IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI SOUTHWESTERN DIVISION

JIMMY ZACCARELLO,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3:13-CV-01161-BCW
	)	
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

ORDER

This matter is before the Court on Defendants' motion to dismiss (Doc. #87). For the following reasons, the Court grants-in-part and denies-in-part the motion.

I. BACKGROUND[1]

A. Defendants' Product.

Defendants design, manufacture, and sell the Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse"). This medical device is used in spinal fusion surgeries and consists of two components: (1) a bone graft substitute ("Infuse Bone Graft"), and (2) a hollow, metal cylinder ("LT-Cage").

On July 2, 2002, the Food and Drug Administration ("FDA") approved Infuse through the required premarket approval process. The FDA indicated Infuse should be used for single-level anterior lumbar interbody fusions placed within the L4-S1 region. The FDA also emphasized that the Infuse Bone Graft must not be used without the LT-Cage. Thus, any

[1] The factual background is based on the allegations in the second amended complaint. The Court assumes as true all well-pleaded facts in the second amended complaint and views them in the light most favorable to Plaintiff, the nonmoving party. Gross v. Weber, 186 F.3d 1089, 1090 (8th Cir. 1999).

operation that uses Infuse in a manner inconsistent with the above constitutes an "off-label" use of the device

B. Plaintiff's Surgery.

On November 10, 2006, Plaintiff underwent a transforaminal lumbar interbody fusion at L4-L5. His physician performed the surgery using Infuse in the following off-label manner: the device was implanted by means of a posterior—not anterior—approach and an LT-Cage was not used. During his surgery, two of Defendants' sales representatives were present in the operating room. A few months after his surgery, Plaintiff began experiencing severe, chronic, and ongoing pain in his lower back, left, hip, and left leg.

C. Plaintiff's Claims.

Plaintiff filed this personal injury lawsuit because he attributes his pain to Defendants' promotion of Infuse for "off-label" uses. Plaintiff alleges that Defendants actively promoted the off-label use of Infuse through its sales representatives and consulting physicians despite known adverse side effects. Plaintiff asserts that he would not have undergone the off-label procedure if he or his surgeon had known of the off-label risks

Based on these allegations, Plaintiff's second amended complaint asserts eleven claims: (1) manufacturing defect, (2) design defect, (3) failure to warn, (4) negligence, (5) strict liability (excluding design defect), (6) breach of express warranty, (7) fraudulent misrepresentation and fraud in the inducement, (8) fraud by concealment, (9) misrepresentation, (10) negligence per se, and (11) violations of the Missouri Merchandising Practices Act ("MMPA").

Defendants move to dismiss all claims under Federal Rule of Civil Procedure 12(b)(6). Defendants primarily argue that Plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Defendants

alternatively argue that Plaintiff's claims fail on independent grounds under both federal and Missouri law.

II. LEGAL STANDARDS

A. Federal Rule Of Civil Procedure 12(b)(6).

To survive a Rule 12(b)(6) motion to dismiss, the complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). This standard requires the plaintiff to plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

B. Federal Rule Of Civil Procedure 9(b).

Rule 9(b) establishes a heightened pleading standard for complaints alleging fraud. To survive a Rule 9(b) challenge, the complaint must plead "such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) (internal citations omitted).

C. Preemption.

Congress enacted the MDA in 1976 and granted the FDA authority to regulate the safety and effectiveness of medical devices sold in the United States. 21 U.S.C. §§ 301 et seq. Under the MDA, different types of medical devices receive different levels of scrutiny.

The devices receiving the most scrutiny are those in Class III, which includes Defendants' Infuse. A Class III device is subject to a rigorous premarket approval process that includes FDA review of the device's benefits, effectiveness, risks of injury, and proposed

labeling. Id. at § 360c(a)(1)(C). After receiving approval, a manufacturer must receive supplemental approval from the FDA before making any changes to the device that affect safety or effectiveness. Id. at § 360e(d)(6)(A)(i).

To preserve the FDA's regulatory authority over medical devices, the MDA includes an express preemption provision that provides, with a few exceptions not applicable here, that:

> [N]o 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).

The Supreme Court discussed this provision in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and established a two-step analysis for determining whether a state-law claim is expressly preempted. First, the court must determine whether the federal government established requirements applicable to the medical device. Id. at 321–23. Second, the court must determine whether the state-law claim would impose requirements "different from, or in addition to," the federal requirements. Id. A state-law claim is expressly preempted if the answer to both questions is "yes."

A state-law claim escapes express preemption if the claim imposes duties that parallel the federal requirements because the second step of the Riegel analysis is not satisfied. But such a claim may nonetheless be impliedly preempted under 21 U.S.C. § 337(a). The Supreme Court discussed implied preemption in Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), and noted that the MDA provides that all actions to enforce FDA requirements "'shall be by and in the name of the United States.'" Id. at 349 n.4 (quoting 21 U.S.C. § 337(a)). The Supreme

Court concluded that a parallel state-law claim is impliedly preempted where it "exist[s] solely by virtue" of the federal requirements. Id. at 353.

III. ANALYSIS

A. Plaintiff's Manufacturing Defect Claim (Count One) Is Expressly Preempted.

In Count One, Plaintiff alleges that his "use of Infuse via [a posterior approach] was a reasonably foreseeable use, as actively marketed and promoted for such use by Defendants." Doc. #76 at ¶ 283. Plaintiff also alleges that "Infuse as implanted into Plaintiff was defective as used, as evidenced by Defendants' failure to comply with manufacturing specifications required by Infuse's [premarket approval]." Id. at ¶ 289.

The Court finds this claim is expressly preempted. Under the first step of the express preemption analysis, the Court concludes that the federal government has established requirements applicable to Infuse. In Riegel, the Supreme Court recognized that specifications listed in a premarket approval are federal requirements and that deviations from those specifications are considered violations of the MDA. 552 U.S. at 323. Because Infuse received approval from the FDA, the federal government has established requirements that apply to it. See Blankenship v. Medtronic, Inc., No. 4:13-CV-1087, 2014 WL 1226491, at *4 (E.D. Mo. Mar. 25, 2014) (concluding the first step of Riegel is "easily answered in the affirmative"); Beavers-Gabriel v. Medtronic, Inc., No. 13-686, 2014 WL 1396582, at *8 (D. Haw. Apr. 10, 2014) (finding this step "appears to be plainly met"); Dunbar v. Medtronic, Inc., No. 14-1529, 2014 WL 3056026, at *3 (C.D. Cal. June 25, 2014) (same).

Under the second step, the Court concludes that Plaintiff's manufacturing defect claim is attempting to impose responsibilities on Defendants that are different from, or in addition to, the federal requirements. Plaintiff does not identify any specific manufacturing requirement

imposed by the FDA that Defendants allegedly violated. Therefore, Plaintiff's claim would require Infuse to be manufactured differently than the FDA authorized. As such, this claim is expressly preempted. See Blankenship, 2014 WL 1226491 at *5 (finding manufacturing defect claim is expressly preempted).

B. Plaintiff's Design Defect Claim (Count Two) Is Expressly Preempted.

In Count Two, Plaintiff alleges that "Infuse, when used off-label as promoted by Defendants, is designed in a materially defective manner." Doc. #76 at ¶ 309. Plaintiff also alleges "Infuse as implanted into Plaintiff was defective as used, as evidence by Defendants' failure to comply with manufacturing specifications required by Infuse's [premarket approval]." Id. at ¶ 305.

The Court finds this claim is expressly preempted. As explained above, the first step of the Riegel analysis is satisfied because the federal government has established requirements applicable to Infuse. The second step is also satisfied. Plaintiff does not allege the design of Infuse deviates from the design approved by the FDA. Therefore, Plaintiff's design defect claim is attempting to impose responsibilities on Defendants that are different from, or in addition to, the federal requirements. Because both steps are met, the Court dismisses this claim as expressly preempted. See Blankenship, 2014 WL 1226491 at *6 (finding claim expressly preempted).

C. Plaintiff's Failure to Warn Claim (Count Three) Is Expressly Preempted.

Plaintiff alleges in Count Three that Defendants knew of the dangers relating to off-label use, had a duty to warn Plaintiff and his physician, and failed to provide adequate warning. Plaintiff specifically claims that "Defendants had a continuing duty to warn Plaintiff and Plaintiff's physician about the dangers of Infuse of which it knew," that "Defendants did know of these dangers of off-label use of Infuse," and that Defendants "breached this duty by failing to

warn Plaintiff and Plaintiff's physician of the dangers of its off-label practice of using Infuse." Doc. #76 at ¶¶ 323–324.

The Court finds this claim is expressly preempted. Because the federal government has established requirements for Infuse, the first step of Riegel is satisfied. The second step is also satisfied because Plaintiff's claim seeks to impose on Defendants labeling or warning requirements that go beyond what federal law requires. In other words, Plaintiff's claim would establish label or warning requirements different from, or in addition to, the federal requirements. Plaintiff's failure to warn claim is dismissed. See Blankenship, 2014 WL 1226491 at *6 (finding claim expressly preempted).[2]

D. Plaintiff's Negligence Claim (Count Four) Is Preempted.

In Count Four, Plaintiff alleges that Defendants breached duties owed to him and his physician by the following acts: (1) improper promotion and marketing of Infuse for off-label uses, (2) failure to warn Plaintiff and Plaintiff's physician of the dangers associated with off-label uses of Infuse, (3) failure to exercise reasonable care in complying with federal law and regulations applicable to the sale and marketing of Infuse, and (4) failure to exercise reasonable care to prevent Infuse from creating an unreasonable risk of harm to Plaintiff and other consumers when used in a reasonably foreseeable manner. Doc. #76 at ¶ 349.

The first step of Riegel is satisfied for all four theories because, as explained above, there are applicable federal regulations for Infuse. The Court, however, must separately analyze the second step of Riegel for each theory. See Dunbar, 2014 WL 3056026 at *4–5 (separately analyzing four similar negligence theories).

[2] To the extent Plaintiff bases this claim on Defendants' alleged failure to file an adverse event report with the FDA, the claim is impliedly preempted. In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205–06 (8th Cir. 2010).

1. First Negligence Theory

The Court finds Plaintiff's negligence theory based on improper promotion and marketing is impliedly preempted. The Court concludes that this theory escapes express preemption because the second step of Riegel is not satisfied. Specifically, the Court finds Plaintiff's claim based on off-label promotion runs parallel to the MDA and, therefore, does not impose requirements that are different from, or in addition to, the federal requirements.

The Court recognizes that this issue—whether the MDA prohibits off-label promotion—is a central dispute between the parties and that each side has identified case law supporting its position. Compare Ramirez v. Medtronic, Inc., 961 F. Supp. 2d 977 (D. Ariz. 2013) ("[T]he FDA prohibits device manufacturers from promoting the off-label use of their products.") with Dawson v. Medtronic, Inc., No. 3:13-CV-663, 2013 WL 4048850, at *6 (D.S.C. Aug. 9, 2013) ("This court is not convinced that off-label promotion violates the FDCA."). The Court therefore spent considerable time reviewing the divergent case law on this issue.

After careful consideration, the Court concludes the MDA prohibits off-label promotion. Specifically, the MDA prohibits "misbranding" of medical devices, which includes either misleading labeling or misleading advertising of the medical device. 21 U.S.C. §§ 331(a), 333, and 321(n). Moreover, MDA regulations prohibit Defendants from advertising Infuse for uses beyond what is provided in the premarket approval. 21 C.F.R. § 814.80. Furthermore, the broader regulatory scheme also supports this understanding of the MDA.[3] See Blankenship, 2014 WL 1226491 at *5 ("If medical device manufacturers were permitted to promote their products for non-approved off-label uses . . . [they] would have little reason to participate in the

[3] This understanding is also supported by the FDA's informal interpretation of its own regulations. See United States v. Caronia, 703 F.3d 149, 155 (2d Cir. 2012) (citing FDA, Draft Guidance, Good Reprint Practices for the Distrib. of Med. Journal Articles & Med. or Sci. Ref. Publ'ns on Unapproved New Uses of Approved Drugs & Approved or Cleared Med. Devices, at 2–3 (2009)).

supplemental approval process."); Beavers-Gabriel, 2014 WL 1396582, at *9 ("Given these federal 'requirements,' the court finds that a claim based on off-label promotion survives express preemption.").

Even though Plaintiff's first negligence theory survives express preemption, the Court finds the claim is barred by implied preemption. This claim is impliedly preempted because Defendants do not have a state-law duty to refrain from off-label promotion. Rather, Defendants' duty "exist[s] solely by virtue" of the MDA. See Blankenship, 2014 WL 1226491 at *8; Beavers-Gabriel, 2014 WL 1396582 at *16 (finding the defendants' duty "to abstain from off-label promotion exists solely by virtue of the federal prohibition"); Dunbar, 2014 WL 3056026 at *5 ("[T]here is no claim for illegal off-label promotion rooted in traditional state tort law.").

2. Second and Fourth Negligence Theory

The Court finds Plaintiff's claims based on these theories are expressly preempted. The first step of Riegel is satisfied because there are federal regulations applicable to Infuse. The second step is also met because, as discussed above regarding Plaintiff's defective design, manufacturing defect, and failure to warn claims, these negligence theories seek to impose on Defendants labeling, manufacturing, and design requirements that are different from, or in addition to, the federal requirements. See Dunbar, 2014 WL 3056026 at *5 (finding similar negligence claims expressly preempted); Beavers-Gabriel, 2014 WL 1396582 at *15.

3. Third Negligence Theory

The Court dismisses this claim for failure to include sufficient facts. Plaintiff does not allege facts regarding a particular violation of federal law and, therefore, fails to state a plausible claim. In addition, without more information, the Court is unable to determine whether the

federal regulations are parallel to the MDA and whether the claim can exist independent from the MDA. See Dunbar, 2014 WL 3056026 at *5 (dismissing similar theory); Beavers-Gabriel, 2014 WL 1396582 at *15 (noting the plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption" (internal quotation and citation omitted) (alteration in original)).

E. Plaintiff's Strict Liability Claim (Count Five) Is Preempted.

In Count Five, Plaintiff alleges that "Infuse was defective due to inadequate warning or labeling" and "was also defective, unsafe, and ineffective for off-label uses that Defendants promoted Infuse to be used for . . . and Defendants knew or should have known that Infuse was defective, unsafe, and ineffective for such off-label uses . . . ." Doc. #76 at ¶¶ 362–363. Plaintiff further alleges "[t]he off-label use of Infuse, as given to Plaintiff, was ineffective, defective and dangerous when manufactured, promoted, and instructed by Defendants, who are strictly liable for injuries arising from its use." Id. at ¶ 368.

To the extent this claim is based on strict liability for failure to warn and manufacturing defect, the claim is expressly preempted for the reasons previously discussed. See Dunbar, 2014 WL 3056026 at *4 (finding strict liability failure to warn claim expressly preempted); Beavers-Gabriel, 2014 WL 1396582 at *13 (same). To the extent this claim is based on strict liability for off-label promotion, the claim is impliedly preempted because there is no state-law duty to abstain from off-label promotion. See Blankenship, 2014 WL 1226491 at *9 ("Plaintiff's strict liability claim is also impliedly preempted because promoting the off-label use of an FDA approved medical device is not unlawful under traditional state tort law which, had predated the federal enactments in question." (internal citation and quotation omitted)).

F. Plaintiff's Breach of Express Warranty Claim (Count Six) Escapes Preemption But Does Not Include Sufficient Facts.

Plaintiff alleges in Count Six that "Defendants utilized journal articles, advertising media, sales representatives, consultants, and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse and expressly warranted to physicians and other members of the general public and medical community that such off-label uses . . . were safe and effective." Doc. #76 at ¶ 376. Plaintiff further alleges "his treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of off-label use of Infuse . . . ." Id. at ¶ 378.

The Court finds that this claim escapes express and implied preemption. This claim is not expressly preempted because, as discussed above, claims based on Defendants' alleged misleading warranties regarding off-label uses of Infuse do not seek to impose requirements different from, or in addition to, the federal requirements. This claim is not impliedly preempted because a breach of express warranty claim based on this theory does not exist solely by virtue of the MDA. See Dunbar, 2014 WL 3056026 at *7 (finding similar claim survives preemption); Beavers-Gabriel, 2014 WL 1396582 at *17 (same).

Nonetheless, the Court dismisses this claim because Plaintiff fails to allege sufficient facts. Under Missouri law, a claim for breach of an express warranty requires the seller to make a statement of fact about the kind or quality of the goods and the statement of fact must be a material factor inducing the buyer to purchase the good. Pfizer v. Smith & Wesson Corp., No. 4:13-676, 2014 WL 636381, at *1 (E.D. Mo. Feb. 18, 2014). Plaintiff fails to include any facts suggesting that Defendants' representations became the basis of the bargain. The second amended complaint also fails to allege the specific warranties Defendant made to Plaintiff or his physician. See id. at *3 (dismissing express breach of warranty claim for lack of factual

allegations); Dunbar, 2014 WL 3056026 at *8 (dismissing similar claim under California law); Beavers-Gabriel, 2014 WL 1396582 at *17 (dismissing similar claim under Hawaii law).

G. Plaintiff's Fraudulent Misrepresentation/Fraud in the Inducement/Fraud by Concealment/Misrepresentation Claims (Counts Seven Through Nine) Escape Preemption But Are Not Alleged With Particularity.

In Count Seven, Plaintiff alleges that "Defendants fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff's physician . . . ." Doc. #76 at ¶ 385. In Count Eight, he alleges that Defendants willfully and intentionally concealed facts that the Infuse product was dangerous and likely to cause serious health consequences to users when used as promoted. Id. at ¶¶ 399–400. In Count Nine, Plaintiff alleges that Defendants made untrue representations of material facts and omitted material information by sponsoring biased medical trials, reports, and articles that inaccurately claimed Infuse was safe for off-label use. Id. at ¶¶ 407–408.

The Court finds these claims survive preemption. Plaintiff's fraud-based claims are not expressly preempted because they are parallel to the federal requirements regarding off-label promotion. These claims are also not impliedly preempted because they are based on traditional state common law that exists independently of the MDA. See, e.g., Rev. Mo. Stat. 407.020 (declaring unlawful acts of fraud and misrepresentation in connection with the sale or advertisement of any merchandise); see also Blankenship, 2014 WL 1226491 at *10 (finding similar claims survive preemption); Beavers-Gabriel, 2014 WL 1396582 at *11 (determining fraud-based claims based on misrepresentations and omissions in promoting off-label use of Infuse are not preempted).

Nonetheless, the Court dismisses Plaintiff's fraud-based claims because they fail to satisfy Federal Rule of Civil Procedure 9(b). Under this rule, the second amended complaint must detail "such matters as the time, place and contents of false representations, as well as the

identity of the person making the representation and what was obtained or given up thereby." Freitas v. Wells Fargo Home Mortg., Inc., 703 F.3d 436, 439 (8th Cir. 2013) (internal quotation omitted). Plaintiff's allegations do not satisfy this standard. Plaintiff provides detailed allegations on studies, journal articles, investigations, and media reports, but he fails to identify (among other things) the particular misrepresentations and knowingly false statements that were made to him and his physician. See Blankenship, 2014 WL 1226491 at *10 (dismissing without prejudice fraud and misrepresentation claims); Beavers-Gabriel, 2014 WL 1396582 at *12–13 (determining complaint failed to allege connection between the defendants' misdeeds and the plaintiff); Dunbar, 2014 WL 3056026 at *7 (rejecting fraud claims based on "boilerplate and general allegations"). These claims are dismissed.

H. Plaintiff's Negligence Per Se Claim (Count Ten) Is Impliedly Preempted.

In Count Ten, Plaintiff alleges negligence per se based on Defendants' violation of "applicable federal statutes and regulations relating to medical devices . . . ." Doc. #76 at ¶ 419. This claim escapes express preemption because there are applicable federal regulations for Infuse and because the claims—being based on violations of the MDA—are parallel claims. But the Court finds this claim is impliedly preempted because the applicable standards of care rely on the MDA and, therefore, the existence of this claim exists solely by virtue of the federal requirements. See Dunbar, 2014 WL 3056026 at *5–6 (concluding a similar claim is impliedly preempted because "a negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages").

I. Plaintiff's MMPA Claim (Count Eleven) Is Not Preempted And Sufficiently States A Claim.

Plaintiff's final claim alleges that Defendants unlawfully misrepresented and concealed facts in connection with the sale or advertisement of Infuse Bone Graft. Doc. #76 at ¶ 427.

Plaintiff further alleges that he "purchased and/or paid for, in part, Infuse Bone Graft that was used in an off-label spinal surgery" and that he "suffered an ascertainable economic loss in that Infuse was purchased and/or paid for, in part, for an off-label procedure based on Defendants' false claims." Id. at ¶ 428.

The Court finds this claim survives preemption to the extent it is based on Defendants' misrepresentations and false claims.[4] A MMPA claim based on this theory survives express preemption because there are federal regulations applicable to Infuse and because Plaintiff's claim parallels federal law. Similarly, this claim is not impliedly preempted because the cause of action does not exist solely by virtue of federal law.

The Court finds that this claim also survives Defendants' other challenges.[5] Defendants argue Plaintiff's claim is barred by a five-year statute of limitations because Plaintiff's surgery was on November 10, 2006, he began experiencing pain "[a] few months" later, and he did not file his complaint until September 20, 2012. A Rule 12(b)(6) challenge based on a statute of limitations defense may be successful when it "appears from the face of the complaint itself that the limitation period has run . . . ." Varner v. Peterson Farms, 371 F.3d 1011, 1016 (8th Cir. 2004) (internal quotation omitted). Although this argument might be successful at summary judgment on a developed factual record, the Court cannot find that the allegations in Plaintiff's second amended complaint demonstrate the claim is barred by the statute of limitations.

Defendants also argue Plaintiff fails to state a plausible claim because "he did not purchase [Infuse]." Doc. #88 at 40. The Court disagrees. To state a claim under the MMPA, a plaintiff must allege (among other things) he purchased merchandise primarily for personal,

[4] To the extent this claim is based on allegations that Defendants should have acted differently in manufacturing, designing, developing, and labeling Infuse, the claim is expressly preempted.

[5] Defendants do not make a Rule 9(b) challenge to this claim.

family, or household purposes. See Owen v. Gen. Motors Corp., 533 F.3d 913, 922 (8th Cir. 2008) (discussing elements of MMPA claim). Plaintiff alleges he paid for, in part, Infuse Bone Graft for a surgery. This allegation is sufficient at the pleading stage. See Gibbons v. J. Nuckolls, Inc., 216 S.W.3d 667, 669 (Mo. banc 2007) (explaining that a consumer who receives the product through a third party is included within the statute). Accordingly, it is therefore

ORDERED the Motion to Dismiss of Defendants Medtronic, Inc., Medtronic Sofamor Danek USA, Inc., Medtronic Vertelink, Inc., Medtronic Sofamor Danek, Inc., and Warsaw Orthopedic, Inc. (Doc. #87) is GRANTED-IN-PART and DENIED-IN-PART. The Court denies the portion related to Count Eleven and grants the rest of the motion.

IT IS SO ORDERED.

DATED: August 6, 2014

/s/ Brian C. Wimes
JUDGE BRIAN C. WIMES
UNITED STATES DISTRICT COURT