds that she fails to state a plausible claim for relief because the KCPA claim, as alleged, conflicts with, and is therefore preempted by, the MDA.

B. Count VII of the Proposed Second Amended Complaint

Rule 15 of the Federal Rules of Civil Procedure governs the procedure for amending pleadings. Where, as here, responsive pleadings have been served, a party may amend only by leave of court, and such leave shall be freely given when justice so requires. Fed. R. Civ. P. 15(a). The decision is entrusted to this court's discretion. *Hall v. Witteman*, No. 07-4128-SAC, 2008 WL 2949567, at *4 (D. Kan. July 30, 3008) (citing *Stewart v. Brd. of Comm'rs for Shawnee Cnty., Kan.*,

216 F.R.D. 662, 664 (D. Kan. 2003)). Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party, bad faith, or futility of amendment. *Id*. Here, defendants argue that futility bars amendment.[1] Specifically, defendants argue that the claim against them as amended suffers from the same defects as the original claim: it flows from alleged violations of federal regulations and is preempted by the MDA.

A court may deny a proposed amendment on the basis of futility if the "amendment would not withstand a motion to dismiss or otherwise fails to state a claim upon which relief may be granted." *Stewart*, 216 F.R.D. at 664 (citing *Ketchum v. Cruz*, 961 F.2d 916, 920 (10th Cir. 1992); *Schepp v. Fremont Cnty., Wyo.*, 900 F.2d 1448, 1451 (10th Cir. 1990)).

Plaintiff's proposed second amended complaint sets out the KCPA claim against the ConvaTec defendants in pertinent part as follows:

> 127. Under the K.S.A. § 50-626, no supplier shall engage in any deceptive act or practice in connection with a consumer transaction and deceptive acts include, but are not limited to the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact. K.S.A. § 50-626(b)(3).
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> . . . .
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> 131. The Defendants, or entities under their control, designed, manufactured, assembled, labeled, branded, marketed, distributed, and/or sold Quick-Set infusion sets, and/or their component parts, including the set used by Plaintiff, that were defective because they were misbranded, were not manufactured in compliance with regulatory standards, were incorrectly manufactured, and/or were manufactured using a defective and/or unapproved change in design, specification, and/or manufacturing process so that the infusion set used by Plaintiff, or her Medtronic MiniMed pump with which it was used, would not vent and/or function properly.
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> 132. The Defendants, or entities under their control, violated the KCPA by engaging

[1] Defendants also argue that allowing amendment would be unduly burdensome and prejudicial because it would "forc[e] them to relitigate a dismissal issue that has already been fully briefed." (Doc. 24 at 3.) For the reasons set out in the court's analysis, the court does not believe the defendants will be required to relitigate fully briefed issues.

> in deceptive acts and practices when they willfully marketed and/or sold Quick-Set infusion sets, and/or their component parts that were defective so that the infusion set used by Plaintiff, or her Medtronic MiniMed pump with which it was used, would not vent and/or function properly.

(Doc. 21-1 at 29–30.)

The parties agree that the question before the court is whether paragraphs 131 and 132, when read with the whole of the allegations contained in the proposed amended complaint, state a claim upon which relief can be granted. The court finds that they do.

Paragraph 131 alleges essentially that defendants designed, manufactured, marketed, distributed, and/or sold a defective product; and paragraph 132 alleges that defendants violated the KCPA by willfully marketing and/or selling that defective product. To the extent the proposed amended language clarifies that the claim is based on failure to state material facts or willful concealment of facts *to consumers* and not to the FDA, the claim avoids the concerns identified by the Supreme Court in *Buckman*. *Woods*, 218 F. Supp. 2d at 810. In other words, the amended language asserts liability flowing from defendants' alleged willful marketing of a defective product to consumers, and not on defendants' alleged failure to report as required by FDA regulations. The court finds that such a claim is not preempted under the *Buckman* rationale.

Furthermore, unlike "fraud on the FDA" claims and regulation violations that the FDA is concerned about, the states have a strong interest in protecting their citizens from fraud, deceptive practices, and personal injuries. *See Lohr*, 518 U.S. at 485 (recognizing the "historic primacy of state regulation of matters of health and safety") This state interest weighs against finding implied preemption. *Buckman*, 531 U.S. at 347.

Defendants appear to recognize that the amended language addresses the problem, but they argue that the complaint does not contain facts to support the allegation that defendants failed to state

material facts to, or willfully concealed facts from, plaintiff. And to the extent that any misrepresentation was based on a failure to comply with the FDA's "regulatory standards," the claim should fail under *Buckman*.

In terms of preemption, an actual conflict may exist if violation of a federal regulation is an essential element of the KCPA claim. However, the court is not prepared to make that determination on the briefing presented. *See Caraker v. Sandoz Pharm. Corp.*, 173 F. Supp. 2d 1018, 1036–37 (S.D. Ill. 2001); *Russell v. Sprint Corp.*, 264 F. Supp. 2d 955 (D. Kan. 2003). Although plaintiff's proposed amended complaint is short on facts specifically supporting the KCPA claim, the court is unwilling, at this point in the litigation, to say that she has not alleged enough facts to state a claim to relief that is plausible on its face. The court concludes that plaintiff should be permitted to amend her complaint. She shall have ten days within which to file her Second Amended Complaint. And plaintiff will be given thirty days from the date of this order within which to obtain service of her Second Amended Complaint. Defendants may, of course, file dispositive motions, including a motion to dismiss, as to the amended complaint.

IT IS THEREFORE ORDERED that Defendants ConvaTec, Inc., Unomedical, Unomedical Infusion Devices, and Unomedical, Inc.'s [the "ConvaTec defendants"] Motion to Dismiss Under Rule 12(b)(6) (Doc. 9) is granted.

IT IS FURTHER ORDERED that Plaintiff's Motion for Leave to Amend and Memorandum of Support (Doc. 21) is granted. Plaintiff is directed to file her Second Amended Complaint within ten days from the date of this order.

IT IS FURTHER ORDERED that Plaintiff's Motion for Enlargement of Time to Obtain Service (Doc. 28) is granted. Plaintiff shall have thirty days from the date of this order within which to obtain service for her proposed Second Amended Complaint.

Dated this 7th day of December, 2011 at Kansas City, Kansas.

s/ Carlos Murguia
CARLOS MURGUIA
United States District Judge