(ENDORSED)
FILED
NOV 18 2013
DAVID H. YAMASAKI
Chief Executive Officer/Clerk
Superior Court of CA County of Santa Clara
BY _____ DEPUTY

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

CHRISTINE COOK, Plaintiff, vs. JEFFREY C. COE, M.D., MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., et al. Defendants.	Case No. 1-13-CV-245210 ORDER RE: DEMURRERS TO FIRST AMENDED COMPLAINT BY DEFENDANTS MEDTRONIC, INC., AND MEDTRONIC SOFAMOR DANEK USA, INC.

The demurrers to the First Amended Complaint by Defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc. came on for hearing before the Honorable Mary E. Arand on November 12, 2013, at 9:00 a.m. in Department 6. The matter having been submitted, the Court orders as follows:

According to the allegations of the first amended complaint ("FAC"), "[t]his case involves a spinal fusion surgery in which a bio-engineered bone graft device, known as InFUSE® Bone Graft [] was implanted in [plaintiff Christine Cook's ("Plaintiff")] spine by Defendant Dr. Jeffrey Coe [("Coe")] in an unconsented and off-label manner wrongfully promoted by Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. [(collectively, "Medtronic")], thereby causing the Plaintiff to suffer from permanent and debilitating injuries and damages." (FAC, ¶ 1.) "InFUSE® is a surgically implanted medical

device containing a genetically engineered protein—rhBMP-2—designed to stimulate bone growth." (FAC, ¶ 3.) "In 2002, the Food and Drug Administration ('FDA') approved InFuse® for use in limited surgical applications to treat degenerative disc disease in the lumbar spine." (FAC, ¶ 4.) "Specifically, InFUSE ® was approved only in Anterior Lumbar Interbody Fusion ('ALIF') procedures involving a single-level fusion from the L4 to S1 region of the lumbar spine using the LT-CAGE® Lumbar Tapered Fusion Device Component ('LT-CAGE')." (*Id.*)

FDA-approved labeling for InFUSE® indicates in bold underlined formatting:

> These components must be used as a system. The InFuse® Bone Graft component must not be used without the LT-CAGE Lumbar Tapered Fusion Device component.

(FAC, ¶ 5.)

"[U]se of InFUSE® in any manner inconsistent with FDA approval, such as the manners by which it was used in the Plaintiff, is termed 'off-label.'" (FAC, ¶ 6.) "On or about July 1, 2008, the FDA disseminated a Public Health Notification to physicians warning them of severe adverse events associated with the off-label use of bone morphogenetic proteins ('BMPs'), including InFUSE®, in the cervical spine." (FAC, ¶ 8.) "Despite actual knowledge of adverse patient events caused by off-label uses of the product, despite being warned to guard against such uses, and despite limited FDA approval, Medtronic fraudulently promoted off-label uses of the InFUSE®, downplayed the risks of adverse events known to be associated with such uses, and overstated risks associated with traditional spinal fusion techniques to further promote the product for off-label applications." (FAC, ¶ 9.) "Medtronic's fraudulent scheme to promote off-label uses of InFUSE® was so extensive that it caught the attention of, among others, the FDA (on numerous occasions)... [since] Medtronic was obligated by law to obtain FDA approval for each use for which it intended to promote and promoted its product." (FAC, ¶¶ 12-13.)

"Because the off-label applications promoted by Medtronic were not, and have not been, subjected to FDA analysis and approval, Medtronic's labeling, instructions, and warnings also failed to adequately inform consumers of the risks associated with such uses... [and a]s a result of the Medtronic and Dr. Coe's wrongful conduct, Plaintiff was caused to undergo an off-label InFUSE® surgery, which directly and proximately caused her to suffer permanent and

debilitating injuries and damages." (FAC, ¶¶ 13-14.) On June 3, 2013, Plaintiff filed the 53-page FAC containing 223 paragraphs against Coe, Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Defendants") for the following causes of action: negligence; negligence per se; strict liability—manufacturing defect; strict liability—design defect; failure to warn; breach of express warranty; breach of implied warranty; fraud; constructive fraud; unfair business practices; and, medical malpractice. Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic defendants") demur to each of the claims of the FAC.

In opposition, Plaintiff "agrees to the voluntary dismissal of her Negligence Per Se (Count Two), Strict Liability—Manufacturing Defect (Count Three), and Breach of Implied Warranty (Count Seven) claims." (Pl.'s opposition to Defs.' demurrer to Pl.'s FAC ("Opposition"), p.1:4-7.) Accordingly, the demurrer to the second, third and seventh causes of action is SUSTAINED without leave to amend.

Medtronic demurs to each of the remaining causes of action on the ground that they are both expressly preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act (21 U.S.C. § 360k(a)) as well as impliedly preempted. Medtronic also argues that the fourth cause of action fails to state sufficient facts to constitute a claim because California law precludes strict liability for design defect claims for manufacturers of prescription medical devices.

1. The Demurrer to the Fourth Cause of Action for Strict Liability—Design Defect is Sustained Without Leave to Amend.

"[A] manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary negligence standard." (*Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal.App.4th 173, 182 (also stating that "a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed").) Here, Plaintiff already has a claim for strict liability—failure to warn. The demurrer

to the fourth cause of action for strict liability—design defect is SUSTAINED without leave to amend. The Court will not address the preemption issue as to this claim.

2. Plaintiff's Argument that Medtronic Has Not and Cannot Demonstrate that the Claims are Preempted Due to a Presumption Against Preemption Lacks Merit.

In opposition, Plaintiff asserts that "there is a 'basic presumption against preemption of state laws' operating traditional state domains... [and, i]n arguing Cook's claims are preempted, Medtronic has not, and cannot, demonstrate Congress, when enacting § 360k, clearly and manifestly intended to supplant California's long-standing concern with protecting the health and welfare of its citizenry from unreasonably dangerous products." (See Pl.'s opposition to Defs.' demurrer to FAC ("Opposition"), p.5:12-26.)

As to the first part of Plaintiff's argument, the United States Supreme Court explained in *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341 (hereinafter, "*Buckman*"), that there is "no presumption against preemption" regarding a state-law cause of action involving Class III medical devices for fraud-on-the-FDA claims because "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." (*Id.* at pp.347-348.) Moreover, the United States Supreme Court, Ninth Circuit and California District Courts have frequently found claims regarding medical devices to be expressly or impliedly preempted. Here, Plaintiff is incorrect that "Medtronic has not, and cannot" demonstrate that the claims are preempted due to any presumption against preemption.

As to Plaintiff's contention that "Medtronic has not, and cannot, demonstrate Congress, when enacting § 360k, clearly and manifestly intended to supplant California's long-standing concern with protecting the health and welfare of its citizenry from unreasonably dangerous products," the United States Supreme Court specifically addressed this point in *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312. In *Riegel*, the plaintiff had a medical device—an Evergreen Balloon Catheter marketed by Medtronic—inserted into his coronary artery that was diffusely diseased and heavily calcified, although the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. (*Riegel, supra*, 552 U.S. at p.320.)

The label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres; however, Riegel's doctor inflated the catheter five times, to a pressure of 10 atmospheres and on its fifth inflation, the catheter ruptured, resulting in a heart blockage requiring emergency coronary bypass surgery. (*Id.*) In determining whether Riegel's state based claims were preempted, the Court first noted the language of the Federal Food, Drug, and Cosmetic Act (FDCA)—21 U.S.C. §301, et seq., as amended by the Medical Device Amendments of 1976 (MDA)[1]—21 U.S.C. § 360c, et seq., which 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.

(*Riegel, supra*, 552 U.S. at p.316, quoting 21 U.S.C. § 360k(a).)

In determining whether Riegel's common law were preempted, the *Riegel* court referenced *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470 (hereinafter "*Lohr*"), a decision cited by Plaintiff in her opposition. (See *Riegel, supra*, 552 U.S. at pp.315-325.) Nevertheless, the *Riegel* court affirmed the Second Circuit's decision that Riegel's claims were indeed preempted by the MDA, noting that the argument that "it is 'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for consumers injured by FDA-approved devices [is without merit because]... this is exactly what a pre-emption clause for medical devices does by its terms." (*Id.* at p.326 (also noting that "the text of the statute--suggests that the solicitude for those injured by FDA-approved devices... was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if

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[1] The United States Supreme Court noted that the MDA were passed in response to the adoption of regulatory measures by several states, including California, requiring premarket approval of medical devices. (*Riegel, supra*, 552 U.S. at p.315.)

juries were allowed to apply the tort law of 50 States to all innovations").) Plaintiff's first argument is without merit.

3. Preemption and the MDA

The United States Supreme Court has decided three preemption cases under the MDA: *Lohr*, *Buckman*, and *Riegel*. "*Lohr* and *Riegel* involved the MDA's express preemption provision, and *Buckman* involved implied preemption." (*Perez v. Nidek Co.* (9th Cir. Cal. 2013) 711 F.3d 1109, 1117.) "[T]he 'rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.'" (*Id.*, quoting *Stengel v. Medtronic Inc.* (9th Cir. 2013) 704 F.3d 1224, 1228; see also *Carrelo v. Advanced Neuromodulation Systems, Inc., et al.* (D.P.R. 2011) 777 F.Supp.2d 303, 309 (stating that "[i]n *Riegel*... [t]he Supreme Court held that... state-law tort actions that are based upon negligence, breach of warranty and strict liability... were preempted by the MDA... [although it also] held that the MDA does not bar a state from imposing a damages remedy for a claim that is premised on a violation of federal law because the state duties in such a case parallel rather than add to federal requirements"; also stating that "[t]hus, state-law claims against Class III medical manufacturers are effectively preempted... [h]owever, there exists a narrow back door through which a plaintiff may still advance state-law tort claims as a parallel action, if the claim alleges that a manufacturer failed to comply with existing federal regulations, such as those established by a device's PMA").)

"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.'" (*Wolicki-Gables v. Arrow Int'l, Inc.* (11th Cir. 2011) 634 F.3d 1296, 1300, quoting *McMullen v. Medtronic, Inc.* (7th Cir. 2005) 421 F.3d 482, 489; see also *Caplinger v. Medtronic, Inc.* (W.D. Okla. 2013) 921 F.Supp.2d 1206, 1214; see also *Houston v. Medtronic, Inc.* (C.D. Cal. July 30, 2013) 2013 U.S. Dist. LEXIS 108996 *1, *15-*16.) "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." (*Id.*) "'To properly plead parallel

claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to the device, and (2) establishing a causal nexus between the alleged injury and the violation.'" (*Houston, supra*, 2013 U.S. Dist. LEXIS 108996 at pp.*15-*16, quoting *Erickson v. Boston Scientific Corp.* (C.D. Cal. 2011) 846 F. Supp. 2d 1085, 1092; see also *Cohen v. Guidant Corp.* (C.D. Cal. Feb. 15, 2011) 2011 U.S. Dist. LEXIS 18786 *1, *3 (also stating that "[a]bsent factual support and details, general allegations that Defendants failed to comply with federal requirements are inadequate to plead parallel claims under *Riegel*"); see also *Eidson v. Medtronic, Inc.* (N.D. Cal. Oct. 3, 2013) 2013 U.S. Dist. LEXIS 144179 *1, * 21.)

A. The claims at issue, generally

Plaintiff's opposition identifies "three primary areas of Medtronic's federal violations: (1) Medtronic's off-label promotion of the bone growth component of Infuse alone, and for use in cervical fusion surgeries, for which the device was both unapproved and known by Medtronic to be unsafe... (2) Medtronic's failure to submit a PMA supplement despite its awareness (indeed promotion) of new indications of Infuse and knowledge of device failures necessitating modification of the device or its labeling... and (3) Medtronic's failures to submit adverse events reports to the FDA when it learned of information reasonably suggesting that Infuse may have caused or contributed to a death or serious injury...." (Opposition, p.6:1-11.)

B. To the extent that the claims are based on alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device, they are expressly preempted.

In the recent case, *Eidson v. Medtronic, Inc.* (N.D. Cal. Oct. 3, 2013) 2013 U.S. Dist. LEXIS 144179 *1, the Northern District of California addressed this exact issue. The plaintiffs were patients whose physicians used the Infuse Device in an off-label manner and alleged that Medtronic encouraged the physicians to use the device in such a manner. (*Id.* at pp.*3-*8.) Like

Plaintiff, the plaintiffs in Eidson alleged claims for negligence, strict liability—design defect, failure to warn, and fraud.[2] (*Id.* at pp.*6-*8.) The *Eidson* plaintiffs similarly alleged that:

> 'Defendants fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of Infuse®;' 2) 'Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the practice of using Infuse® off-label by utilizing a posterior-approach, using Infuse® for an off-label indication, and by using Infuse® without an LT Cage;' 3) '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;' and 4) 'Plaintiffs' physicians were justified in relying, and did rely, on Defendants' concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to make off-label use of Infuse for lumbar spine fusion surgery. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and misrepresentations . . . , Plaintiff has been injured.'

(*Id.* at pp.*28-*29.)

The *Eidson* court found that "[t]o the extent that Eidson's fraudulent misrepresentation/ fraudulent inducement claim is based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device, the claim is expressly preempted." (*Id.* at pp.*31-*32.) The court reasoned that "requiring Defendants to alter the Infuse Device's warnings and label in order to provide extra warnings beyond those already approved during the PMA process would impose labeling and warning requirements 'different from, or in addition to' federal requirements for the Infuse Device." (*Id.* at p.*32.)

Similarly, in *McGuan v. Endovascular Technologies, Inc.* (2010) 182 Cal.App.4th 974, the plaintiff's claim for fraudulent concealment alleged that defendants "withheld from the FDA, surgeons and public, reports of serious failures and resulting problems caused by the device" and failed to disclose that a medical device "was dangerous, defective, and likely to cause serious consequences to users." (*Id.* at pp.983-984.) The Sixth District determined that the claim was

[2] Plaintiff additionally alleges claims for breach of express warranty, constructive fraud and unfair business practices.

expressly preempted because "the jury would be required to find that the warnings, which were approved by the FDA, were inadequate... [and thus] would impose 'requirements' that are 'different from, or in addition to' those imposed by the FDA." (*Id.*)

Accordingly, any claim, to the extent that it is based on alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device, are expressly preempted.

C. To the extent that the first cause of action is based on Medtronic's promotion of the off-label usage, it is impliedly preempted.

The FAC alleges that "[a] manufacturer violates the FDCA if its conduct demonstrates intent to encourage product use inconsistent with or outside the scope of the product's approved label... [and] it is illegal [under the FDCA] for device and drug manufacturers, such as Medtronic, to actively promote products for uses not approved by the FDA, which is precisely the conduct in which Medtronic engaged to drive sales of InFUSE®." (FAC, ¶¶ 34-38.)

The *Eidson* court also addressed this issue. As with Plaintiff's allegations, "the claim is in substance a claim for violating the FDCA and exists solely by virtue of the federal ban on off-label promotion." (*Eidson, supra*, 2013 U.S. Dist. LEXIS 144179 at pp.*54-*55.) "The state law does not exist independently of federal requirements... [and the] negligence claim based on Defendants' promotion of off-label use is impliedly preempted." (*Id.*; see also *Houston, supra*, 2013 U.S. Dist. LEXIS 108996 at p.*27 (stating that "any negligence claim based solely on illegal off-label promotion is impliedly preempted under *Buckman* and §337(a)").) Thus, to the extent that the first cause of action for negligence is based on Medtronic's promotion of the off-label usage, it is impliedly preempted.

D. Similarly, to the extent that the first cause of action is based on Medtronic's failure to submit a PMA supplement, it is likewise impliedly or expressly preempted.

The second category of allegations asserted by Plaintiff in her opposition is premised on "Medtronic's failure to submit a PMA supplement despite its awareness (indeed promotion) of new indications of Infuse and knowledge of device failures necessitating modification of the

device or its labeling." Only the first cause of action alleges such a failure by Medtronic.[3] (See FAC, ¶ 134, subpara. (e) (alleging negligence for "failing to seek a PMA supplement or supplements").)

The FAC does not allege that a medical device manufacturer has a continuing duty to submit a PMA supplement. (See FAC, ¶¶ 31-32.) Instead, the FAC alleges that it is a violation of the FDCA if a manufacturer introduces an adulterated device, such as a Class III device that does not comply with PMA requirements. (See FAC, ¶ 35.) As stated by the Fourth District's explanation of the PMA process in *Blanco v. Baxter Healthcare Corp.* (2008) 158 Cal.App.4th 1039, the FDA—as a specific federal requirement—approves a PMA application as to a particular device, approving of a specific product's design, testing, intended use, manufacturing methods, performance standards, and labeling. (*Id.* at p.1052.) "Once the FDA approves a PMA application for a device, the manufacturer must comply with those conditions of approval in the PMA order." (*Id.* at p.1053.) "Any deviation from those conditions of approval concerning safety and effectiveness must be approved by the FDA." (*Id.*) Here, any state law claim based on a failure to seek a PMA supplement would impose requirements 'different from, or in addition to' federal requirements, and thus are expressly preempted. (See *Enlow v. St. Jude Med., Inc.* (W.D. Ky. 2003) 210 F. Supp. 2d 853, 858 (stating that "any of the plaintiff's claims seeking to impose a state requirement that differs from, adds to, or impedes the implementation and enforcement of the design, manufacturing processes, or labeling contained in mechanical heart valve's original PMA or PMA Supplement is preempted"); see also *Alfred v. Mentor Corp.* (W.D. Ky. Mar. 5, 2007) 2007 U.S. Dist. LEXIS 15535 *1, *8-*15 (state law claims seeking to enforce additional requirements to PMA process are preempted); see also *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc. (In re Medtronic, Inc.)* (8th Cir. 2010) 623 F.3d 1200, 1205 (same).)

Other courts have noted that such claims are impliedly preempted as well as they are essentially fraud-on-the-FDA claims. (See *Purchase v. Advanced Bionics, LLC* (W.D. Tenn.

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[3] The second cause of action for negligence per se also alleges a failure to seek a PMA supplement (see FAC, ¶ 145, subpara. (a)); however, Plaintiff agreed to voluntary dismissal of that claim.

2011) 896 F. Supp. 2d 694, 696 (stating that "[t]o the extent that Plaintiffs' claims are based on Advanced Bionics' purported failure to submit a PMA Supplement Application and obtain PMA approval ..., the claims are impliedly preempted [because] claims premised on PMA approval are disguised fraud-on-the-FDA claims and, therefore, impliedly preempted"); see also *Littlebear v. Advanced Bionics, LLC* (N.D. Okla. 2012) 896 F. Supp. 2d 1085, 1092 (same).)

Either way, to the extent that the first cause of action is based on Medtronic's failure to submit a PMA supplement, it is preempted—be it expressly or impliedly.

E. To the extent that the claims are based on a failure to disclose that the Infuse Device has not been approved for off-label use, they are expressly preempted.

In *Perez v. Nidek Co.* (9th Cir. Cal. 2013) 711 F.3d 1109, the plaintiff alleged that the defendant manufacturer obtained three PMAs for a laser eye-treatment medical device to treat nearsightedness, but the laser was not approved for treating nearsightedness at the time of his operation. (*Id.* at p.1112.) The plaintiff alleged a fraud by omission claim, asserting that the defendants misled patients "by failing to disclose that the Laser was not FDA approved for hyperopic surgeries, even though [defendant manufacturer] Nidek and the doctors knew or should have known that the [patients] believed the Laser was FDA approved for such surgeries." (*Id.* at p.1117.) In holding that the "fraud by omission claim is expressly preempted by §360k(a)," the *Perez* court stated that the claim "effectively seeks to write in a new provision to the FDCA: that physicians and medical device companies must affirmatively tell patients when medical devices have not been approved for a certain use." (*Id.* at pp.1118-1119.) "We do not pass judgment on whether this would be a wise rule for the FDA to adopt." (*Id.* at p.1119.) "It is sufficient for our inquiry that it has not done so." (*Id.*)

Here, the FAC similarly alleges that Medtronic failed to warn and/or disclose that off-label use of InFUSE® was not FDA approved and/or would not be approved in the future. (See, e.g., FAC, ¶¶ 134, subpara. (c).) To the extent that the claims are based on a failure to disclose that the Infuse Device has not been approved for off-label use, they are expressly preempted.

F. To the extent that claims are based on alleged misrepresentations and omissions made while promoting the off-label use of the Infuse Device, or for Medtronic's failure to report adverse events to the FDA, the claims are not preempted. However, the claims nevertheless fail to allege facts showing an alleged violation of FDA regulations or requirements related to the device, and establishing a causal nexus between the alleged injury and the violation.

There are two limited bases for Plaintiff's claims that may not be preempted. However, as currently alleged the causes of action fail to state facts properly pleading parallel claims that survive preemption: the non-negligence claims based on Medtronic's alleged misrepresentations and omissions made while promoting off-label uses of the Infuse Device; and, the claims based on Medtronic's alleged failure to report adverse events to the FDA. (See *Eidson, supra*, 2013 U.S. Dist. LEXIS 144179 at pp.*43-*48, *54-*56; see also *Stengel v. Medtronic, Inc.* (9th Cir. 2013) 704 F.3d 1224, 1233; see also *Ramirez v. Medtronic Inc.* (D. Ariz. Oct. 24, 2013) 2013 U.S. Dist. LEXIS 152977 *1, *5-*7; see also *Alton v. Medtronic, Inc.* (D. Or. Sept. 6, 2013) 2013 U.S. Dist. LEXIS 127190 *1, *75-*78, *84-*87, *91-*94; but see *Caplinger v. Medtronic, Inc.* (W.D. Okla. 2013) 921 F. Supp. 2d 1206, 1219-1221 (stating that a claim "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... is impliedly preempted... [because t]he 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... [and t]o determine whether said conduct is improper would require reliance on the requirements of the FDCA"; but also noting that whether a claim "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... is preempted, however, can not be determined due to the lack of specificity in plaintiff's Amended Complaint").)

The Court notes that the Sixth District case of *McGuan, supra*, 182 Cal.App.4th 974, is inapposite as to claims based on these limited bases because the facts in *McGuan* did not involve alleged misrepresentations and omissions made while promoting off-label uses, and the court in *McGuan* was addressing a motion for summary judgment, an evidentiary motion. In its

discussion of a claim for fraud on patients and their physicians, the *McGuan* court specifically stated that "[i]t is undisputed that the FDA found no violations of federal regulations after March 2001… [t]hus, if plaintiffs were allowed to proceed with their state law fraud claims, a finding of liability would also 'conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (*McGuan, supra*, 182 Cal.App.4th at p.986.)

Nevertheless, as Medtronic argues, the claims fail to allege facts properly pleading parallel claims that survive preemption. (See *Houston, supra*, 2013 U.S. Dist. LEXIS 108996 at pp.*15-*16 (stating that "to properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to the device, and (2) establishing a causal nexus between the alleged injury and the violation'"); see also *Cohen v. Guidant Corp.* (C.D. Cal. Feb. 15, 2011) 2011 U.S. Dist. LEXIS 18786 *1, *3 (also stating that "[a]bsent factual support and details, general allegations that Defendants failed to comply with federal requirements are inadequate to plead parallel claims under *Riegel*"); see also *Eidson v. Medtronic, Inc.* (N.D. Cal. Oct. 3, 2013) 2013 U.S. Dist. LEXIS 144179 *1, * 21.)

Based on the foregoing, it is ORDERED AS FOLLOWS:

The demurrer to the second, third, fourth, and seventh causes of action is SUSTAINED WITHOUT LEAVE TO AMEND. The demurrer to the first, fifth, sixth, and eighth through tenth causes of action of the FAC is SUSTAINED with 10 days leave to amend.

Plaintiff's request for judicial notice and Medtronic's requests for judicial notice were not the basis for the decision. Both parties' requests for judicial notice are DENIED.

Dated: November 15, 2013

Mary E. Arand
Judge of the Superior Court

SUPERIOR COURT OF CALIFORNIA COUNTY OF SANTA CLARA	(ENDORSED) FILED NOV 18 2013 DAVID H. YAMASAKI Chief Executive Officer/Clerk Superior Court of CA County of Santa Clara BY _____ DEPUTY
Plaintiff: Christine Cook	
Defendants: Jeffrey C. Coe, M.D., Medtronic, Inc., Medtronic Sofamor Danek USA, Inc.	MARK ROSALES
PROOF OF SERVICE OF: Order Re: Demurrers to First Amended Complaint by Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc.	Case No: 113CV245210

CLERK'S CERTIFICATE OF SERVICE: I certify that I am not a party to this case and that a true copy of this document was served as follows:

[ ] By personal service on the parties and on the date shown below.

[X] By first class mail, postage prepaid, addressed as shown below and mailed on the date shown below.

DATED: 11/18/13

David H. Yamasaki, Chief Executive Officer/Clerk

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