IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

PATRICIA CAPLINGER,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. CIV-12-630-M
	)	
MEDTRONIC, INC., a Minnesota corporation, and MEDTRONIC SOFAMOR DANEK USA, INC., a Tennessee corporation,	)	
	)	
Defendants.	)	

ORDER

Before the Court is defendants' Motion to Dismiss Plaintiff's Amended Complaint, filed August 9, 2012. On September 4, 2012, plaintiff filed her response, and on September 20, 2012, defendants filed their reply.

I. Background

On August 25, 2010, plaintiff had a posterior lumbar interbody fusion surgery at the L5-S1 spine to correct a degenerative disc condition.[1] The Infuse® Bone Graft product ("Infuse Device") was used in the surgery. In October and November 2010, plaintiff's symptoms returned and worsened and included a drop foot condition in her right leg allegedly resulting from exuberant bone growth caused by the use of the Infuse Device. In December 2010, plaintiff's drop foot condition caused a tear of the anterior cruciate ligament in her right knee, which required surgery in February 2011. Because of exuberant bone growth in plaintiff's lumbar spine, revision surgery was required on September 9, 2011. Exuberant bone growth is continuing and will likely require a second revision surgery.

[1]A posterior lumbar interbody fusion surgery is performed through the back.

The Infuse Device was made by defendants. It is a medical device consisting of three parts: (1) a recombinant human bone morphogenetic protein, (2) a collagen scaffold, and (3) an interbody fusion device (essentially, a cage). The Infuse Device is used for the treatment of degenerative disc disease in a surgical procedure known as spinal fusion. The Infuse Device is a Class III medical device approved by the Federal Drug Administration ("FDA") through the Premarket Approval ("PMA") process. The Infuse Device has been approved for use in lumbar surgery that is performed through the abdomen (anterior) but has not been approved for use in lumbar surgery that is performed through the back (posterior). The Infuse Device was initially approved on July 2, 2002. The FDA has since approved thirty-seven supplements to its PMA.

On June 4, 2012, plaintiff filed the instant action. On July 23, 2012, plaintiff filed an Amended Complaint. In her Amended Complaint, plaintiff alleges seven causes of action against defendants in connection with their Infuse Device: (1) fraudulent misrepresentation and fraud in the inducement, (2) constructive fraud, (3) strict products liability – failure to warn, (4) strict products liability – design defect, (5) breach of express and implied warranty, (6) negligence, and (7) negligent misrepresentation.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), defendants now move this Court to dismiss plaintiff's Amended Complaint with prejudice. Defendants assert that plaintiff's claims are expressly preempted in their entirety by the Medical Device Amendments of 1976, 21 U.S.C. § 360(k), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), because they seek to impose state-law requirements on the design, manufacture, or labeling of the Infuse Device that are different from or in addition to the federal requirements imposed by the FDA. Moreover, defendants assert that to the extent plaintiff's claims seek to enforce the provisions of

federal law governing the promotion of medical devices for "off-label" uses, they are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and prohibited by the "no private cause of action" clause of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 337(a).

II. The Statutory and Regulatory Framework and the PMA Process

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq., has long required FDA approval for the introduction of new drugs into the market; however, the introduction of new medical devices was left largely for the states to supervise as they saw fit. *See Riegel*, 552 U.S. at 315. The regulatory landscape changed in the 1960's and 1970's, as complex devices proliferated and some failed, most notably the Dalkon Shield. *See id.* As a result, Congress stepped in with the passage of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq., which swept back some state obligations and imposed a regime of detailed federal oversight. *See id.* at 316.

> The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. § 360c(a)(1)(A); FDA, Device Advice: Device Classes, http:// www.fda.gov/ cdrh/ devadvice/ 3132.html (all Internet materials as visited Feb. 14, 2008, and available in Clerk of Court's case file). Class II, which includes such devices as powered wheelchairs and surgical drapes, *ibid.*, is subject in addition to "special controls" such as performance standards and postmarket surveillance measures, § 360c(a)(1)(B).
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> The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, FDA, Device Advice: Device Classes, *supra*. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and

> the device is "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," or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii).

Id. at 316-17.

The MDA established a rigorous regime of premarket approval for new Class III devices.

> A manufacturer must submit what is typically a multivolume application. FDA, Device Advice – Premarket Approval (PMA) 18, http://www.fda.gov/cdrh/devadvice/pma/printer.html. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(1)(G).
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> The FDA spends an average of 1,200 hours reviewing each application, [*Medtronic, Inc. v.*] *Lohr*, [518 U.S. 470,] 477 . . . and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. . . .
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> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).

> After completing its review, the FDA may grant or deny premarket approval. § 360e(d). It may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. The agency is also free to impose device-specific restrictions by regulation. § 360j(e)(1).
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> If the FDA is unable to approve a new device in its proposed form, it may send an "approvable letter" indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions. 21 CFR § 814.44(e). Alternatively, the agency may send a "not approvable" letter, listing the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable. § 814.44(f).
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> Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c).
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> After premarket approval, the devices are subject to reporting requirements. § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. § 360e(e)(1); see also § 360h(e) (recall authority).

Id. at 317-320.

III. Discussion

A. Motion to dismiss standard

Regarding the standard for determining whether to dismiss a claim pursuant to Rule 12(b)(6), the United States Supreme Court has held:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotations and citations omitted). Further, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not shown - that the pleader is entitled to relief." *Id.* at 679 (internal quotations and citations omitted). Additionally, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Id.* at 678 (internal quotations and citations omitted). Finally, "[a] court reviewing the sufficiency of a complaint presumes all of plaintiff's factual allegations are true and construes them in the light most favorable to the plaintiff." *Hall v. Bellmon*, 935 F.2d 1106, 1109 (10th Cir. 1991).

B. Express preemption

The MDA includes an express preemption provision that states:

> 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).[2] In *Riegel*, the United States Supreme Court employed a two-step analysis for determining whether state law claims are preempted under § 360k(a). First, the Supreme Court considered whether PMA of a medical device by the FDA imposes federal "requirements" under the MDA. *See Riegel*, 552 U.S. at 321-23. The Court concluded that PMA imposes federal "requirements" within the meaning of the MDA. *See id.* at 322-23. Second, the Supreme Court considered whether the state common law claims would impose requirements "different from, or in addition to" the requirements imposed by the PMA process and that relate to safety and effectiveness. *See id*. at 322-23. The Court concluded that the plaintiffs' state common law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device would impose requirements "different from, or in addition to" the requirements imposed by the PMA process. *Id.* at 323. In reaching that conclusion, the Supreme Court noted that

> excluding common law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater

[2]The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption.

> effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id. at 325.

When determining whether a state requirement is "in addition to" the requirements imposed by federal law, courts have found "[w]here a federal requirement permits a course of conduct and the state makes its obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (internal quotations and citation omitted).

However, the Supreme Court has made clear that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330.

> In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.

Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (8th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original). Further, "[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Id.* at 1301 (internal quotations and citation omitted). "Plaintiffs must also

allege a link between the failure to comply and the alleged injury." *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011).

C. Implied preemption

The FDCA states that an action for "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted § 337(a) in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The Supreme Court found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government. 21 U.S.C. § 337(a)." *Buckman*, 531 U.S. at 352. The Supreme Court then found that "although *Medtronic*[, *Inc. v. Lohr*, 518 U.S. 470 (1996)] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Buckman*, 531 U.S. at 353. Concluding, the Supreme Court found:

> [i]n sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.

Id.

> Thus, a private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist. So, for example, a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA.
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> This does not mean . . . that a plaintiff can never bring a state-law claim based on conduct that violates the FDCA. Indeed . . . the conduct on which the plaintiff's claim is premised *must* violate the

> FDCA if the claim is to escape express preemption by § 360k(a). Instead, to avoid being impliedly preempted under *Buckman*, a claim must rely[ ] on traditional state tort law which had predated the federal enactments in question[ ]. 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. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009) (internal quotations and citations omitted).

D. Interplay between express and implied preemption

Considering the law regarding express preemption and the law regarding implied preemption 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 at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777) (emphasis in original). Thus, "[f]or a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Riley*, 625 F. Supp. 2d at 777.

E. The parties' arguments

1. Defendants' arguments

Defendants assert that because plaintiff's claims would require a determination that the Infuse Device should have been labeled, designed or manufactured differently from the manner

required by the FDA, those claims are preempted and must be dismissed. Specifically, defendants assert that because each of plaintiff's claims seeks to impose state law requirements on the design, manufacture, or labeling of the Infuse Device that are different from or in addition to those imposed by the FDA through the PMA process, *Riegel* and its progeny compel dismissal. Defendants further assert that to the extent that plaintiff's claims seek to enforce the FDCA's provisions governing the approval or off-label promotion of medical devices, they also are impliedly preempted and barred by § 337(a).

Regarding plaintiff's fraudulent misrepresentation, fraud in the inducement, constructive fraud, negligent misrepresentation, and failure to warn claims (both based in strict liability and negligence), defendants contend that plaintiff does not allege that defendants failed to provide any of the warnings required by the FDA through the PMA process but instead alleges that defendants should have given additional warnings beyond those required by the FDA. Defendants, therefore, conclude that plaintiff's claims are preempted because they would require a finding that, as a matter of Oklahoma law, defendants failed to provide adequate warnings despite having labeled the Infuse Device as required by the FDA and would, thus, impose labeling requirements "different from, or in addition to," those imposed by federal law. Defendants further assert that plaintiff's off-label promotion allegations do not immunize plaintiff's claims from express preemption under § 360k(a). Defendants contend that to comply with the state law duty that plaintiff's failure-to-warn theory imposes, defendants would be forced to provide certain, unspecified warnings about the alleged risks of off-label use and would thus be forced to provide labeling to accompany the Infuse Device that is "different from, or in addition to" that already approved by the FDA through the PMA process.

Defendants also contend that plaintiff's fraud and misrepresentation claims fail because they are not pled with particularity as required by Federal Rule of Civil Procedure 9(b). Specifically, defendants contend that plaintiff's Amended Complaint does not set forth the time, place and contents of the alleged false representations, the identity of the party making the alleged false statements and the consequences thereof. Finally, defendants contend that plaintiff cannot base her failure to warn claims on defendants' representative's failure to fully disclose all pertinent information and properly instruct plaintiff's surgeon regarding the off-label use of the Infuse Device for plaintiff's surgery because such a claim would require defendants, through their representative, to have used warnings different from, or in addition to, those required by the FDA.

Regarding plaintiff's strict liability design defect claim, defendants state that although plaintiff alleges that the Infuse Device suffered from a defective design, she does not allege that the design of the device that she received was anything other than the design approved by the FDA through the PMA process. Defendants assert that claims that attack the FDA-approved design of a Premarket Approved device are preempted regardless of whether they are based in strict liability or negligence. Defendants further assert that plaintiff's off-label allegations cannot save her design defect claim from preemption because even if plaintiff could prevail on her design defect claim as a matter of state law by convincing a jury that the Infuse Device was "unsafe" with respect to a given off-label use, such a claim would impose a state law requirement that the device have been designed differently from the manner approved by the FDA through the PMA process.

Regarding plaintiff's breach of express and implied warranty claims, defendants contend that for plaintiff to prevail on these claims, a jury would have to find that the Infuse Device was not safe or effective but that such a jury finding would inevitably contradict the FDA's conclusive

determination, via the PMA process, that the Infuse device is safe and effective. Defendants, therefore, contend that because plaintiff's warranty claims challenge the safety and effectiveness of a Premarket Approved device, they are expressly preempted.

Additionally, defendants contend that plaintiff has failed to allege any parallel claim that might survive preemption. Specifically, defendants assert that plaintiff has not demonstrated how the duties and obligations imposed by state and federal law are genuinely equivalent or identical or how the alleged federal violations caused injury. For example, defendants allegedly violated a federal requirement that manufacturers not promote devices for off-label uses. The state law requirement that defendants allegedly violated is the requirement that a manufacturer provide adequate warnings to physicians about the risks of its medical device. But a duty not to promote devices for off-label use is not parallel to a duty to warn of device risks. Defendants assert that it is possible to violate the purported state law requirement while complying with the federal requirement, and vice versa, thereby demonstrating that the two requirements are not "parallel" and that an alleged violation of the federal duty to refrain from off-label promotion cannot save plaintiff's state law failure-to-warn claims from express preemption.

Finally, defendants contend that even if allegations of off-label promotion or other federal statutory or regulatory violations could save plaintiff's claims from express preemption, her claims would still be impliedly preempted under *Buckman* and barred by § 337(a). Specifically, defendants assert that by seeking to impose liability based on defendants' alleged violation of the FDA's restriction on off-label promotion, plaintiff is trying to usurp the FDA's exclusive authority to police purported violations of its own regulations and this Court should reject plaintiff's attempt to encroach upon the FDA's discretionary authority to enforce the restrictions on off-label promotion.

Defendants further contend that to the extent plaintiff's claims rest on allegations of regulatory violations, they are not only impliedly preempted but are also barred by the FDCA's no-private-right-of-action clause, § 337(a). Any effort by plaintiff to fashion a state law cause of action out of an alleged federal statutory violation with no counterpart in established state law is an attempt at private enforcement of the FDCA barred by § 337(a). There is no pre-existing state law duty to abstain from off-label promotion (or to comply with the various federal statutes and regulations listed in the complaint). Defendants contend that plaintiff is seeking to hold defendants liable for conduct that was not unlawful under traditional state tort law which had predated the federal enactment and is attempting to pursue claims that include as a critical element something that exists solely by virtue of the FDCA.

2. Plaintiff's arguments

Plaintiff asserts that the FDA only approved the Infuse Device for anterior procedures and specifically asked defendants to take measures to prohibit the off-label use and off-label promotion of posterior uses. Plaintiff further asserts that posterior use is considered a "new indication" for which defendants were obligated to obtain FDA approval if it sought to promote such use, yet, defendants never obtained the FDA's approval for posterior use of the Infuse Device. Because defendants failed to obtain said approval, plaintiff contends defendants' intentional promotion of the Infuse Device for such off-label uses was in violation of federal law and FDA regulations and, thus, defendants are not entitled to the preemption defense.

Additionally, plaintiff asserts that she is alleging "parallel" claims arising out of defendants' illegal off-label promotion that are not preempted by federal law. Plaintiff contends that defendants were obligated to obtain FDA approval for all of the uses for which they intended to promote the

Infuse Device and once defendants chose to intentionally promote the Infuse Device for off-label/unapproved uses, it resulted in a violation of federal law. Plaintiff then contends that defendants' failure to obtain approval for posterior use of the Infuse Device, their intentional off-label promotion of the Infuse Device, and their failure to provide adequate warnings for the off-label/unapproved uses, thus, subjects them to state law tort liability.

Plaintiff further asserts that the *Buckman* case is not applicable to the case at bar and does not impliedly preempt plaintiff's parallel claims of illegal off-label promotion. Plaintiff contends that her claims are traditional state tort law claims based on negligence, warning defects, and fraud on her, not fraud on a federal agency. Plaintiff states that she is not complaining of fraud on the FDA but rather claims that she and her physician were deceived and injured by defendants' actions in (a) illegally promoting the Infuse Device for off-label/unapproved uses, (b) utilizing undisclosed paid consultants to market the off-label use of the Infuse Device, and (c) failing to provide adequate warnings regarding the risks and dangers associated with the promoted off-label uses.

Regarding her breach of warranty claims, plaintiff contends that even if the Court deems plaintiff's other claims preempted, her breach of warranty claims cannot be preempted because such claims are specifically excluded from preemption by FDA regulations, 21 C.F.R. § 808.1(d), and arise out of defendants' own voluntary (as opposed to FDA imposed) off-label warranties and representations. Plaintiff further asserts that imposing liability on defendants for violating their express and implied warranties would not impose any additional state law obligations on defendants.

Finally, plaintiff contends that her claims arising out of defendants' acts during her surgery are not preempted. Plaintiff alleges that even though defendants' representative was aware of the specific use of the Infuse Device for plaintiff's surgery, the representative breached her duty by

failing to provide the necessary information regarding the excessive danger involved in using the Infuse Device for a posterior-approach lumbar spine fusion. Plaintiff asserts that her negligence and constructive fraud claims against defendants arising out of the representative's actions/inactions during surgery do not challenge the design, manufacture, and labeling of the Infuse Device so as to implicate *Riegel* preemption.

F. Court's analysis

1. Effect of allegations of off-label promotion on preemption

As set forth above, plaintiff asserts that because defendants promoted off-label use of the Infuse Device for posterior approach lumbar spine fusion in violation of federal law, § 360k(a) preemption does not apply. In other words, plaintiff contends that § 360k(a) does not preempt any claim that arises out of the promotion of an off-label use of a device.[3]

The Court finds that such a contention must fail because it is inconsistent with the text of § 360k(a) and allegations of promotion of off-label use of a device in violation of federal law does not automatically immunize a plaintiff's claims from being subject to a preemption analysis under § 360k(a). As the court is *Riley* aptly stated:

> under § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable "to the *device*." If there are – and, as *Riegel* makes clear, the PMA process unquestionably imposes such requirements – then any state requirements that are different from, or in addition to, those federal

[3]The Court would note that the Supreme Court recognized in *Buckman* that off-label use is not illegal or even disfavored under federal law but is an accepted and valuable part of the practice of medicine. "'[O]ff-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350.

> requirements are preempted. Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used.

Riley, 625 F. Supp. 2d. at 779 (emphasis in original). For the same reasons, the Court finds that nothing in § 360k(a) suggests that the preemption analysis somehow depends on how the device is being promoted to be used. Accordingly, the Court finds that regardless of plaintiff's off-label promotion allegations, each of plaintiff's claims must be analyzed to determine whether it is preempted under § 360k(a) or § 337(a).[4]

2. Plaintiff's fraudulent misrepresentation and fraud in the inducement claim

In her Amended Complaint, plaintiff alleges that "Defendants fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and her physicians." Amended Complaint at ¶ 93. Plaintiff further specifically alleges the following to establish defendants' liability for fraudulent misrepresentation and/or fraud in the inducement:

> a. Defendants fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label posterior-approach use of their Infuse® product;
> b. Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label use of Infuse® in posterior-approach lumbar spine surgery;
> c. Defendants fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

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[4]The Court also finds that plaintiff's off-label promotion allegations do not somehow turn plaintiff's claims into "parallel" claims that are not preempted. Specifically, the Court finds that the federal requirement that manufacturers not promote devices for off-label uses is not genuinely equivalent to the state law requirements that a manufacturer provide adequate warnings to physicians about the risks of its medical device and that a manufacturer not produce a product with a defective design. It is possible to violate the state law requirement while complying with the federal requirement and vice versa.

Amended Complaint at ¶ 94.

Having carefully reviewed plaintiff's Amended Complaint, the Court finds that there are a number of different possible bases for plaintiff's fraudulent misrepresentation/fraud in the inducement claim. First, plaintiff's claim may be based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device. The Court finds that this basis for a fraudulent misrepresentation/fraud in the inducement claim is preempted under § 360k(a). Specifically, the Court finds that allowing this type of fraudulent misrepresentation/fraud in the inducement claim to proceed would permit a finding that defendants were required to alter the Infuse Device's warning and label and to provide additional warnings above and beyond those on the Infuse Device's label and accompanying the device – a label and warnings that were specifically approved by the FDA as part of the PMA process. This would establish labeling and warning requirements different from, or in addition to, federal requirements for the Infuse Device.

Second, plaintiff's claim may be based upon alleged misrepresentations and omissions regarding defendants' practice of promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery. The Court finds that this basis for a fraudulent misrepresentation/fraud in the inducement claim is impliedly preempted under *Buckman* and § 337(a). While plaintiff's allegations regarding defendants' practice of promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery could be a violation of the FDCA and, thus, plaintiff's claim would not be expressly preempted under § 360k(a), plaintiff's fraudulent misrepresentation/fraud in the inducement claim is not based on conduct that would give rise to a recovery under state law even in the absence of the

FDCA. The conduct plaintiff complains of – how defendants are promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery – is governed by the FDCA. To determine whether said conduct is improper would require reliance on the requirements of the FDCA. Further, even the concept of "off-label use" is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law. While plaintiff couches her claim as a state law fraudulent misrepresentation/fraud in the inducement claim, this claim is in substance a claim for violating the FDCA and, thus, is clearly preempted under *Buckman* and § 337(a).

Finally, plaintiff's claim may be based upon alleged misrepresentations and omissions defendants made while promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery. Whether this basis for plaintiff's fraudulent misrepresentation/fraud in the inducement claim is preempted, however, can not be determined due to the lack of specificity in plaintiff's Amended Complaint. It is entirely unclear what specific alleged misrepresentations and/or omissions plaintiff claims defendants made while promoting and marketing the off-label use, and, thus, it is impossible for this Court to determine whether allowing this type of fraudulent misrepresentation/fraud in the inducement claim to proceed would permit a finding that would require statements and warnings to be made that would be different from or in addition to the statements and warnings made on the label and materials that were specifically approved by the FDA as part of the PMA process.

Additionally, whether this basis for plaintiff's fraudulent misrepresentation/fraud in the inducement claim is preempted or not, the Court finds that this basis should be dismissed because it is not pled with particularity as required by Federal Rule of Civil Procedure 9(b). "[A] complaint

alleging fraud [must] set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof." *Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006) (internal quotations and citations omitted). Plaintiff's Amended Complaint does not set forth any of these required items and should, therefore, be dismissed.

3. Plaintiff's constructive fraud claim

In her Amended Complaint, plaintiff alleges:

> 105. Defendants had specific knowledge of the use of the Infuse® in Patricia Caplinger's particular surgery. Defendants, participated in the surgery, and breached her duty to fully disclose all pertinent information to Dr. Rahman regarding the use of Infuse® for Patricia Caplinger's surgery. The representative's failure to provide known dangers for Plaintiff's surgery fraudulently caused Infuse® to be used in the surgery and subsequently caused Patricia Caplinger's injuries.
>
> 106. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances, in light of the generally recognized and prevailing best scientific knowledge, and to produce and market Infuse® in as safe a manner and condition as possible.
>
> 107. Specific defects . . . in the Infuse® product, rendered it defective and unreasonably dangerous.

Amended Complaint at ¶¶ 105-107.

Having carefully reviewed plaintiff's Amended Complaint, the Court finds that plaintiff's constructive fraud claim is preempted under § 360k(a). As set forth in the allegations above, in her constructive fraud claim, plaintiff is specifically alleging that the Infuse Device was defective and unreasonably dangerous and was not produced and marketed in as safe a manner and condition as possible. To permit a jury to second-guess the Infuse Device's design, manufacturing, labeling, warning, and marketing would risk interference with the federally-approved design, manufacturing, labeling, warning, and marketing requirements. Plaintiff's constructive fraud claim would,

therefore, establish design, manufacturing, labeling, warning, and marketing requirements different from, or in addition to, federal requirements for the Infuse Device. The Court finds that this is the exact type of claim that is expressly preempted under § 360k(a) and plaintiff's constructive fraud claim, therefore, should be dismissed.

To the extent that plaintiff's constructive fraud claim is based on defendants' representative's statements during plaintiff's surgery, the Court finds that it is not pled with particularity as required by Federal Rule of Civil Procedure 9(b). Specifically, the Court finds that plaintiff has not set forth the contents of the alleged misrepresentations or omissions. It is impossible for the Court to know if plaintiff is alleging that defendants' representative failed to provide particular warnings and information specific to plaintiff's surgery or if plaintiff is alleging that defendants' representative failed to provide the same general warnings and information regarding the Infuse Device which the Court has already found would risk interference with the PMA process and the federally-approved warning and labeling requirements. Accordingly, the Court finds that plaintiff's constructive fraud claim should be dismissed.

4. Plaintiff's strict products liability – failure to warn claim

Plaintiff also alleges a strict products liability failure to warn claim. In her Amended Complaint, plaintiff specifically alleges the following regarding this claim:

> 116. The warnings accompanying the Infuse® product did not adequately warn Plaintiff and her physicians, in light of its scientific and medical knowledge at the time, of the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.
>
> 117. The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or

> consumer would expect when using the product in a manner reasonably foreseeable to Medtronic. Medtronic either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the off-label use of Infuse® for posterior-approach lumbar spine fusion surgery had they known of the safety risks related to Infuse®.

Amended Complaint at ¶ 116-117 (emphasis added).

Having reviewed the Amended Complaint, the Court finds plaintiff's strict products liability failure to warn claim is preempted under § 360k(a). Specifically, the Court finds that allowing plaintiff's strict products liability failure to warn claim to proceed would permit a finding that defendants were required to provide warnings above and beyond those on the Infuse Device's label and accompanying the device – a label and warnings that were specifically approved by the FDA as part of the PMA process. Plaintiff's strict products liability failure to warn claim would, therefore, establish labeling and warning requirements different from, or in addition to, federal requirements for the Infuse Device. The Court finds that this is the exact type of claim that is expressly preempted under § 360k(a) and plaintiff's strict products liability failure to warn claim, therefore, should be dismissed.

5. Plaintiff's strict products liability – design defect claim

In her Amended Complaint, plaintiff alleges that the Infuse Device was "defectively designed at the time that it left the Defendants' control and was placed into the stream of commerce." Amended Complaint at ¶ 122. Plaintiff alleges the Infuse Device was defectively designed "because the design was unsafe when used in the manner promoted by Defendants and in a manner reasonably foreseeable by Defendants" and "because the risks of danger in the design outweigh the benefits of the design." Amended Complaint at ¶¶ 123, 124. Finally, plaintiff alleges "[t]he foreseeable risks of harm posed by using the Infuse® product in a manner promoted by

Defendants could have been reduced or avoided by adopting a reasonably alternative design." Amended Complaint at ¶ 126.

Having reviewed the Amended Complaint, the Court finds plaintiff's strict products liability design defect claim is preempted under § 360k(a). Specifically, the Court finds that allowing plaintiff's strict products liability design defect claim to proceed would permit a finding that a design defect rendered the Infuse Device unreasonably dangerous, even if defendants complied with all FDA regulations addressed to design. To permit a jury to second-guess the Infuse Device's design would risk interference with the federally-approved design standards and criteria. Plaintiff's strict products liability design defect claim would, therefore, establish design requirements different from, or in addition to, federal requirements for the Infuse Device. The Court finds that this is the exact type of claim that is expressly preempted under § 360k(a) and plaintiff's strict products liability design defect claim, therefore, should be dismissed.

6. Plaintiff's breach of express and implied warranty claim

In her Amended Complaint, plaintiff alleges 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 and impliedly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in posterior procedures was safe and effective." Amended Complaint at ¶ 129. Having carefully reviewed plaintiff's Amended Complaint, the Court finds that plaintiff's breach of express and implied warranty claim is preempted. To succeed on the express and implied warranty claim, as alleged by plaintiff in her Amended Complaint, plaintiff must persuade a jury that the Infuse Device was not safe and effective, a finding that would be contrary to the FDA's

approval. Additionally, "[a] state common law claim is preempted if it 'actually conflicts with the federal requirement – either because compliance with both is impossible, or because the state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1208 (quoting *Lohr*, 518 U.S. at 507 (Breyer, J., concurring) (quotations and citations omitted)). The Court finds that, as alleged, plaintiff's breach of express and implied warranty claim interferes with the FDA's regulation of Class III medical devices and is, therefore, conflict preempted. Finally, plaintiff contends her breach of express and implied warranty claim cannot be preempted because such a claim is specifically excluded from preemption by FDA regulations, 21 C.F.R. § 808.1(d). *Riegel* explicitly rejected this contention, explaining that § 808.1(d) "add[s] nothing to our analysis but confusion." *Riegel*, 552 U.S. at 339. Accordingly, the Court finds that plaintiff's breach of express and implied warranty claim should be dismissed.

7. Plaintiff's negligence claim

In relation to her negligence claim, plaintiff alleges that defendants:

> had an affirmative duty to fully and adequately warn Plaintiff and her physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for posterior-approach lumbar spine fusion surgery. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and her physicians.

Amended Complaint at ¶ 136. Plaintiff also alleges that "[m]isrepresentations made by Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and her physicians the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing

practices." Amended Complaint at ¶ 137. Plaintiff further specifically alleges the following to establish defendants' liability for negligence:

> a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing of Infuse® for off-label use in posterior-approach lumbar spine fusion surgeries;
> b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, extopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.
> c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®.

Amended Complaint at ¶ 139.

Having carefully reviewed plaintiff's Amended Complaint, the Court finds that to the extent that plaintiff's negligence claim is based upon defendants' failure to warn, plaintiff's negligence claim is preempted under § 360k(a). Specifically, the Court finds that allowing plaintiff's negligence claim based upon a failure to warn to proceed would permit a finding that defendants were required to provide warnings above and beyond those on the Infuse Device's label and accompanying the device – a label and warnings that were specifically approved by the FDA as part of the PMA process. Plaintiff's negligence claim based upon a failure to warn would, therefore, establish labeling and warning requirements different from, or in addition to, federal requirements for the Infuse Device. The Court finds that this is the exact type of claim that is expressly preempted under § 360k(a) and plaintiff's negligence claim based upon a failure to warn, therefore, should be dismissed.

To the extent that plaintiff's negligence claim is based upon defendants' promotion and marketing of the Infuse Device for off-label uses, the Court finds it is impliedly preempted under

Buckman and § 337(a). While plaintiff's allegations regarding defendants' practice of promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery could be a violation of the FDCA and, thus, plaintiff's claim would not be expressly preempted under § 360k(a), plaintiff's negligence claim based upon defendants' promotion and marketing of the Infuse Device is not based on conduct that would give rise to a recovery under state law even in the absence of the FDCA. As set forth in the Court's analysis of plaintiff's fraudulent misrepresentation/fraud in the inducement claim, the conduct plaintiff complains of – how defendants are promoting and marketing to physicians the off-label use of the Infuse Device in posterior-approach lumbar spine surgery – is governed by the FDCA. To determine whether said conduct is improper would require reliance on the requirements of the FDCA. Further, even the concept of "off-label use" is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law. While plaintiff couches her claim as a state law negligence claim, this claim is, in substance, a claim for violating the FDCA and, thus, is clearly preempted under *Buckman* and § 337(a).

Finally, to the extent that plaintiff is basing her negligence claim on some other violation of federal law, the Court finds that plaintiff has not alleged sufficient facts to survive a motion to dismiss. Plaintiff "cannot simply incant the magic words Medtronic violated FDA regulations in order to avoid preemption." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (internal quotations and citation omitted). Merely alleging that defendants failed to exercise reasonable care "by not complying with federal law and regulations applicable to the sale and marketing" of the Infuse Device is insufficient to overcome

the preemptive reach of § 360k(a) without some factual detail as to how defendants violated the federal regulations.

Accordingly, the Court finds that plaintiff's negligence claim should be dismissed.

8. Plaintiff's negligent misrepresentation claim

Plaintiff's final claim alleged in her Amended Complaint is a negligent misrepresentation claim. In relation to her negligent misrepresentation claim, plaintiff alleges that specific defects in the Infuse Device rendered it defective and unreasonably dangerous. *See* Amended Complaint at ¶ 146. Plaintiff further alleges that "Defendants made untrue representations and omitted material information to Plaintiff and her physicians by sponsoring biased medical trials, reports and articles that concluded that the dangers inherent to off-label use of Infuse® did not exist or were significantly less than the actual dangers." Amended Complaint at ¶ 147. Plaintiff also alleges that "Defendants were negligent in making the untrue misrepresentations and omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their Infuse® product." Amended Complaint at ¶ 149.

Having carefully reviewed plaintiff's Amended Complaint, the Court finds that plaintiff's negligent misrepresentation claim is preempted by § 360k(a). To permit a jury to second-guess the Infuse Device's design, manufacturing, labeling, and warnings would risk interference with the federally-approved design, manufacturing, labeling, and warning requirements. Plaintiff's negligent misrepresentation claim would, therefore, establish design, manufacturing, labeling, and warning requirements different from, or in addition to, federal requirements for the Infuse Device. The Court, therefore, finds that plaintiff's negligent misrepresentation claim should be dismissed.

G. Need for discovery

Plaintiff also asserts that defendants' motion is premature because she has not yet had a chance to initiate, much less complete, discovery. Plaintiff contends that she will need to do significant discovery into the full scope of defendants' off-label promotional efforts, the warnings, if any, it provided to physicians, including plaintiff's physician, regarding such off-label posterior uses, and the risks of off-label use known to defendants but which they failed to warn about when they illegally promoted the Infuse Device for off-label uses.

Having reviewed the parties' submissions, the Court finds that discovery is unnecessary to resolve defendants' motion to dismiss. Specifically, the Court finds that the issue of federal medical device preemption is a question of law and may properly be decided on a motion to dismiss prior to any discovery being conducted. Accordingly, the Court finds that defendant's motion to dismiss is not premature.

IV. Conclusion

For the reasons set forth above, the Court GRANTS defendants' Motion to Dismiss Plaintiff's Amended Complaint [docket no. 31].

IT IS SO ORDERED this 6th day of February, 2013.

Vicki Miles-LaGrange

VICKI MILES-LaGRANGE
CHIEF UNITED STATES DISTRICT JUDGE