UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

GARY HAWKINS,

Plaintiff,

v.

MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants.

CASE NO. 1:13-CV-00499 AWI SKO

ORDER DENYING DEFENDANTS' MOTION TO STRIKE AND GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

(Docs. 49, 50)

I. INTRODUCTION

Defendants MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC. bring motions to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted and to strike allegedly redundant, immaterial, impertinent, or scandalous portions of Plaintiff GARY HAWKINS' complaint under Federal Rule of Civil Procedure 12(f). For the reasons set forth below, Defendants' motion to dismiss will be granted in part and denied in part. The dismissed portions of the complaint will be dismissed without leave to amend. Defendants' motion to strike will be denied.

II. BACKGROUND

Plaintiff commenced this action on April 4, 2013, bringing causes of action for 1) Fraudulent Misrepresentation and Fraud in the Inducement, 2) Strict Products Liability - Failure to Warn, 3) Strict Products Liability - Design Defect, 4) Strict Products Liability - Misrepresentation,

and 5) Products Liability - Negligence. This Court granted Defendants' motion to dismiss with prejudice as to Plaintiff's third cause of action; strict products liability for design defect. See Doc. 44 at 26. All of Plaintiff's other causes of action were dismissed with leave to amend. See Doc. 44 at 27. The remainder of the background information which predates the filing of Plaintiff's amended complaint (Doc. 48) is omitted. For the omitted information, see this Court's order granting Defendants' motion to dismiss. (See Doc. 44.)

Plaintiff filed a first amended complaint on March 31, 2014. See Doc. 48 ("FAC"). Plaintiff's FAC contains causes of action for 1) Fraudulent Misrepresentation and Fraud in the inducement, 2) Products Liability – Failure to Warn, 3) Strict Products Liability – Misrepresentation, and 4) Products Liability – Negligence.

It is alleged that Defendants' INFUSE® Bone Graft device ("INFUSE®" or "device") caused Plaintiff's injuries when Plaintiff was implanted with the device in an off-label manner not approved by the U.S. Food and Drug Administration ("FDA"). FAC at ¶¶ 12, 290-293.

INFUSE® is used in spinal fusion surgeries to stimulate bone growth. FAC at ¶ 2. INFUSE® is a Class III medical device regulated by the FDA pursuant to the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA"). FAC at ¶¶ 40-41, 45. Class III devices receive the highest level of oversight by the FDA. Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008). New devices must undergo a "rigorous" safety evaluation known as premarket approval before entry into the market. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). The premarket approval process evaluates the safety and effectiveness of the device, including the proposed labeling. Riegel, 552 U.S. at 318. "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." Riegel, 552 U.S. at 319; 21 U.S.C. §360e(d)(6)(A)(i). INFUSE® was granted premarket approval by the FDA for limited uses in 2002. FAC at ¶¶ 54-55.

The device itself consists of a collagen carrier sponge soaked with liquid protein rhBMP-2 ("INFUSE® Bone Graft Component") and a metallic cage ("LT-Cage"). FAC at ¶¶ 54, 57. The protein-soaked sponge is placed inside the LT-Cage which is inserted into the patient's spine. FAC

at ¶¶ 4, 33-35. The premarket approval specifies that the FDA-approved INFUSE® device consists of all component parts which must be used together. FAC at ¶¶ 54, 57. The INFUSE® device –was approved only for use in a single-level fusion in the L4-S1 region of the lumbar spine . . . via the Anterior Lumbar Interbody Fusion (–ALIF") procedure and in combination with a LT-Cage." FAC at ¶ 58. Use of the device in a manner not approved by the FDA is considered an –off-label" use, but medical practitioners are not prohibited from using a legally marketed device such as INFUSE® in a manner that has not been approved by the FDA. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001) (–Buckman"); see 21 U.S.C. §396.

Plaintiff underwent three surgeries wherein he was implanted with INFUSE®. FAC at ¶¶ 290-292. These surgeries occurred on July 17, 2006, February 25, 2010, and August 2, 2010. FAC at ¶¶ 290-292. All three surgeries were performed in an off-label manner not approved by the FDA. FAC at ¶¶ 290-292. Specifically, Plaintiff was implanted with INFUSE® without the use of the LT-Cage and using a posterior approach. FAC at ¶¶ 290-292. Thereafter, Plaintiff experienced ectopic bone growth with resulting nerve impingement and permanent nerve damage. FAC at ¶ 293.

III. LEGAL STANDARD

A. Rule 12(b)(6)

A complaint may be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure if it appears beyond doubt that a plaintiff can prove no set of facts in support of the claim that would entitle her to relief. Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Balistreri v. Pacifica Police Department, 901 F.2d 696, 699 (9th Cir. 1990). To survive a motion to dismiss, –[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all allegations in the complaint are true even if doubtful in fact." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal citations omitted). A 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) (internal citations omitted). 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 alleged misconduct. Iqbal, 556 U.S. at 663.

When deciding a motion to dismiss, all allegations of material fact in the complaint are taken as true and construed in the light most favorable to the plaintiff. Western Mining Council v. Watt, 643 F.2d 618, 624 (9th Cir.1981). However, the court is not required to accept conclusory allegations, allegations contradicted by exhibits attached to the complaint, matters not subject to judicial notice, unwarranted deductions of fact, or unreasonable inferences. Daniels-Hall v. National Educ. Ass'n, 629 F.3d 992, 998 (9th Cir. 2010). "A district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." Lopez v. Smith, 203 F.3d 1122, 1127 (9th Cir. 2000). "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003).

In alleging fraud or mistake, Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud or mistake," including "the who, what, when, where, and how of the misconduct charged." Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir.2003) (internal quotation marks omitted). The "time, place, and specific content of the false representations" must be set forth in the complaint. Edwards v. Marin Park, Inc., 356 F.3d 1058, 1066 (9th Cir.2004) (citation omitted). In addition, "'[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false.'" Vess, 317 F.3d at 1106 (quoting Decker v. GlenFed, Inc. (In re GlenFed, Inc. Sec. Litig.), 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc)).

B. Rule 12(f)

Rule 12(f) of the Federal Rules of Civil Procedure allows the court to strike from "any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). The purpose of a Rule 12(f) motion is to avoid the costs that arise from litigating spurious issues by dispensing with those issues prior to trial. See Whittlestone, Inc. v. Handi-Craft Co., 618 F.3d 970, 973 (9th Cir 2010); Sidney-Vinstein v. A.H. Robins Co., 697 F.2d 880, 885 (9th Cir.1983). Immaterial matter is defined as matter that "has no essential or important relationship to the claim for relief or the defenses being pleaded." Whittlestone, 618 F.3d at 974. Impertinent matter is defined as "statements that do not pertain, and are not

necessary, to the issues in question." Id. Scandalous matters are allegations "that unnecessarily reflects on the moral character of an individual or states anything in repulsive language that detracts from the dignity of the court," and "includes allegations that cast a cruelly derogatory light on a party or other person." Quatela v. Stryker Corp., 820 F.Supp.2d 1045, 1050 (N.D. Cal. 2010). Redundant allegations are allegations that "constitute a needless repetition of other averments or are foreign to the issue." Wilkerson v. Butler, 229 F.R.D. 166, 170 (E.D. Cal. 2005).

Granting a motion to strike may be proper if it will make the trial less complicated or if allegations being challenged are so unrelated to plaintiff's claims as to be unworthy of any consideration as a defense and that their presence in the pleading will be prejudicial to the moving party. See Fantasy, Inc. v. Fogerty, 984 F.2d 1524, 1527-28 (9th Cir. 1993).[1] Motions to strike are generally viewed with disfavor –because of the limited importance of pleadings in federal practice," and will usually be denied unless the allegations in the pleading have no possible relation to the controversy. Buereerong v. Uvawas, 922 F.Supp 1450, 1478 (C.D. Cal. 1996); accord Sliger v. Prospect Mortgage, LLC, 789 F.Supp.2d 1212, 1216 (E.D. Cal. 2011); see also Buick v. World Sav. Bank, 637 F.Supp.2d 765, 771 (E.D. Cal. 2008).

IV. DISCUSSION

A. Federal Preemption Framework

As this Court discussed in its previous order, the MDA contains express and implied preemption provisions which provide only a —narrow gap' through which a state-law claim must fit to escape preemption." Hawkins v. Medtronic, Inc., 2014 WL 346622, *5 (E.D. Cal. Jan. 30, 2014) (quoting Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1120 (9th Cir. 2013). –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)." Perez, 711 F.3d at 1120 (citing In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis in both).

[1] Reversed on other grounds, Fogerty v. Fantasy, Inc., 510 U.S. 517 (1994).

a. Express Preemption

The MDA's express preemption provision reads, in relevant part:

> [N]o 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). In Riegel, the Supreme Court articulated a two-part test for determining whether a claim is expressly preempted based on section 360k: (1) whether the federal government established ~~"r~~equirements applicable to the device in question, and, if so, (2) whether the state common law claims are based on state law requirements regarding the ~~"s~~afety and effectiveness" of the device ~~"t~~hat are different from, or in addition to the federal [requirements]." Reigel 552 U.S. at 321-322 (citing § 360k(a)); see Hawkins, 2014 WL 346622, *3.

Since INFUSE® is a Class III FDA approved device, it is subject to MDA requirements. Hawkins, 2014 WL 346622 at *5-6. If any of Plaintiff's state law claims impose requirements different from or in addition to the federal requirements they are expressly preempted.

b. Implied Preemption

The implied preemption provision found in 21 U.S.C. Section 337(a) requires that any action to enforce the provisions of the FDCA ~~"b~~e by and in the name of the United States." 21 U.S.C. § 337(a). As the Supreme Court explained in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, actions which seek to enforce an exclusively federal requirement not grounded in traditional state tort law are impliedly preempted by section 337(a). Claims that ~~"e~~xist solely by virtue of the FDCA … requirements" are impliedly preempted. Buckman, 531 U.S. at 353.

c. Off-Label Promotion

This Court has reviewed the recent decisions regarding whether off-label promotion violates the FDCA and whether the truth or falsity of the off-label promotion plays a role in that

determination. The Ninth Circuit has not issued any published opinion directly addressing this issue but the district courts in this circuit have, for the most part, taken one of three positions. First, at least one district court in this circuit has held that off-label promotion is not prohibited by federal law, thus concluding that claims alleging off-label promotion (regardless of the truth or falsity of the promotion) are expressly preempted. See, e.g. Schuler v. Medtronic, Inc., 2014 WL 988516, *1 (C.D. Cal. March 12, 2014) (relying on United States v. Caronia, 703 F.3d 149 (2nd. Cir. 2012), where the Second Circuit found that the FDCA does not criminalize the simple promotion of off-label use because such an interpretation would raise First Amendment concerns but off-label promotion could constitute "evidence of [a drug's] intended use"). This position has gained little traction in this circuit. Second, several district courts held that off-label promotion violates Section 311 of the FDCA – prohibiting misbranding of class III medical devices – where the off-label promotion is false or misleading. See Martin v. Medtronic --- F.Supp.2d ---- , 2014 WL 3635292,*9-10 (D. Ariz. 2014) (holding that the FDCA does prohibit untruthful off-label promotion, discussing but not deciding whether truthful off-label promotion violates the FDCA, and finding that plaintiff's fraud in off-label marketing claim escaped preemption); Eidson v. Medtronic, Inc., --- F.Supp.2d ----, 2014 WL 1996024, at *15 (N.D. Cal. May 13, 2014) ("Eidson II") (same). Third, several district courts, including this Court, have indicated that off-label promotion – regardless of its truth or falsity – violates the FDCA. See Beavers-Gabriel v. Medtronic, Inc., --- F.Supp.2d ----, 2014 WL 1396582, *9 (D. Haw. 2014) (holding that "the FDCA prohibits 'misbranding' of medical devices, which includes either misleading labeling or misleading advertising of the medical device, and 21 C.F.R. § 814.80 prohibits Defendants from advertising the INFUSE® Device for uses beyond what is provided in the PMA approval)[2]; Hawkins, 2014 WL 346622 at *7; see also, Houston v. Medtronic, Inc., 957 F.Supp.2d 1166, 1179 (C.D. Cal. 2013) ("Houston I") (concluding that "federal law forbids device manufacturers to promote any off-label uses, and certainly prohibits false or misleading off-label promotion"); Ramirez v. Medtronic, Inc., 961 F.Supp.2d 977, 990 (D. Ariz. 2013) (citing, inter alia, Carson v.

[2] The PMA approval letter for the INFUSE® Device provides that the device "is indicated for spinal fusion procedures in skeletally mature patients with degenerative disk disease at one level from L4-S1" and the "Bone Graft / LT-Cage™ devices are to be implanted via an anterior open or an anterior laparoscopic approach." Doc. 49-2, Defendants' Request for Judicial Notice ("RJN") at Exhibit A.

Depuy Spine, Inc., 365 Fed.Appx. 812, 815 (9th Cir. 2010) (observing that ~~"w~~hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA")).

Courts appear split on two issues which separate the three separate positions: (1) whether off-label promotion – by itself – constitutes misbranding in violation of 21 U.S.C. § 331 and (2) whether off-label promotion of the device ~~"a~~dvertised in a manner that [was] inconsistent with any condition to approval specified in the PMA approval order for the device" in violation of 21 C.F.R. § 814.80. In this case, all of Plaintiff's causes of action based on off-label promotion require, and Plaintiff appears to allege, that Medtronic made false or misleading representations. See FAC at ¶¶ 296, 315(a)(i), 315(b), 329, 340; see also Doc. 49-1 at 12 ("~~P~~laintiff's off-label promotion-based claims are based on alleged misrepresentations and omissions."). Accordingly, it is unnecessary for this Court to determine whether or not accurate off-label promotion violates the FDCA. It is sufficient for this Court to conclude, as the vast majority of the courts in this Circuit have, that – if nothing else – the MDA prohibits false or misleading off-label promotion of a Class III FDA approved medical device.

B. Plaintiff's Substantive Claims

Plaintiff has amended his complaint in an effort to remedy the shortcomings identified in the original complaint including: the failure to satisfy the particularity requirements of Federal Rules of Civil Procedure Rule 9 as to his misrepresentation based causes of action and the failure to establish the causal nexus necessary to support a claim of failure to report adverse events to the FDA. Plaintiff's causes of action fall into two categories: those requiring a finding of false or misleading practices during the course of off-label promotion and those alleging a failure to warn.

1. State law claims requiring a finding of false or misleading practices during the course of off-label promotion

This Court indicated, in its January 30, 2014 Order, that to the extent Plaintiff's fraud claim alleged that Medtronic had misrepresented, concealed, and omitted known information regarding the off-label use of INFUSE®, during the affirmative promotion of off-label use of INFUSE®, it was not expressly or impliedly preempted. Hawkins v. Medtronic, Inc., 2014 WL

346622, *11 (E.D. Cal. Jan. 30, 2014). Plaintiff has pled three claims based on false or misleading off-label promotion: (1) fraudulent misrepresentation and fraud in the inducement, (2) strict products liability based on misrepresentation, and (3) negligent misrepresentation. All of the claims appear to be based on the allegedly false or misleading representations and differ mostly in the level of intent attributed to Medtronic.

a. Preemption

Defendants have again moved for dismissal of Plaintiff's fraud and misrepresentation causes of action based on an argument that these claim are preempted. This Court previously held – in line with other courts in this circuit – that Plaintiff's fraudulent and strict products liability misrepresentation claims, to the extent that they are based on "misrepresentations, concealments, or omissions that result[ed] from [off-label promotion of INFUSE®] lie[] parallel to the federal requirement that prohibits [off-label promotion.]" Hawkins, 2014 WL 346622 at *11, 17; see Arvizu v. Medtronic, Inc., --- F.Supp.2d -----, 2014 WL 4204933, *6 (D. Ariz. 2014) (holding that plaintiff's claims alleging false off-label promotion survived express and implied preemption); Dunbar v. Medtronic, Inc., 2014 WL 3056026, *6 (C.D. Cal. June 25, 2014) (same); Eidson II, 2014 WL 1996024 at *7 (same); Houston I, 957 F.Supp. at 1179 (same); but cf. Schuler, 2014 WL 988516 at *1 (holding that off-label promotion does not violated federal law, thus plaintiff's claim is expressly preempted). The Court considers Defendants' motion a request for reconsideration of its prior holding regarding preemption as to Plaintiff's misrepresentation based claims.[3]

Defendants argue that because "off-label marketing of [a medical device] is itself not inherently fraudulent" (Doc. 49-1 at 10 (citing cases)) that Plaintiff's claims alleging off-label promotion incorrectly conflate off-label promotion and falsity such that a violation of state law could be found where federal law is fully complied with. Accordingly, Defendants assert that the state fraud and misrepresentation causes of action are not "genuinely equivalent" to any prohibition of off-label promotion. Doc. 49-1 at 10. Defendants point to Plaintiff's assertion that, "M[edtronic] deceptively promoted off-label use of INFUSE® through its sales representatives by

[3] The Court addresses preemption separately from the pleading requirements of Rule 9, but recognizes that inadequate pleading of Plaintiff's reliance on Defendants' alleged misrepresentations could both (1) require dismissal for failure to state a claim and (2) render Plaintiff's claim preempted. See Houston I, 957 F.Supp. at 1174.

having the representatives tell physicians who asked that the off-label use being adopted by those surgeons was common, prevalent, or normal," as evidence that Plaintiff does not distinguish between off-label promotion and falsity since, by Plaintiff's own estimate, 95% of all spinal fusions involving INFUSE® were performed in an off-label manner. Although the Court agrees that Plaintiff appears to conflate the two separate notions, it does not follow that Plaintiff's entire fraud cause of action is expressly preempted. Rather, if the sections of Plaintiff's claims that contain statements which Defendant alleges to be neither false nor misleading, are found to be neither false nor misleading, then they would fail to state a claim under California law for any of the three claims requiring on false or misleading conduct. See Schouest v. Medtronic Inc., --- F.Supp.2d ----, 2014 WL 1213243, *9 (S.D. Tex. 2014) (Mere off-label promotion, divorced from any negligent or fraudulent misrepresentations, would likely not run afoul of state tort law. (citations)).[4] Accordingly, this Court does not read Plaintiff's allegations to contend that Defendants' alleged misconduct constituted misrepresentation because it was off-label promotion but because it was untrue. Since that is the case, no state law liability could be found unless there is also a finding that Medtronic deceptively engaged in off-label promotion.

Based on the above discussion of the MDA's prohibition of false or misleading off-label promotion and the understanding that Plaintiff's state law causes of action related to off-label promotion all require a finding that Medtronic's representations were false or misleading in order to find liability, Plaintiff's (1) fraudulent misrepresentation and fraud in the inducement, (2) strict products liability based on misrepresentation,[5] and (3) negligent misrepresentation claims (all based on conduct that took place during off-label promotion) impose no requirements different from or in addition to those imposed under federal law; Plaintiff's misrepresentation claims escape

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[4] See also Herrejon v. Ocwen Loan Servicing, LLC, 980 F.Supp.2d 1186, 1202 (E.D. Cal. 2013) (quoting Engalla v. Permanente Medical Group, Inc., 15 Cal.4th 951, 974 (1997)) (listing the elements of fraud: ~~(~~a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage); Eidson I, 981 F.Supp.2d 868 (indicating that a plaintiff can state a strict products liability misrepresentation claim based on alleged misrepresentations and omissions made while promoting the off-label use of INFUSE®); Kremen v. Cohen, 99 F. Supp.2d 1168, 1175 (N.D. Cal. 2000) rev'd in part on other grounds, 337 F.3d 1024 (9th Cir. 2003) (listing the elements of negligent misrepresentation: ~~(~~1) a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the truth and justifiable reliance thereon by the party to whom the misrepresentation was directed, and (5) damages").

[5] The Court will address the existence of a claim for strict products liability based on misrepresentation in California in Section IV(B)(1)(d), infra.

express preemption. See, e.g., Beavers–Gabriel, 2014 WL 1396582, at *9; Schouest, 2014 WL 1213243, at *8; Eidson v. Medtronic, Inc., 981 F.Supp.2d 868, 884–85 (N.D. Cal. 2013) (–Eidson I"); Houston I, 957 F.Supp.2d at 1179–80.

Defendants next contend that Plaintiff's claims based on off-label promotion are impliedly preempted because the concept of off-label promotion –exists only as a creation of the FDCA scheme." Doc. 49-1 at 11 (citing Hawkins, 2014 WL 346622 at *19). Defendants' reliance on this Court's previous order regarding negligent in off-label promotion is unavailing in this context. This Court, like the courts in Eidson I and Houston I, was presented with a negligence claim that alleged (among other things) that Defendants were negligent by promoting their product off-label. As this Court explained, –[a] state law cause of action cannot rest solely on the off-label promotion of INFUSE®." Hawkins, 2014 WL 346622 at *19. A claim that could result in liability based only on non-disclosure that the promoted use was off-label would be impliedly preempted under Buckman as explained by the Court in Perez. 711 F.3d at pp. 1119-1120. In that situation, Plaintiff would be suing *because* the conduct (purportedly) violates the FDCA.

The negligence claim presented by Plaintiff's FAC alleges –that Medtronic negligently and affirmatively misrepresented to Plaintiff and Plaintiff's physicians the true risks of INFUSE®."[6] This reshaping of Plaintiff's negligence claim removes it from the grasp of implied preemption because he now alleges that Defendants were negligent by making misrepresentations during the course of off-label promotion, not because they engaged in off-label promotion. A state tort duty exists independent of the FDCA for the former claim but does not for the latter. Compare Schouest, 2014 WL 1213243, *9 (finding a parallel claim where plaintiff alleged that Medtronic –negligently, carelessly and recklessly represented that the off-label use of INFUSE® … was safe when, in fact, it was unsafe."); Eidson II, 2014 WL 1996024 at *17 (finding no implied preemption where plaintiff alleges that defendants engaged in affirmatively fraudulent conduct when promoting for off-label use); Scovil v. Medtronic, Inc., 995 F.Supp.2d 1082, 1096 (D. Ariz. 2014) (finding implied preemption as to –researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing INFUSE®" but

[6] The specific factual content of the alleged misrepresentations is addressed in Section IV(B)(1)(b), infra.

not as to ―merchandising," ―advertising," and ―promoting" because off-label promotion violates federal law.); with Martin, 2014 WL 3635292 at *14 (finding implied preemption where plaintiff alleges a duty to abstain from off-label promotion); Houston I, 957 F.Supp.2d at 1178 (same). The California Second District Court of Appeals recognized the same when it decided that a ―negligence claim based on [misrepresentations made during] off-label promotion is not [impliedly] preempted" because that ―claim is rooted in traditional state tort law and exists regardless of the FDCA." Coleman v. Medtronic, Inc., 233 Cal.App.4th 413, 433-434 (2014), as modified (Feb. 3, 2014) ordered published by 175 Cal.Rptr.3d 809 (Apr. 30, 2014).

Accordingly, to the extent that Plaintiff's negligence claim is based on misrepresentations made during the course of off-label promotion is not impliedly preempted. Otherwise, Plaintiff's negligence claim is not parallel to federal requirements.

Defendants request that this Court reconsider its holding that omission during off-label promotion is a non-preempted basis for fraud liability. As discussed above, where off-label promotion is false it certainly violates federal law. California fraud jurisprudence allows recovery for fraud based on ―a misrepresentation, including a false representation, concealment, or nondisclosure." Hawkins, 2014 WL 346622 at *10 (citing cases). Any nondisclosure or omission that tends to render false Medtronic's off-label promotion of INFUSE® both violates the FDCA and is a basis for fraud liability under California law. Accordingly, as to Plaintiff's fraudulent misrepresentation and fraud in the inducement claim, this Court stands by its previous ruling; because that claim relies on traditional state tort law and to the extent that the claim is based on ―misrepresentations, concealments, and omissions made during the affirmative promotion of off-label use[s] of INFUSE" as safe when, in fact, they were not safe, it states a parallel claim. Hawkins, 2014 WL 346622 at *11; see Eidson II, 2014 WL 1996024 at *16 (where the court distinguished the identical fraud claim as the claim at bar from the preempted claim in Perez by noting that here Medtronic is alleged to have falsified medical research and made false statements via sales representatives and opinion leaders whereas in Perez the alleged omission was a failure to disclose that the device was not approved for the promoted off-label use.)

b. Rule 9(b)

The same feature that allowed this claim to avoid express preemption – that it is based on false representations regarding off-label use, which violates the FDCA – also subjects it to the heightened pleading standards of Rule 9(b). As a result, Plaintiff's fraudulent misrepresentation and fraud in the inducement cause of action was dismissed because Plaintiff failed to meet the requirements of Rule 9(b); generally requiring a plaintiff to identify the "the who, what, when, where, and how of the alleged misconduct." See Hawkins, 2014 WL 346622 at *2; citing Vess, 317 F.3d at 1106. This Court noted that "nothing in the complaint point[ed] to specific content in [Medtronic sponsored] articles or statements made by the named opinion leaders that were allegedly false or why the representations were untrue." Hawkins, 2014 WL 346622 at *12. The Rule 9(b) particularity requirement is not satisfied unless the pleading "identifies the circumstances constituting fraud ... so that the defendant can prepare an adequate answer from the allegations." Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir.1989). That is, the allegations must be sufficiently specific "to give defendants notice of the particular misconduct which is alleged to constitute the fraud ... so that they can defend against the charge and not just deny that they have done anything wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir.1985).

The Eidson II court, in addressing similar allegations regarding Medtronic promotion of the INFUSE device, focused on factual allegations detailing "(1) specific scientific articles funded by Medtronic, including their authors, dates of publication, and what information was misstated or omitted in them; (2) misleading statements and omissions made by named "opinion leaders" in the course of promotional activities," and (3) allegedly deceptive activities undertaken by Defendants' sales representatives," holding that such allegations were "sufficient to place Medtronic on notice of the particular misconduct alleged," thereby satisfying the particularity requirements of Rule 9. Eidson II, 2014 WL 1996024 at *22; see also Alton v. Medtronic, Inc., 970 F.Supp.2d 1069, 1098 (D. Or. 2013). That court accepted the plaintiffs' general allegations of reliance; finding that allegations of misrepresentations in "specific studies and presentations" were adequate to satisfy Rule 9(b), despite the plaintiffs not having pled which specific studies or presentations they or

their doctors relied upon. Eidson II, 2014 WL 1996024 at *22 (citing with approval Alton, 970 F.Supp.2d at 1105-1106 (holding that plaintiff's fraud cause of action stated a claim where plaintiff provided detailed allegations of concealment and misrepresentation regarding off-label uses by Medtronic without identifying which specific misrepresentation(s) the plaintiff's surgeon relied upon); and Houston v. Medtronic Inc., 2014 WL 1364455, *8-9 (C.D. Cal. Apr. 2, 2014) ("Houston II") (holding that Rule 9(b) was satisfied when it considered allegations of specific misstatements regarding off-label use by specific Medtronic consultants to plaintiff's implanting physician).

There is some discussion among district courts as to whether reliance - although an element of Plaintiff's misrepresentation claims - is a condition of the mind that need not comply with the particularity requirements of Rule 9(b). Compare Fed R. Civ. Proc. 9 ("conditions of a person's mind may be alleged generally"); Herremans v. BMW of North America, LLC, (holding that reliance is a condition of the mind not subject to the heightened standard of Rule 9(b)); Andrews Farms v. Calcot, Ltd., 527 F.Supp.2d 1239, 1252 (E.D. Cal 2007) (same); with Kane v. Chobani, Inc., 973 F.Supp. 2d 1120, 1135 (N.D. Cal. 2014) (holding that plaintiffs' allegations of reliance "fail[ ] to meet the heightened pleading requirement under Rule 9(b)"); In re Countrywide Fin. Corp. Sec. Litig., 588 F.Supp.2d 1132, 1198 (C.D.Cal.2008) (holding that "t[]he reliance element is subject to the pleading requirements of Rule 9(b) because it is one of the "circumstances constituting fraud'"). Based on the Eidson II court's explanation that "where a plaintiff's fraud claim is based on a long-term promotional campaign involving a large number of false statements, the plaintiff is *not* required to identify in the pleadings precisely when each false statement was made and on which the plaintiff or his agent relied," this Court is persuaded that Rule 9(b) should not apply to pleading reliance. Eidson II, 2014 WL 1996024 at *22 (emphasis original)(citation omitted). This Court agrees that reliance need not comply with the particularity requirements of Rule 9(b), especially considering (1) the impracticality of requiring Plaintiff to allege misrepresentations which were not made to Plaintiff directly, but rather to his agent and (2) Plaintiff's allegation of the broad scope of the scheme of misrepresentation which Plaintiff alleges to have dominated the available medical literature. Accordingly, reliance must only satisfy Rule 8

and the Twombly/Iqbal plausibility standard as is discussed in Section IV(B)(1)(c), infra.

Plaintiff has re-pled his fraudulent misrepresentation and fraud in the inducement cause of action, supplementing his prior allegations with claims detailing how Medtronic: (1) sponsored studies that ~~"~~may have inaccurately represented INFUSE®'s risks and may have overemphasized the side effects of prior more traditional treatments," (FAC at ¶ 278) (2) was aware adverse events relating to the INFUSE® device and actively concealed them, (3) deliberately omitted risks of off-label use, including ectopic bone growth, inflammatory reactions, and osteolysis, and (4) provided incorrect dosing information regarding off-label use of INFUSE®, resulting in an inability for physicians to accurately predict bone growth and the surrounding risks (See FAC at ¶¶ 222, 259). In that regard, Plaintiff has articulated ten alleged falsehoods attributable to Medtronic:

> a. MEDTRONIC deceptively promoted off-label use of Infuse® through its sales representatives by having its sales representatives assist in operating rooms during off-label surgeries, giving implicit approval to those experimental surgeries which MEDTRONIC knew to be high-risk;
>
> b. MEDTRONIC deceptively promoted off-label use of Infuse® through its sales representatives by having its sales representatives give advice to surgeons during off-label surgeries, including advice regarding dosing, concentrations, and loading of cages, despite the fact that proper dosing, concentrations, and technique in the context of off-label use had not been established, and was high-risk and experimental;
>
> c. MEDTRONIC deceptively promoted off-label use of Infuse® through its sales representatives by having the representatives distribute or parrot the false and misleading medical literature that was written and/or edited by MEDTRONIC;
>
> d. MEDTRONIC deceptively promoted off-label use of Infuse® through its sales representatives by having the representatives tell physicians who asked that the off-label use being adopted by those surgeons was common, prevalent, or normal;
>
> e. MEDTRONIC deceptively promoted off-label use of Infuse® by having the sales representatives refer physicians to speak to and meet with MEDTRONIC's paid physician consultants who were prepped to promote the off-label use of Infuse® on a peer-to-peer basis;
>
> f. MEDTRONIC deceptively promoted off-label use of Infuse® by having the sales representatives refer physicians to cadaver labs and institutes for hands-on training in off-label uses of Infuse® via MEDTRONIC's paid physician consultants;
>
> g. MEDTRONIC deceptively promoted off-label use of Infuse® by having its distributors purchase gifts for physicians and facilities with the aim of inducing

them to use Infuse® off-label;

h. MEDTRONIC deceptively promoted off-label use of Infuse® by instructing and arranging for ~~"O~~pinion Leaders" and other paid physician consultants to promote off-label uses of Infuse® at conferences, in VIP meetings, during ~~"p~~oster presentations" at society meetings, and via hands-on demonstrations and trainings;

i. MEDTRONIC deceptively promoted off-label use of Infuse® by paying kickbacks to Key Opinion Leaders, and then actively ghostwriting, tampering with, and editing the published medical literature on Infuse®, such that the literature appeared to reflect a complication rate of approximately 0% rather than the true complication rate of greater than 40%.

j. MEDTRONIC deceptively promoted off-label use of Infuse® by choosing not to report to the FDA known adverse events that were being reported to MEDTRONIC and which MEDTRONIC knew were likely the result of off-label use of Infuse®. By April 2008, over 500,000 surgeries had been performed using Infuse. The true rate of adverse events occurring from 2002 to 2008 was conservatively 10-50%. Thus, by April 2008, even if the rate were only 10%, at least 50,000 adverse events had occurred. Given how closely Medtronic representatives worked with surgeons on an ongoing basis – being present in the operating room during implantation and revision operations, they were necessarily aware of the majority of these adverse events. Nevertheless, by the end of 2008, only 262 adverse events involving Infuse had been reported to the FDA. In contrast, after The Spine Journal exposed data about the true adverse event rate in 2011, the number of reported adverse events sharply increased even while Infuse utilization declined. In 2013 alone, there were 3001 reported adverse events.

FAC at ¶¶ 300(a-j).

i. Misrepresentations in articles allegedly attributable to Medtronic

Plaintiff has alleged that Medtronic engaged ~~"o~~pinion leaders" or ~~"th~~ought leaders" in a marketing campaign from 2002 to the present to persuade spine surgeons to use INFUSE in ~~"d~~angerous off-label uses in the spine." FAC at ¶ 11. Plaintiff pleads – in detail – that misrepresentations existed in Medtronic sponsored (and allegedly ghostwritten and edited) articles, when the articles were published, their content, and why that content is false or misleading. See FAC at ¶¶ 221-227, 229-232.[7] Several of the articles attributed to Medtronic contained misrepresentations regarding the safety of a posterior off-label use of INFUSE®, the

[7] As explained by this Court in its previous order, the ~~"c~~omplaint [must] point[] to specific content in those articles or statements made by the named opinion leaders that were allegedly false, or why the representations were untrue. [The allegations previously made were] not "specific enough to give [D]efendants notice of the particular misconduct ... so that they [could] defend against the charge," but instead [left] them to ~~"j~~ust deny that they have done anything wrong.'" Hawkins, 2014 WL 346622 at *12. (citation omitted).

approach taken by Plaintiff's surgeon. See FAC at ¶¶ 226(a) (alleging underreporting of adverse events related to posterior INFUSE® use in 2002 study), 79 (alleging similar misrepresentations regarding a 1999 clinical trial), 227(h-i) (study published after Plaintiff's surgery but alleging the same misrepresentations), 228 (same). Plaintiff also alleges that the Medtronic sponsored articles contained misrepresentations regarding the safety of off-label use of INFUSE® without the LT-Cage™. See FAC at ¶¶ 226(d) (study regarding purported success of fusion surgeries in cervical spine using rhBMP-2 protein without LT-Cage™), 226(g) (study regarding purported success of anterior lumbar fusions using "threaded allograft cortical bone dowels" rather than the LT-Cage™). Plaintiff has alleged that – contrary to the figures reported by Medtronic-sponsored trials and articles – the actual adverse event rate associated with INFUSE® "range[d] from 10-50% depending on the approach." FAC at ¶ 258. Those misrepresentations were alleged to be known to Medtronic at the time of the studies and publications. See FAC at ¶¶ 95-97

Plaintiff's amended allegations have provided information regarding promotions of INFUSE® across a broad spectrum, detailing not just the off-label misrepresentations relied on by Plaintiff's implanting surgeon in performing Plaintiff's surgery but also a good deal of information regarding on-label and off-label uses of INFUSE® generally, much of which likely falls outside the appropriate scope of this action. See FAC at ¶¶ 254-257, 260-285. Of the alleged misrepresentations made by Medtronic funded studies, many appear to relate to on-label use of INFUSE®.[8] See FAC at ¶¶ 227(a) (alleging misrepresentation(s) regarding "[a]nterior lumbar interbody fusion using rhBMP–2 with tapered interbody cages"), 227(b) (alleging misrepresentation(s) regarding "outcomes of anterior lumbar interbody fusion using [rhBMP-2] ... [and] tapered cylindrical metal fusion cage"); 227(c) (alleging misrepresentations regarding "clinical trials using the LT–CAGE lumbar tapered fusion device"); 227(j) (alleging misrepresentation(s) regarding "[a]nterior [l]umbar [i]nterbody [a]rthrodesis with use of [i]nterbody [f]usion [c]ages and [rhBMP-2]"). Some of Plaintiff's other allegations do not specify

[8] "INFUSE® is approved by the FDA and indicated only for spinal fusion procedures … at one level from L4-S1 … for surgery performed through the abdomen … [and] in combination with an LT Cage.'" FAC at ¶ 4; See FAC at ¶ 58. Anterior Lumbar Interbody Fusion ("ALIF") with the INFUSE® device – consisting of the LT-Cage™ tapered fusion device, a hollow metal cylinder, and the bone graft component, a collagen sponge that acts as a carrier for rhBMP-2 growth protein – is the only FDA approved use of INFUSE®. See FAC at ¶¶ 52-54.

whether the alleged misrepresentations relate to on-label or off-label promotion of INFUSE®, and if the promotion was for an off-label use, what the specific off-label procedure was. See FAC at ¶¶ 229-232, 246-249, 254-268. As explained in this Court's prior order, a cause of action for fraudulent misrepresentation only escapes express preemption so far as it is based on misrepresentations, concealments, and omissions that occurred during the *off-label* promotion of INFUSE®. Hawkins, 2014 WL 346622 at *12. Misrepresentations regarding on-label use of INFUSE® fall within the purview of the FDA premarket approval scheme.

Although Plaintiff's extensive pleadings extend beyond well beyond what is necessary to state a claim for fraud based on off-label misrepresentation and extend into allegations of on-label misrepresentation, they have alleged – with sufficient specificity for the pleading stage –who the Medtronic-sponsored authors were, when the articles were published, the content of the allegedly false articles promoting off-label procedures, and why that content was false. Plaintiff's amended complaint satisfies the Rule 9(b) requirement to plead the specific circumstances surrounding the alleged fraud such that Medtronic is on notice of the alleged misconduct attributed to it and can defend against such allegations.

ii. Misrepresentations made by Medtronic sales representatives and opinion leaders

Plaintiff has also alleged Medtronic directed its sales representatives to promote off-label uses of INFUSE®. See FAC at ¶ 113. The deceptive off-label promotion by Medtronic sales representatives is alleged to include: (1) directing surgeons to Medtronic sponsored articles and consultants both of which promoted off-label use of INFUSE®; (2) recommending dosages of rhBMP-2 growth hormone to use in off-label procedures; and (3) guiding surgeons through off-label procedures during surgery, all in spite of Medtronic's knowledge that such procedures were high risk and experimental. FAC at ¶¶ 113, 149, 150, 152, 155, 300, 319, 329. Additionally, Plaintiff alleges that Medtronic sales representatives (4) purchased gifts for physicians and facilities in an attempt to induce them to use INFUSE®. See FAC at ¶¶ 300(g), 319(g), 329(g). Plaintiff has further alleged that Medtronic (5) paid "opinion leaders" to promote off-label use of INFUSE® at conferences, in VIP meetings, during "poster presentations' at society meetings, and

via hands-on demonstrations and trainings." FAC at ¶¶ 300(h), 319(h), 329(h). The first three and the fifth items all allege a course of conduct that promotes INFUSE® as safe in spite of Medtronic's knowledge that such procedures are ~~h~~high risk and experimental." FAC at ¶¶ 300, 329. This overarching claim of misrepresentation of risk of off-label use is supported by the voluminous specific factual representations described above. See, e.g., FAC at ¶¶ 79-85, 254-289. These allegations, in conjunction with the allegations outlined in the previous section, are sufficiently particular to satisfy Rule 9(b); Defendants are on notice of the circumstances constituting the alleged fraud such that they can prepare an adequate answer from the allegations.[9]

c. Reliance

In its January 30, 2014 order, this Court further indicated that the lack of particularity in Plaintiff's complaint also raised a question regarding whether the alleged misrepresentations attributed to Medtronic were actually relied upon by Plaintiff's surgeon. Hawkins, 2014 WL 346622, *12-13. As addressed above, this Court will only require Plaintiff to plead in conformity with the plausibility standard laid out in Iqbal.

Adequately pleading the reliance element of the fraud based claims has been a stumbling block for plaintiffs in many of the litigations surrounding the INFUSE® device at the district court level. Several district courts have noted that the largely general and boilerplate allegations in the Medtronic actions fail to identify the connection between Medtronic's alleged misdeeds and the individual plaintiffs. See, e.g., Martin, 2014 WL 3635292,*9-10 (holding that plaintiff did not state a claim where she had ~~n~~not alleged which misrepresentations were relied on by her … surgeon. Instead she generally allege[d] that _[d]efendants through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained, and encouraged [plaintiff's] surgeon to engage in the off[-]label procedure utilizing a posterior approach without the required LT Cages™.'"); Beavers-Gabriel, 2014 WL 1396582, at *12 (where plaintiff's assertion that ~~P~~Plaintiff and Plaintiff's physicians … relied on M[edtronic]'s concealment of information and misrepresentations about the safety risks related to INFUSE® in deciding to use INFUSE® in an off-label manner," were inadequate to identify what particular misrepresentations were relied

[9] The fourth item appears to suggest that some of the implanting physicians or hospitals were parties to the fraudulent scheme described by Plaintiff's FAC. Plaintiff has not pled that allegation with the requisite particularity.

upon, who made the particular misrepresentations, and when); Zaccarello v. Medtronic, Inc., --- F.Supp.2d ----, 2014 WL ,*7 (W.D. Mo. 2014) (same); Dunbar, 2014 WL 3056026, *7 (same); see also, Anderson v. Medtronic, Inc., Doc. 65-1, 2014 WL 5289802 (Minn. Oct 16, 2014) (examining largely boilerplate and nonspecific allegations regarding Medtronic influencing medical literature, conferences, and statements by sales representatives and determining that those allegations did not provide the requisite specificity). Other district courts have found that the general allegation that a plaintiff's doctor relied upon misrepresentations made by Medtronic sponsored medical literature, conferences, and statements by sales representatives - despite the failure to plead what statements were relied upon, who made the misstatements, when they were made – were sufficient to plead reliance. See Arvizu, 2014 WL 4204933 at *7; Eidson II, 2014 WL 1996024, *20-21; Houston II, 2014 WL 1364455, *8-9; Scovil, 995 F.Supp.2d at 1097; Alton, 970 F.Supp.2d at 1098. Because the latter approach is more consistent with the requiring reliance to be pled under Rule 8 rather than Rule 9(b), it is the approach that this court will adopt.

To that end, Plaintiff has explained his allegation that Medtronic sales representatives ~~–a~~ffirmatively promoted INFUSE® for off-label procedures [to Plaintiff's implanting surgeon] by telling him that other surgeons were using the product in posterior and other off-label surgeries and were obtaining excellent results…, that INFUSE® was safe and effective for off-label use…, [and by] giving him dosing instructions for use in off-label procedures, providing intra-operative support for his off-label surgeries, and remaining in the operating room and providing advice throughout off-label procedures…." FAC at ¶ 305(a-c). Plaintiff has also alleged that his implanting surgeon attended ~~–s~~pine surgery society meetings at which M[edtronic's] Key Opinion Leaders presented on INFUSE® in off-label surgeries, portraying such off-label use as being low risk and desirable." FAC at ¶ 305(d). Finally, Plaintiff has alleged that his implanting surgeon was familiar with the published scientific literature regarding INFUSE® and was under the impression, based on Medtronic's alleged scheme of misrepresentation of adverse event occurrences, that INFUSE® was safe for off-label procedures. FAC at ¶ 305(e). ~~–W~~hen adverse events began to be reported [at] society meetings in the spine surgery community, [Plaintiff's implanting surgeon] stopped using INFUSE® off-label …." FAC at ¶ 306. Had he known about the potential

complications prior to Plaintiff's surgery, he would not have used INFUSE®. See FAC at ¶ 306.

Plaintiff has alleged the dates of publication of the allegedly false literature sponsored by Medtronic and the date of the operating room support is necessarily the same as that of Plaintiff's surgery.

These allegations are more than sufficient to plead reliance under Rule 8.

d. Strict Products Liability - Misrepresentation

Defendants move to dismiss Plaintiff's "strict products liability – misrepresentation" claim on the ground that it is not a recognized cause of action under California law. Doc. 49-1 at 28.[10] As a threshold matter, "[g]enerally, there is no [California] tort of innocent misrepresentation." Thrifty Payless, Inc. v. Americana at Brand, LLC, 218 Cal.App.4th 1230, 1243 (2013). In the strict products liability context, the California Fourth District Court of Appeal, in an unpublished opinion, addressed whether the above-captioned claim is actionable under California law. Suglia v. Lifestyle Custom Cycles, LLC, 2010 WL 4657235, *6-7 (2010). Although that court did not come to a definitive answer, it pointed out that no California court has determined the viability of (and this Court's own research has yielded no California case where damages were awarded for) a claim based on innocent misrepresentation by a manufacturer in the last 20 years. Suglia, 2010 WL 4657235, at *6-7; but see Hauter v. Zogarts, 14 Cal.3d 104, 112-114 (holding that plaintiff stated a claim pursuant to Rest.2d Torts, § 402B, recognized under California law).

In further support of Defendants' position, the Houston II court noted that "[i]n California, strict liability has been imposed for three types of product defects: manufacturing defects, design defects, and warning defects.'" Houston II, 2014 WL 1364455 at *8 n. 4 (quoting, O'Neil v. Crane Co., 53 Cal.4th 335, 347 (2012). No court that has considered the viability of a claim captioned "strict products liability – misrepresentation" brought in relation to injuries sustained from off-

[10] In this Court's previous order it relied on the California Supreme Court's adoption of Restatement (Second) of Torts § 402B, without addressing whether such a claim is still recognized in California. See Hauter v. Zogarts, 14 Cal.3d 104, 111 (1975). Section 402B reads:

> One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though
> (a) it is not made fraudulently or negligently, and
> (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller.

label use of the INFUSE® device has found that it stated a claim. E.g. Houston II, 2014 WL 1364455 at *8 n.4; Harris v. Medtronic, RG12-636341, 2013 WL 4011624 at *3 (Cal. Sup.Ct. Aug. 1, 2013) (―The court knows of no state law claim [for ―strict liability - misrepresentation.]" To the extent that plaintiff sought to allege an affirmative misrepresentation claim pursuant to CACI 1900, it is duplicative of the fraudulent misrepresentation and fraud in the inducement claim.) This Court agrees with the conclusion reached by the Houston II court; due to the lack of authority for such a claim, this Court will grant Medtronic's motion to dismiss as to this claim.

e. Conclusion

All considered, Plaintiff's factual allegations are sufficient to support a cognizable claim of fraudulent misrepresentation and fraudulent inducement and negligent misrepresentation. However, Plaintiff's ―Strict Products Liability – Misrepresentation" claim no longer appears to be viable under California law and will be dismissed.

2. Failure to Warn

―To state a claim for strict products liability for failure to warn, a plaintiff must allege that the defendant failed to adequately warn of a known or knowable risk where that failure caused the plaintiff's injuries." Hawkins, 2014 WL 346622 at *13 (citing cases). Plaintiff alleges that his failure to warn claim entitles him to relief under three different theories of recovery: (1) overpromotion, (2) misrepresentations and omissions made during off-label promotion, and (3) failure to report adverse events to the FDA. See Doc. 54 at 11. All of those claims are necessarily dependent on a finding that ―Medtronic failed to warn Plaintiff and Plaintiff's physicians of the dangers of off-label use of INFUSE®." FAC at ¶ 314. This Court previously made clear that ―premarket approval established the warning requirements applicable to the device and Defendants cannot be made to go beyond those warning requirements." Hawkins, 2014 WL 346622 at *14.

a. Overpromotion

Plaintiff's first theory regarding Medtronic's purported failure to warn alleges that Medtronic ―overpromoted" INFUSE® for use in off-label procedures. FAC at ¶ 315a. Plaintiff alleges that, as a result of that overpromotion, Medtronic ―negated and nullified any warnings it

had given to Plaintiff and Plaintiff's physicians." FAC at ¶ 315a(i); see Stevens v. Parke, Davis & Co., 9 Cal.3d 51, 65 (1973). The misrepresentation theories discussed above are distinct from the overpromotion claim because, in order to find liability as to the misrepresentation claims, Plaintiff need only prove that Defendants have committed affirmative misrepresentations upon which Plaintiff's surgeon relied. Conversely, to prevail on a failure-to-warn claim Plaintiff must prove ~~–t~~hat the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Anderson v. Owens–Corning Fiberglas Corp., 53 Cal.3d 987, 1002 (1991); see also Rosa v. Taser Int'l, Inc., 684 F.3d 941, 946 (9th Cir.2012).

Most formulations of overpromotion theory have been described, not as a stand-alone causes of action, but as ~~–o~~ne way that a plaintiff in a failure-to-warn case can overcome a manufacturer's argument either (1) that it provided adequate warnings or (2) that the doctor's decision to prescribe a drug despite his awareness of its dangers was an intervening cause sufficient to vitiate the manufacturer's liability." Baker v. Bayer Healthcare Pharmaceuticals Inc, 2014 WL 5513854, *3 (N.D. Cal. Oct. 32, 2014) (quoting Motus v. Pfizer, Inc., 196 F.Supp.2d 984, 998 (C.D. Cal. 2001)). Accordingly, in order for an overpromotion claim to provide liability, a finding of the inadequacy of the existing warning must be made. See Stevens, 9 Cal.3d at 65-67 (~~–T~~he warnings … were not so clearly effective as to defeat ... the inference that they were nullified by overpromotion…. It was within reason for the jury to find such warnings inadequate."). To highlight the problem, in Stevens - the primary authority relied upon by Plaintiffs to support this theory - the court specifically discussed how ~~–m~~ere compliance with regulations … as to warnings … issued by the [FDA] may not be sufficient to immunize the [pharmaceutical] manufacturer from liability" for overpromotion. Stevens, 9 Cal.3d at 65. Where state law liability could be found notwithstanding compliance with the federal requirements, those state law duties are not parallel to the federal requirements and will be preempted. Hawkins, 2014 WL 34662 at *4 (citing Riegel, 552 U.S. at 328).

Plaintiff contends that this theory does not require a determination that additional warnings should have been provided. Indeed, he recognizes that any claim that would require additional

warnings would be preempted. Rather, he contends that this theory relies only on Medtronic's alleged deceptive affirmative promotion of INFUSE® - in violation of federal law - which overcame or caused to be overlooked the otherwise-adequate warning. See Doc. 54 at 16. Plaintiff's claim does not assert that the FDA-approved warning is inadequate to warn for any of the FDA-approved uses of INFUSE®. Essentially, Plaintiff contends that by promoting as safe off-label uses but not warning of complications resulting from those off-label uses Defendants simultaneously created and violated their duty to warn of the dangers of off-label use. To avoid liability, Plaintiff claims that Defendants could have complied with federal law prohibiting false off-label promotion.

Plaintiff treats his overpromotion theory as a claim sounding in misrepresentation rather than failure to warn. Although the precise contours of overpromotion are ill-defined under California law, all cases that have discussed overpromotion have done so in the context of a failure to warn. See, e.g., Baker, 2014 WL 5513854 at *3; Motus, 196 F.Supp.2d at 998; Stevens, 9 Cal.3d at 65. The fact Defendants may have engaged in false off-label promotion is only a predicate step in an overpromotion claim. See Coleman, 233 Cal.App. 4th at 430 (–we are unaware of any case law recognizing a state law claim for failure to warn based upon allegations that a manufacturer had a duty to refrain from marketing altogether rather than marketing with adequate warnings.") In order to provide liability, an overpromotion claim must show that the Plaintiff or his physician was not adequately warned of the danger posed by the device. A finding of inadequacy of warning cannot be made without the necessary corollary that an additional or different warning should have been given to remedy the failure to adequately warn. The Eidson II court held as much when it found that a nearly identical claim could permit a finding of liability for failure to warn despite Medtronic's compliance with FDA warning requirements. Eidson II, 2014 WL 1996024 at * 18. Overpromotion is a claim that, at its core, imposes liability where a warning is inadequate.

Accordingly, Plaintiff's claim that Defendants could have avoided liability for a failure to warn claim by refraining from engaging in false off-label promotion does not impact the

preemption determination.[11] Even assuming that Defendants' false off-label promotion in violation of federal requirements rendered the (otherwise adequate) FDA-approved warnings inadequate, "[w]arnings required to remedy an insufficient warning are no different from warnings required to remedy a complete failure to provide any warnings – both necessitate additional warnings." Hawkins, 2014 WL 346622 at *14. No additional warnings are required under federal law. Because Plaintiff's overpromotion theory would require a finding of inadequacy of the FDA-approved INFUSE® warning (i.e. would impose requirements different from or in addition to federal requirements) this theory is expressly preempted. See Eidson II, 2014 WL 1996024, *18 (holding that the same overpromotion claim could permit a finding of liability for failure to warn despite Medtronic's compliance with FDA warning requirements). [12] This theory could not be cured by pleading of additional facts. It will be dismissed with prejudice.

Misrepresentation during off-label promotion

Plaintiff's second theory of recovery under its failure to warn cause of action alleges that Medtronic "affirmatively misrepresented and omitted information regarding the risks of the very off-label use Medtronic was promoting." FAC at ¶ 315(b)

The Eidson II court addressed the same claim and correctly concluded that this claim is expressly preempted. Eidson II, 2014 WL 1996024 at *19. That court noted that California's cause of action for failure to warn does not require a showing that defendant engaged in any misleading or deceptive misrepresentation. See Eidson II, 2014 WL 1996024 at *18 (citing California Civil Jury Instructions 1205 & 1222 (setting out the elements of strict liability and negligent failure to warn.) As a result, liability could be found under this theory despite a finding that no misleading or deceptive misrepresentation took place. As a result, this claim is expressly preempted.

b. Failure to report adverse events to the FDA

i. Preemption

As this Court's previous order explained, "manufacturers are required by the FDCA to report to the FDA adverse events where an approved device may have caused or contributed to a

[11] As a practical matter, the alleged conduct in question – making false statements regarding the safety of off-label use – is actionable. However, that claim is appropriately raised as fraudulent or negligent misrepresentation.

[12] Defendants claim that Plaintiffs overpromotion claim, if it exists, is impliedly preempted. Since this claim is disposed of on other grounds, this Court need not address whether overpromotion is impliedly preempted.

death or serious injury, or where a recurring malfunction would likely cause or contribute to a death or serious injury." Hawkins, 2014 WL346622 at *8 (citing Stengel v. Medtronic, 704 F.3d 1224, 1226–27 (9th Cir 2013) cert. denied 134 S.Ct. 2839 (July 23, 2014); 21 C.F.R. § 803.50(a); and 21 U.S.C. § 360i(a)). The Court expressed no opinion in its previous order as to whether or not California law required Medtronic to report adverse events to the FDA. Rather, this Court dismissed plaintiff's failure to warn cause of action as inadequately pled but recognized that a state law duty to report adverse events to the FDA theory could avoid preemption if a causal nexus between the failure to report and Plaintiff's injury were adequately pled. Hawkins, 2014 WL346622 at *8; see Eidson II, 2014 WL 1996024, at *7 (quoting Erickson v. Boston Scientific Corp., 846 F.Supp.2d 1085, 1092 (C.D.Cal.2011)).

In Stengel, the Ninth Circuit recognized that under Arizona law a warning to a third party such as the FDA could satisfy a manufacturer's duty to warn if ~~"~~there is reasonable assurance that the information [would] reach those whose safety depends on their having it." Stengel, 704 F.3d at 1233. Since this Court's previous order most of the lower courts that have considered the issue have found that California law imposes a duty to report adverse events to a third party, specifically the FDA, that parallels the duty found in Stengel. See, e.g., Eidson II, 2014 WL 1996024 at *20; Houston II, 2014 WL 136445 at *7; Coleman, 223 Cal.App.4th at 433. This Court sees no reason to depart from the well-reasoned conclusion of those courts. Medtronic's independent California law duty to warn could have been satisfied by reporting adverse events to the FDA; conversely, Medtronic's failure to report adverse events to the FDA can form the basis of a failure to warn claim which escapes implied preemption.

ii. Causal Nexus

The Court now addresses whether Plaintiff's amended pleadings are sufficient to establish a causal nexus between Medtronic's alleged failure to report adverse events to the FDA and Plaintiff's injury. Plaintiff's surgeries occurred in July of 2006, February of 2010, and August of 2010. FAC at ¶¶ 290-292. Accordingly, this Court will only examine failures to report prior which plaintiff alleges should have taken place prior to August 2010.

Plaintiff's amended complaint alleges that ~~"~~Medtronic … failed to … communicate the

growing number of adverse events to the FDA from 2002 to 2011, as it was required to do by federal law." FAC at ¶ 315(c). When an adverse event is reported the FDA records that adverse event in a MAUDE database, ~~a~~ public database known to, and discussed in the medical community, including Plaintiff's physicians." FAC at ¶ 315(c)(viii). Plaintiff alleges that his ~~p~~physician [relied] on [the] absence of reported events in deciding to use INFUSE® in an off-label manner … and Plaintiff's physician would not have … used INFUSE® off-label … if [he] had known the true safety risks." FAC at ¶ 322.

Plaintiff alleges that as a result of the above-outlined scheme of misrepresentation by opinion leaders, sales representatives, and paid consultants, Medtronic minimized and failed to report known adverse events related to INFUSE® device. Plaintiff relies heavily upon a study by Dr. Eugene Carragee published in a special edition of the Spine Journal specifically addressing the INFUSE® device. See FAC at ¶¶ 228, 232, 254, 259-260. Dr. Carragee, along with other Spine Journal authors, reported that the true rate of adverse events attributable to INFUSE® as implanted in a posterior lumbar interbody fusion technique had a 25% to 50% risk of associated adverse events rather than the near perfect safety reported by Medtronic sponsored studies. See FAC at ¶¶ 232, 272-273. On a more general level, the Spine Journal authors estimated that adverse events associated with use of INFUSE® in spinal fusion range from 10% to 50% depending on the approach. FAC at ¶ 258. By April of 2008, over 500,000 surgeries had been performed using the INFUSE® device, approximately 95% of which were for off-label uses. FAC at ¶ 315(c)(ii). Despite the estimated adverse event occurrence rate, only 262 adverse events involving INFUSE® were reported by the end of 2008; only 844 adverse events were reported by August 2011. FAC at ¶¶ 319(j), 315(c)(v). Assuming a 10% adverse event rate (the low end of Dr. Carragee's estimate) there had actually been approximately 50,000 adverse events by April 2008. FAC at ¶ 315(c)(iii).

Dr. Carragee's conclusion was reached using the same date available to Medtronic at the time that the allegedly ghostwritten and deceptive literature was published. FAC at ¶ 232. Along that line, Defendants make note that part of Dr. Carragee's analysis was based on ~~d~~documents provided [by authors who were Medtronic-paid consultants] to the FDA" along with their study that allegedly misrepresented adverse event rates. See Doc. 49-1 at 25 (citing FAC at ¶ 228).

Defendants contend that because Dr. Carragee relied on documents provided to the FDA in determining whether adverse events occurred that ~~–a~~dverse events associated with these trials were reported to the FDA." Doc. 56 at 19 (emphasis omitted). If device manufacturers were only required to provide raw data to the FDA such that the FDA could determine whether an adverse event had taken place, then Defendants' argument would find traction. As it is, Defendants are required to report adverse events to the FDA. See 21 U.S.C. § 360i(a); 21 C.F.R. § 803.50(a). The thrust of Plaintiff's failure to report theory is that Defendants knew of adverse events and purposely failed to record them as such. The fact that the data associated with the study tends to indicate that adverse events took place is not helpful to Defendants if those adverse events were not reported.

Plaintiff has amended his complaint to include sufficient factual allegations to support a claim for failure to warn the FDA. See Eidson II, 2014 WL 1996024 at *20-21 (Dr. Carragee's study was sufficient to show a large scale underreporting of adverse events and support an inference of causation sufficient to survive a motion to dismiss); Houston II, 2014 WL 1364455 at *7-8 (same); Coleman, at 223 Cal.App.4th at 420, 428-429.

C. Defendants' Motion to Strike

A motion to strike will only be granted as to redundant, immaterial, impertinent, or scandalous matter. Defendants seek to have three categories of allegations stricken from Plaintiff's FAC: (1) allegations referencing or arising from the Staff Report generated by the Senate Finance Committee in October of 2012 (~~–S~~taff Report"), regarding the clinical studies conducted for the INFUSE® Device (FAC at ¶¶ 176, 201, 219, 277-285), and the letters from Senators Grassley and Baucus to Medtronic in 2008 and 2011 (~~–S~~enator Letters") (FAC at ¶¶ 192-193, 204, 233-253); (2) allegations relying on Spine Journal articles written by Dr. Eugene Carragee, regarding his opinion that Medtronic underreported adverse event occurrence rates (FAC at ¶¶ 228, 232, 258, 260-261); and (3) allegations relying on documentation and testimony in related cases and settlement agreements (FAC at ¶¶ 91, 98-99, 105-106, 114-115, 132-143, 147-169, 208, 216).

Defendants assert that references to the Staff Report should be excluded ~~–b~~ecause such investigations have no bearing on the central issue in this case – whether an alleged defect of the

INFUSE® device *caused* Plaintiff's injuries." Doc. 50-1 at 9 (emphasis in original). As the previous sections of this order have exemplified, "whether an alleged defect of the INFUSE® Device" caused Plaintiff's injuries" is not the only relevant issue before this Court. Plaintiff has alleged a large scheme of misrepresentation as to the safety of the INFUSE® device for off-label uses. Plaintiff's claims that Medtronic paid consultants to misrepresent the safety of the INFUSE® device for off-label purposes are - at least inferentially - supported by the Staff Report and Senator Letters. See, e.g. FAC at ¶ 176 ("MEDTRONIC … paid more than $45 million to the 12 spine surgeons who authored the first 13 studies sponsored by MEDTRONIC on INFUSE®"), ¶ 192 (Dr. Kulko, who Plaintiff alleges to be a paid Medtronic consultant who gave presentations promoting the safety of INFUSE® for off-label uses, was not reported on a list of paid consultants for INFUSE®),¶ 244 ("it was reported that MEDTRONIC gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of INFUSE®"), ¶ 278 ("MEDTRONIC employees collaborated with the physician authors to edit – and in some cases, write – segments of published studies on INFUSE®. The studies may have inaccurately represented INFUSE®'s risks and may have overemphasized the side effects of prior more traditional treatments"). The factual material underlying the Senator Letters and Staff Report is not immaterial and will not be stricken.

Defendants' motion to strike contends that "Plaintiff's claims, which rely on the Carragee articles … are not plausible on [their] face and would not survive a motion to dismiss." Doc. 50-1 at 13. This argument has been decided in Plaintiff's favor above and is not a basis for striking the Carragee articles. Assuming that the Carragee articles lacked any connection to Plaintiff's surgeon's decision to use INFUSE®, they still tend to indicate that a large scale failure to report adverse events took place. Since that is a provable issue in the case this Court will not strike the Carragee articles on that ground.

Next, Defendants move to strike references to other suits and settlements with the DOJ. The factual allegations – although unquestionably drawn in part from other suits and settlements – relate to Medtronic's knowledge of adverse events and risks, (FAC at ¶ 98, 106) discussions regarding whether to report adverse events, (FAC at ¶ 105) and policies encouraging physicians to

promote the safety of off-label uses (FAC at ¶ 115, 132). Such factual allegations are not immaterial to this action and will not be stricken on that ground.

Defendants further encourage the Court to strike the Staff Report, Senator Letters, Dr. Carragee's articles, and references to other suits based on a litany of evidentiary objections to each. Doc. 50-1 at 11-16. Although the report, letters, articles, or transcripts from various suits themselves or particular items of evidence related to each may not be admissible, that is not the inquiry before the court. At this stage, the Court cannot make the determination that no evidence in support of those allegations would be admissible. As such, this Court will not strike any of the items in the complaint on the grounds that no evidence in support of those potentially relevant factual allegations could be admissible.[13]

V. CONCLUSION

Based on the foregoing, IT IS HEREBY ORDERED THAT:

1. Defendants' motion to dismiss Plaintiff's first cause of action for Fraudulent Misrepresentation and Fraud in the Inducement is DENIED;
2. Defendants' motion to dismiss Plaintiff's second cause of action for Strict Products Liability – Failure to warn is DENIED in part and GRANTED in part as follows:
   a. Plaintiff's first failure to warn theory of recovery for overpromotion cannot state a claim. That theory is DISMISSED with prejudice;
   b. Plaintiff's second failure to warn theory of recovery for misrepresentation during off-label promotion is preempted. That theory is DISMISSED with prejudice;
   c. Plaintiff's third failure to warn theory of recovery for failure to warn the FDA states a claim;
3. Defendants' motion to dismiss Plaintiff's third cause of action for Strict Products Liability – Misrepresentation is GRANTED. That cause of action is DISMISSED with prejudice;

[13] Defendants' objections as to admissibility are largely unripe and would be better addressed in a later state of the litigation as evidentiary objections. See, e.g. Amini Innovation Corp. v. McFerran, Inc., 2014 WL 3362800, *5 (C.D. Cal. 2014) (denying motion to strike potentially relevant material where motion was based on unripe evidentiary objections); City of Los Angeles v. Wells Fargo & Co., ---F.Supp.2d ----, 2014 WL 2206368, *13 (C.D. Cal. 2014)(denying motion to strike as impertinent or immaterial where factual material pled only served as contextual support; advising that a challenge admissibility is appropriately made as an evidentiary objection).

4. Defendants‘ motion to dismiss Plaintiff‘s fourth cause of action for Products Liability – Negligence is DENIED;

5. Defendants‘ motion to strike is DENIED.

IT IS SO ORDERED.

Dated: November 20, 2014

SENIOR DISTRICT JUDGE