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 GRANTING DEFENDANTS' MOTION TO DISMISS WITH LEAVE TO AMEND**

I. INTRODUCTION

Defendants MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC. bring this motion to dismiss Plaintiff GARY HAWKINS' complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. For the reasons set forth below, Defendants' motion is GRANTED and the complaint if DISMISSED with leave to amend.

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. 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"). Compl. at ¶¶ 12, 278-281.

INFUSE® is used in spinal fusion surgeries to stimulate bone growth. Compl. 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"). Compl. 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. Compl. 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"). Compl. at ¶¶ 54, 57. The protein-soaked sponge is placed inside the LT-Cage which is inserted into the patient's spine. Compl. at ¶¶ 4, 33-35. The premarket approval specifies that the FDA-approved INFUSE® device consists of all component parts which must be used together. Compl. 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." Compl. 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); see 21 U.S.C. §396.

Plaintiff underwent three surgeries wherein he was implanted with INFUSE®. Compl. at ¶¶ 278-80. These surgeries occurred on July 17, 2006, February 25, 2010, and August 2, 2010. Compl. at ¶¶ 278-80. All three surgeries were performed in an off-label manner not approved by

the FDA. Compl. at ¶¶ 278-80. Specifically, Plaintiff was implanted with INFUSE® without the use of the LT-Cage and using a posterior approach. Compl. at ¶¶ 278-80. Thereafter, Plaintiff experienced ectopic bone growth with resulting nerve impingement and permanent nerve damage. Compl. at ¶ 281.

III. LEGAL STANDARD

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)).

IV. DISCUSSION

A. MDA Preemption

Defendants argue that all of Plaintiff's claims are preempted by the MDA—either expressly by 21 U.S.C. Section 360k(a) or impliedly by 21 U.S.C. Section 337(a). Plaintiff argues that each cause of action states a parallel claim that survives preemption. The express preemption provision found in 21 U.S.C. Section 360k(a) states 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). The implied preemption provision found in 21 U.S.C. Section 337(a) states in relevant part: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. §337(a). "The Supreme Court has decided three preemption cases under the MDA. The 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." Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013).

1. Express Preemption

A state law claim will be expressly preempted by Section 360k(a) when 1) there are federal requirements applicable to the medical device and 2) the state law claim seeks to impose requirements that relate to safety and effectiveness of the device that are "different from, or in addition to" those federal requirements. Riegel, 552 U.S. at 321-22. Premarket approval is federal safety review of the medical device that imposes "requirements" specific to the subject device. Riegel, 552 U.S. at 322-23 ("Premarket approval, in contrast, imposes 'requirements' under the MDA as we interpreted it in Lohr . . . . [P]remarket approval is specific to individual devices."). "[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Riegel, 552 U.S. at 323. The premarket approval, therefore, establishes federal requirements for the medical device from which the manufacturer cannot deviate.

State law tort duties likewise impose "requirements" applicable to the device. Riegel, 552 U.S. at 323-24 ("In Lohr, five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements specific to a medical device . . . . We adhere to that view."). Even though these duties are generally applicable (i.e. they are applicable to more than just the specific medical device), they are clearly more than incidentally applicable to the FDA-approved device. Riegel, 552 U.S. at 328 ("Nothing in the statutory text [of Section 360k(a)] suggests that the preempted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.") (emphasis in original).

"State requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Riegel, 552 U.S. at 330 (quoting 21 U.S.C. §360k(a)(1)). "Thus, [Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (citing Lohr, 518 U.S. at 495; also citing Lohr, 518 U.S. at 513 (O'Connor, J., concurring in part

and dissenting in part)). To state a parallel claim that avoids preemption, a claim must be based on a state law duty that is "genuinely equivalent" to the federal requirement. Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011); McMullen v. Medtronic, Inc., 421 F.3d 482, 487 (7th Cir. 2005). If 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. See Riegel, 552 U.S. at 328; see also Wolicki-Gables, 634 F.3d at 1300. Further, state law claims will be expressly preempted when the duties they impose could require deviation from the federal requirements applicable to the device or require actions not mandated by the federal requirements. See Riegel, 552 U.S. at 319 ("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."); see Stengel, 704 F.3d at 1234 (Watford, J. concurring) (requiring reporting of adverse events directly to doctors would be preempted); see Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1118-19 (9th Cir. 2013) (finding duty to disclose lack of FDA approval for off-label procedure not required by FDCA and therefore preempted).

2. Implied Preemption

A state law claim will be impliedly preempted when it is not based on a violation of state law tort duties. Buckman, 531 U.S. at 353. Claims not tied to state law tort duties are essentially private actions to enforce the FDCA and are barred by Section 337(a). Perez, 711 F.3d at 1119. The court in Buckman refused to allow the "fraud-on-the-FDA" claims brought by plaintiff that "exist solely by virtue of the FDCA disclosure requirements." Buckman, 531 U.S. at 353. Permitting such claims would disrupt the statutory scheme that gives the FDA the authority to enforce FDCA requirements. Buckman, 531 U.S. at 348; see Perez, 711 F.3d at 1119. "[A]lthough [Lohr] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." Buckman, 531 U.S. at 353. To avoid implied preemption, a cause of action must rely on traditional state tort law. Buckman, 531 U.S. at 353.

All told, these cases identify a "'narrow gap' through which a state-law claim must fit to escape preemption." Perez, 711 F.3d at 1120. "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). "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 v. Medtronic, Inc., 2013 WL 3927839, *5 (C.D. Cal. 2013) (quoting Erickson v. Boston Scientific Corp., 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011)) (internal quotation marks omitted).

B. Issues Common to Plaintiff's Causes of Action

Before addressing each of Plaintiff's causes of action, this Court will address two issues applicable to each cause of action in the preemption discussions below: 1) whether premarket approval imposes federal requirements on the INFUSE® device when it is promoted and/or used off-label, and 2) the extent to which certain alleged FDCA violations will survive preemption.

1. Premarket Approval Imposes Federal Requirements on the INFUSE® Device Regardless of Off-label Promotion or Use

Plaintiff argues that express preemption under Section 360k(a) is not applicable to his claims because the INFUSE® device promoted by Defendants and used in his surgeries was not of the form or used in a manner approved by the FDA. He contends that no federal device-specific requirements exist because premarket approval was not granted for the INFUSE® Bone Graft Component alone. According to Plaintiff, promotion and use of INFUSE® without the LT-Cage is not the FDA-approved form of the device and therefore falls outside of the protection of Section 360k(a). If this argument is accepted, then Section 360k(a) will not preempt Plaintiff's state law claims because there are no federal device-specific requirements applicable to INFUSE® as used in Plaintiff's surgeries. See Riegel, 552 U.S. at 321; see Lohr, 518 U.S. at 500.

Use of the INFUSE® Bone Graft Component without the LT-Cage is simply an off-label use of the device. While Plaintiff is correct that the premarket approved form of INFUSE® includes all of its component parts, the off-label use of the device does not make Section 360k(a) inapplicable here because the premarket approval is as controlling of the individual components of INFUSE® as it is to the device as a whole. A device necessarily includes the components that together form the whole. The component parts of a device are subject to federal safety review through the premarket approval process. Component parts must be included in an application for premarket approval for the FDA to consider as part of the evaluation of the entire device. See 21 U.S.C. §360e(c). The INFUSE® Bone Graft Component therefore played a necessary part in the FDA's evaluation of the safety and effectiveness of the device as a whole. The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself. See Bass v. Stryker Corp., 669 F.3d 501, 508 (5th Cir. 2012); see Eidson v. Medtronic, Inc., 2013 WL 5533081, *8, fn. 3 (N.D. Cal. 2013); see Houston, 2013 WL 3927839, *7.

Additionally, the application of Section 360k(a) is "with respect to a *device*," not the manner in which the device is actually used. See 21 U.S.C. §360k(a) (emphasis added); accord Houston, 2013 WL 3927839, *7. Under the FDCA, medical practitioners are free to use an approved device in any manner they see fit, including off-label use. Buckman, 531 U.S. at 350; 21 U.S.C. §396. Such use, however, does not summarily preclude a finding of express preemption. See generally Riegel, 552 U.S. 312; see generally Perez, 711 F.3d 1109. The manner in which the device is used does not change the scope of Section 360k(a) preemption as it applies to a medical *device*. The federal requirements set forth in the premarket approval therefore apply to the INFUSE® Bone Graft Component whether or not the LT-Cage is used.

It makes no difference for this determination whether the Defendants actively promoted the off-label use of the INFUSE® Bone Graft Component without the LT-Cage, as alleged in the complaint. In Perez, the defendants "engaged in a nationwide scheme to modify the approved Laser to enable it to correct farsightedness before it was approved for that purpose" by modifying the software components of the laser. Perez, 711 F.3d at 1112-13. The defendants "continued to

sell, distribute, lease, use, service, and *market*" the device with the unapproved software after the FDA informed doctors that the laser was adulterated. Perez, 711 F.3d at 1113 (emphasis added). The court determined that the laser was subject to device-specific requirements under premarket approval and found the plaintiffs' fraud-by-omission claim to be expressly preempted in spite of the modification and promotion of the device for off-label use. Perez, 711 F.3d at 1118; see also Alton v. Medtronic, Inc., 2013 WL 4786381, *22 (D. Ore. 2013). A finding that Section 360k(a) is inapplicable here because the device was used or promoted off-label would be inconsistent with Perez, which is controlling.

In sum, the off-label use or promotion of INFUSE® does not remove the device or any of its components from the provisions of Section 360k(a). Premarket approval imposes federal requirements on the INFUSE® device as a whole as well as each of its component parts, including the INFUSE® Bone Graft Component. A device approved by the FDA does not fall completely outside of the provisions of Section 360k(a) simply because it is promoted for an off-label use. It is still necessary for a plaintiff to state parallel claims to avoid preemption. If it is found that Plaintiff's state law claims impose requirements different from or in addition to the federal requirements, those claims will be expressly preempted by Section 360k(a).

2. Alleged FDCA Violations

Five causes of action are identified in the complaint: 1) fraudulent misrepresentation and fraud in the inducement, 2) strict products liability for failure to warn, 3) strict products liability for design defect, 4) strict products liability for misrepresentation, and 5) products liability for negligence. Each cause of action begins by incorporating the rest of the complaint into that cause of action.

Plaintiff identifies a number of FDCA statutes and regulations in his complaint. Compl. at ¶¶ 122-128. It is alleged that Defendants "violated these FDCA statutes and accompanying regulations by promoting INFUSE® for off-label uses, and by failing to account for adverse events and update its labeling, directions for use, and advertising to account for the adverse events resulting from these off-label uses." Compl. at ¶ 129. It is also alleged that Defendants "misrepresented material and important health and safety product risk information" to Plaintiff and

his physicians. Compl. at ¶ 284. Lastly, Plaintiff alleges that Defendants "failed to comply with federal laws and regulations applicable to the sale and marketing of INFUSE®." Compl. at ¶ 336g.

It is possible to construe all of Plaintiff's causes of action as being based on conduct violative of the FDCA, namely off-label promotion of INFUSE®, failure to report adverse events to the FDA, deficiencies in the INFUSE® label (such as misrepresentations and omissions, inadequate directions, instructions, or warnings in the label itself, or failure to update the label in response to adverse events), and non-compliance with unspecified federal laws and regulations. The alleged conduct that is common to all of Plaintiff's causes of action will be discussed here to the extent possible. Only the surviving FDCA violations will be discussed with the individual causes of action.

i. Off-Label Promotion of INFUSE® Violates the FDCA

Plaintiff discusses at great length the off-label promotion of INFUSE® and bases his claims in part on that conduct. Defendants argue that off-label promotion is not prohibited by the FDCA. If Defendants were correct that the off-label promotion of INFUSE® was not a violation of federal law then all state law claims based on the alleged off-label promotion would be preempted. See Riegel, 552 U.S. at 328. (holding that where state law liability could be found in the absence of a violation of federal law that the state law cause of action is preempted.) As explained below, Defendants are incorrect; off-label promotion is prohibited by the FDCA.

Defendants rely on United States v. Caronia, 703 F.3d 149 (2d Cir. 2012) to support the argument that off-label promotion is not prohibited by the FDCA. In his opposition to the motion to dismiss, Plaintiff does not address the argument directly, but does cite federal district court cases from outside this circuit that found off-label promotion of FDA-approved devices to be unlawful. Pl. Opp., at p. 5-6 (citing U.S. ex. Rel. Nowak v. Medtronic, Inc., 806 F.Supp.2d 310, 317 (D. Mass. 2011) and U.S. v. Caputo, 288 F.Supp.2d 912, 920 (N.D. Ill. 2003)). None of the cited authority is controlling here.

The Ninth Circuit has considered this issue and found that off-label promotion is unlawful. Carson v. Depuy Spine, Inc., 365 Fed.Appx. 812, 815 (9th Cir. 2010) (unpublished). Although

not binding, this Court finds the Ninth Circuit's reasoning persuasive. "[T]he marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA." Carson, 365 Fed.Appx. at 815. This holding has been followed by other district courts in similar cases. See Houston, 2013 WL 3927839, *10; See Eidson, 2013 WL 5533081, at *10. It will be followed here as well. The allegation of unlawful off-label promotion of INFUSE® identifies a violation of FDCA requirements applicable to the device on which a parallel state law claim may be based.

ii. Failure to Report Adverse Events to the FDA Is Not Sufficiently Pled

Manufacturers are required by the FDCA to report to the FDA adverse events where an approved device may have caused or contributed to a death or serious injury, or where a recurring malfunction would likely cause or contribute to a death or serious injury. Stengel, 704 F.3d at 1226-27; 21 C.F.R. §803.50(a); see 21 U.S.C. §360i(a). The court in Stengel found that a failure to report adverse events to the FDA supported a parallel claim under Arizona law for a failure to warn because "Arizona law contemplates a warning to a third party such as the FDA." Stengel, 704 F.3d at 1233. The concurring opinion in Stengel, however, noted that basing the plaintiff's state law failure to warn claim on a duty to warn doctors directly would be preempted because reporting to doctors is not required by FDA regulations. Stengel, 704 F.3d at 1234 (Watford, J., concurring). The court in Perez confirmed this proposition, stating that "had the plaintiffs predicated their claim on a failure to warn doctors directly—an action not required by FDA regulations—that claim would have been preempted because it would have been an addition to the federal requirement." Perez, 711 F.3d at 1118.

It appears, then, that for a claim based on a failure to report adverse events to the FDA to survive preemption, there must be a state law duty to report, disclose, or warn that flows "to a third party such as the FDA." Stengel, 704 F.3d at 1233. The federal reporting requirement flows to the FDA, but not to Plaintiff or his physicians. See 21 C.F.R. §803.50; see 21 U.S.C. §360i. If the state law duty does not contemplate reporting, disclosure, or warnings to the FDA, it is not parallel to the federal requirement and the claim will be expressly preempted for imposing an additional requirement. Stengel, 704 F.3d at 1234 (Watford, J., concurring).

Here, however, Plaintiff has not pleaded sufficient facts to support any claims under this theory because a causal connection between his injuries and the alleged failure to report is absent. Plaintiff generally alleges that Defendants failed to report adverse events to the FDA. He also generally alleges that these failures caused or contributed to his injuries. What is not alleged is any factual content that would support the causal nexus. The only specific example provided in the complaint of Defendants' failure to report an adverse event notes that the event was ultimately reported three months after the fact. Compl. at ¶ 164. No dates are provided that might allow the inference that *timely* reporting could have affected the off-label use of INFUSE® during Plaintiff's surgeries. As it sits, under this theory, the complaint provides only a conclusory allegation that the failure to report caused Plaintiff's injuries and his right to relief has not risen above the speculative level. Twombly, 550 U.S. at 555. Thus, claims based on Defendants' failure to report adverse event to the FDA cannot stand because they are not adequately pled.

iii. Claims Affecting the FDA-Approved Label of INFUSE® are Expressly Preempted

"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). The FDA has already determined that the INFUSE® label—including the uses, warnings, directions, and other content specified in it—provides a reasonable assurance of the device's safety and effectiveness. Premarket approval established the federal requirements applicable to INFUSE®, its label, and other such conduct. Defendants are not required and in fact are not permitted to go beyond or stop short of those standards. Plaintiff does not allege that the INFUSE® device was labeled other than as approved by the FDA during premarket approval. See Compl. at ¶ 59, fn. 1.[1] This raises the possibility that Defendants could be found to have "violated state tort law notwithstanding compliance with the relevant federal requirements." Riegel, 552 U.S. at 330. Any re-labeling required by Plaintiff's state law claims would be different from or in

[1] A claim based on an FDA-approved label could be permitted to the extent that a plaintiff alleges that the device's label deviated from the approved label. If the device was not labeled according to the federal specifications, such a claim would allege an FDCA violation and could support a state law claim if the duties lie parallel.

addition to the federal premarket approval requirements that approved the labeling of INFUSE®.

Further, permitting those claims to proceed could result in a finding that the FDA-approved label was inadequate, as well as a general finding that the device itself is unsafe notwithstanding the FDA's determination that the device is safe as labeled. Premarket approval is federal safety review within the statutory scheme established by the FDCA. A state law claim that could conclude that an FDA-approved device is unsafe flies in the face of the premarket approval process. Accordingly, any state law claims that would require Defendants to make changes to the FDA-approved INFUSE® label are expressly preempted.

iv. Violations of Other Unspecified FDCA Statutes and Regulations

It is possible to construe Plaintiff's causes of action as being based, in part, on violations of unspecified FDCA provisions and FDA regulations. As an example, Plaintiff alleges that "Defendants negligently failed to exercise reasonable care in that they failed to comply with federal law and regulations applicable to the sale and marketing of INFUSE®." Compl. at ¶ 336g. Plaintiff does not identify which federal laws and regulations were violated. To that extent, those claims must fail because without specifying the federal requirements and the duties they impose, it is impossible to determine whether any state law duties lie parallel. Plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." Wolicki-Gables, 634 F.3d at 1301. These claims will be preempted because it cannot be determined that parallel claims exist based on the allegations in the complaint. Plaintiff has failed to "state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678.

C. Plaintiff's State Law Causes of Action

As noted above, any claims based on deficiencies in the INFUSE® label and other non-compliance with unspecified federal laws and regulations are expressly preempted and will not be examined further. Likewise, Plaintiff has failed to state a claim based on the failure to report adverse events to the FDA because facts sufficient to establish a causal connection between the failure to report and Plaintiff's injuries have not been pled. Accordingly, Plaintiff's state law

causes of action are considered to be based solely on the alleged unlawful off-label promotion of INFUSE®.

1. Fraudulent Misrepresentation and Fraud in the Inducement

Plaintiff's first cause of action is for fraudulent misrepresentation and fraud in the inducement. To plead a cause of action for fraud, Plaintiff must allege 1) a misrepresentation, including a false representation, concealment, or nondisclosure, 2) knowledge of falsity, 3) intent to defraud or induce reliance, 4) justifiable reliance, and 5) resulting damages. Philipson & Simon v. Gulsvig, 154 Cal.App.4th 347, 363 (2007); Gil v. Bank of America, Nat. Ass'n, 138 Cal.App.4th 1371, 1381 (2006).

The complaint alleges the following:

> 284. In connection with their INFUSE® products, the MEDTRONIC Defendants fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff's physicians, all as alleged in this Complaint. Plaintiff and Plaintiff's physicians would not have decided to use INFUSE® off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA, had they known of the safety risks related to INFUSE®.
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> 285. The MEDTRONIC Defendants marketed their INFUSE® product to and for the benefit of Plaintiff, and marketed it to Plaintiff's physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects in their INFUSE® product, and that Plaintiff and Plaintiff's physicians would use the product.
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> 287. The MEDTRONIC 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®;
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> 288. The MEDTRONIC Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label practice of utilizing a posterior approach, using INFUSE® in at least six locations, using INFUSE® without an LT cage, and otherwise using it in a manner not approved by the FDA;
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> 289. The MEDTRONIC Defendants fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of

> INFUSE® and the relative benefits and availability of alternate products, treatments and/or therapies.
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> 290. The MEDTRONIC Defendants knew, or should have known, that they were concealing and misrepresenting true information about the known comparative risks and benefits of the use of INFUSE® and the relative benefits and availability of alternate products, treatments and/or therapies.
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> 291. The MEDTRONIC Defendants knew that Plaintiff and Plaintiff's physicians would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and Plaintiff's physician's decision whether or not to use INFUSE® off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA.
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> 292. The MEDTRONIC Defendants intended to cause Plaintiff and Plaintiff's physicians to rely on their concealment of information and misrepresentations about the safety risks related to INFUSE® to induce them to make off-label use of INFUSE® for Plaintiff's lumbar spine fusion surgery.
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> 293. Plaintiff and Plaintiff's 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.
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> 294. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to INFUSE® and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiff has been injured and has incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

The allegations in the complaint support a cause of action for fraud under California law. This cause of action, therefore, is not impliedly preempted under Buckman because it relies on traditional state tort law and does not "exist solely by virtue of the FDCA . . . requirements." Buckman, 531 U.S. at 353.

Plaintiff's cause of action for fraudulent misrepresentation and fraud in the inducement is based on misrepresentations, concealments, and omissions made during the affirmative promotion of the off-label use of INFUSE®. The allegation essentially provides that the off-label use of INFUSE® was promoted to Plaintiff and his physicians as a safe application of the device. See Compl. at ¶¶ 119, 121. This claim is not expressly preempted because it parallels the federal law

that makes off-label promotion of a medical device unlawful. See Carson, 365 Fed.Appx. at 815.

As the complaint alleges, Defendants misrepresented, concealed, and omitted important information related to the safety of the device when used in an off-label manner. The misrepresentations, concealments, and omissions that support this cause of action all occurred during the course of affirmatively promoting the off-label use of the INFUSE® device. Defendants were prohibited by the FDCA from *any* off-label promotion of INFUSE®. See Carson, 365 Fed.Appx. at 815. A state law claim that is based on any misrepresentations, concealments, or omissions that result from this prohibited activity therefore lies parallel to the federal requirement that prohibits any affirmative promotion of the off-label use of the INFUSE® device in the first place. Therefore, this cause of action is not expressly preempted.

Courts in similar cases have likewise held that fraud causes of action based on misrepresentations, concealments, and omissions that occurred during the off-label promotion of INFUSE® escape express preemption. See Eidson, 2013 WL 5533081, at *10-11; see Houston, 2013 WL 3927839, *9-10. Other courts have found that such claims could escape express preemption, but failure to allege the specific misrepresentations, concealments, and omissions prevented the courts from actually determining "whether allowing [the] fraud claims to proceed would impose different or additional requirements for the purpose of determining express preemption." Kashani-Matts v. Medtronic, Inc., 2013 WL 6147032, *5 (C.D. Cal. 2013); see Caplinger v. Medtronic, Inc., 921 F.Supp.2d 1206, 1220 (W.D. Ok. 2013).[2]

Plaintiff has alleged that "[Defendants], while providing spine surgeons with Medtronic-funded studies and published articles purporting to support the efficacy and safety of the off-label uses, simultaneously and systematically concealed or downplayed other non-Medtronic-funded studies and articles demonstrating serious and frequent adverse events caused by the same off-label uses." Compl. at ¶ 119. It is alleged that Defendants "*actively promoted* the off-label procedures" that caused Plaintiff's spine surgeon to perform the off-label INFUSE® procedure.

[2] The latter decisions may be based in part on the understanding that fraud claims based exclusively on omissions will be preempted. If based only on alleged omissions, a state law duty to disclose safety information could go beyond the federal disclosure requirements and would therefore be in addition to the federal requirements. Following that reasoning, a state law fraud claim based on affirmative misrepresentations only could survive preemption, while claims based on non-affirmative conduct like omissions could be preempted.

Compl. at ¶ 121 (emphasis added). Plaintiff's complaint, taken as true, asserts that Defendants made misrepresentations, concealments, and omissions during the off-label promotion of INFUSE® as part of Defendants' overall scheme. Such conduct cannot be separated. Defendants' active promotion involved a combination of representations, concealments, and the omission of important safety information. In that regard, it does not matter whether there was an affirmative statement, active concealment, or knowing omission made to support the claim because the entire effort—including all misrepresentations, concealments, and omissions made by Defendants—was essential to Defendants' promotion of the off-label use of INFUSE®. Accordingly, Plaintiff's first cause of action may be based on any misrepresentations, concealments, and omissions that occurred during the off-label promotion of INFUSE®.

Although otherwise facially valid, this cause of action must be dismissed because it falls short of the requirements for pleading fraud with particularity. Fed.R.Civ.P. 9(b). Plaintiff alleges: "MEDTRONIC's off-label promotion of INFUSE® to Plaintiff's surgeon was false and misleading, in that it overemphasized the purported benefits of the off-label use, and hid, minimized, or downplayed the true risks and dangers of the off-label use, all of which were known to MEDTRONIC at all relevant times." Compl. at ¶ 121. The complaint devotes numerous paragraphs to describing Defendants' payments to "opinion leaders" and their alleged role in the unlawful off-label promotion of INFUSE® by preparing articles concerning INFUSE® that were published in medical journals. See Compl. at ¶¶ 10-11, 171-220. However, nothing in the complaint points to specific content in those articles or statements made by the named opinion leaders that were allegedly false, or why the representations were untrue. This type of allegation is not "specific enough to give [D]efendants notice of the particular misconduct . . . so that they can defend against the charge," but instead leaves them to "just deny that they have done anything wrong." Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir.2009) (citation omitted).

The lack of particularity also raises a question regarding Plaintiff's reliance on the alleged misrepresentations. Plaintiff alleges: "In this particular case, MEDTRONIC actively promoted the off-label procedures to Plaintiff's spine surgeon, and Plaintiff's spine surgeon would not have performed the off-label INFUSE® procedure in the absence of such promotion." Compl. at ¶ 121.

Plaintiff fails to allege not only the content of the off-label promotion directed at his spine surgeon and on which the surgeon relied, but he also fails to allege who made those representations to his surgeon and when the representations were made. Rule 9(b) requires more than the generalized allegations made here.

Therefore, Plaintiff's first cause of action is for fraudulent misrepresentation and fraud in the inducement will be DISMISSED.

2. Strict Products Liability-Failure to Warn

Plaintiff's second cause of action is for strict products liability for 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. Carlin v. Superior Court, 13 Cal. 4th 1104, 1112 (1996); Chavez v. Glock, Inc., 207 Cal.App.4th 1283, 1304 (2012). "The theory underlying a warning defect cause of action is that the product is dangerous because it lacks adequate warnings or instructions." Chavez, 207 Cal.App.4th at 1304 (citing Barker v. Lull Engineering Co., Inc., 20 Cal.3d 413, 428 (1978)).

The complaint alleges the following:

> 297. MEDTRONIC had a duty to warn Plaintiff and Plaintiff's physicians about the dangers of INFUSE® of which it knew, or in the exercise of ordinary care, should have known, at the time the INFUSE® left the Defendants' control. The MEDTRONIC Defendants did know of these dangers of off-label use of INFUSE®, and breached this duty by failing to warn Plaintiff and Plaintiff's physicians of the dangers of its off-label practice of using INFUSE® off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA.
>
> * * *
>
> 300. Defendants knew or should have known of the substantial dangers involved in the reasonably foreseeable use of INFUSE®, whose defective design, manufacturing, and lack of sufficient warnings caused INFUSE® to have an unreasonably dangerous propensity to cause catastrophic injuries.
>
> 301. The warnings accompanying the INFUSE® product did not adequately warn Plaintiff and Plaintiff's physicians, in light of its scientific and medical knowledge at the time, of the dangers associated with INFUSE® when used off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using

> INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA, including, but not limited to, pain and weakness in limbs, loss of sensation, radiculitis, subsidence, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.
>
> 302. The warnings accompanying the INFUSE® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to MEDTRONIC. MEDTRONIC either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the off-label use of INFUSE®, including, but not limited to, pain and weakness in limbs, loss of sensation, radiculitis, subsidence, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.
>
> 303. Defendants failed to provide adequate warnings, instructions, guidelines or admonitions to members of the consuming public, including Plaintiff and Plaintiff's physicians, of the design and manufacturing defects, which Defendants knew, or in the exercise of reasonable care should have known, to have existed in INFUSE®.
>
> * * *
>
> 306. Plaintiff's physician relied on MEDTRONIC's inadequate warnings in deciding to use INFUSE® in an off-label manner. Plaintiff and Plaintiff's physician would not have made off-label use of INFUSE® off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA had they known of the true safety risks related to INFUSE®.
>
> 307. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, and of MEDTRONIC's failure to provide adequate warnings about them, Plaintiff sustained serious injuries of a personal and pecuniary nature from approximately July 2006 to the present.

The allegations support a cause of action for strict products liability for failure to warn and thus survive implied preemption.

Plaintiff's cause of action for strict products liability for failure to warn must be based on failure to provide adequate warnings during the off-label promotion of INFUSE®, meaning the affirmative warnings that were actually provided regarding off-label use of INFUSE® were insufficient. Permitting this claim would impose state law requirements in addition to the federal requirements and must be preempted. Premarket approval established the warning requirements applicable to the device and Defendants cannot be made to go beyond those warning requirements. Judge Watford's concurring opinion in Stengel noted that FDA regulations permit the issuance of post-sale warnings without FDA approval, "but those regulations did not require such warnings."

Stengel, 704 F.3d at 1234 (Watford, J. concurring) (citing 21 C.F.R. §814.39(d)) (determining that the permissive but not mandatory regulation could not support a parallel claim). To avoid the alleged state law violation, Defendants would be required to provide a warning concerning off-label use of INFUSE® that is not required under the FDCA. Warnings 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. The latter would be preempted for requiring a warning beyond the FDA-required warnings and the former should be as well.

It has not gone unnoticed that this finding preempts claims that are in fact related to Defendants' FDCA violations related to off-label promotion of INFUSE®. As the Seventh Circuit stated in Bausch v. Stryker Corp., 630F.3d 546 (7th Cir. 2010), "[s]ection 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law." Bausch, 630 F.3d at 553. Defendants are alleged to have violated the federal prohibition against off-label promotion of an approved medical device. To avoid preemption, the state law duty and the applicable federal requirement must be "genuinely equivalent." Wolicki-Gables, 634 F.3d at 1300; McMullen, 421 F.3d at 487. An affirmative duty to *provide* adequate warnings is not genuinely equivalent to a federal requirement to *refrain* from a particular type of promotion. This is the case even when that promotion makes the warnings actually provided inadequate.

It has been found that off-label promotion of a medical device in a manner similar to that alleged in the complaint creates a new "intended use" of the device pursuant to 21 C.F.R. Section 801.4. See Alton, 2013 WL 4786381, *27. Such an intended use has by definition not been approved by the FDA. The court in Alton determined that the defendant's conduct violated the FDCA, "namely its duty to provide 'adequate directions' as to that intended use in its product labeling." Alton, 2013 WL 4786381, *27 (citing 21 U.S.C. § 352(f)(1); also citing 21 C.F.R. § 801.5). The Alton court found that the plaintiff's failure to warn claim was a parallel claim, but then found the claim to be preempted, at least in part. See Alton, 2013 WL 4786381, *27 ("It is clear that Alton's failure to warn claim is preempted under [s]ection 360k(a) to the extent recognition of the claim would constitute imposition of any warning requirement in addition to or

different from the 'adequate directions for use' that would be mandated under the FDCA for PLIF surgery involving the bone-protein component alone.). The Alton court allowed the plaintiff's claims to stand insofar as the state law claims paralleled defendant's duty pursuant to the FDCA to update its label in response to the new intended use. See Alton, 2013 WL 4786381, *27 ("However, to the extent that [defendant's] compliance with its FDCA labeling obligations as to the allegedly intended use at issue here would constitute compliance with Oregon's statutory products liability scheme regarding [defendant's] duty to warn in connection with that same allegedly intended use, it is equally clear that his claim would escape express preemption.").

This Court has construed Plaintiff's cause of action to be based on a failure to provide adequate warnings during the off-label promotion of INFUSE®. Avoiding state law liability would require providing additional warnings not required by the FDCA. Likewise, a finding that Defendants created a new intended use of the INFUSE® device giving rise to a duty to provide adequate directions in the product label would require making changes to the INFUSE® label that has been approved by the FDA. As such, a parallel claim could not be based on the federal requirement that Defendants provide adequate directions because doing so would require Defendants to make changes to the FDA-approved label based on a state law requirement. Such a claim cannot survive express preemption.

It may be sound policy to require medical device manufacturers to provide additional direction and warnings for promoted off-label uses, but doing so would run afoul of other federal requirements applicable to the device and requires a finding of preemption. Although Defendants were prohibited from engaging in any off-label promotion of INFUSE® in the first place, they also were prohibited from making changes to the FDA-approved label. That the claim must fail in spite of Defendants' violation of the FDCA may suggest a need to reevaluate the preemption scheme in situations where an off-label use is actively promoted, but it is not within the power of this Court to do so. As the court stated in Perez

> Perez 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. We do not pass judgment on whether this would be a wise rule for the FDA to adopt. It is sufficient for our

inquiry that it has not done so.

Perez, 711 F.3d at 1118-19. Here, it is sufficient for the inquiry at hand that allowing the failure to warn claim to proceed would require additional warnings not mandated by the federal requirements.

Therefore, Plaintiff's second cause of action for strict products liability based on a failure to warn will be DISMISSED.

3. Strict Products Liability-Design Defect

Plaintiff's third cause of action is for strict products liability for design defect. Defendants argue that this claim must be dismissed because "California has adopted the Restatement (Second) of Torts Section 402A Comment (k), which precludes liability for manufactures of prescription medical devices under a design defect theory." Def. Memo of Pts and Auth., at p. 20; see Artiglio v. Superior Court, 22 Cal.App.4th 1388, 1397 (1994). Plaintiff states in his opposition to Defendants' motion to dismiss that this argument is not disputed. Pl. Opp., at p. 2, fn. 1.

Therefore, Plaintiff's third cause of action for strict products liability for design defect will be DISMISSED.

4. Strict Products Liability-Misrepresentation

Plaintiff's fourth cause of action is for strict products liability for misrepresentation. California follows the Restatement (Second) of Torts §402B, which states:

> 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.

Hauter v. Zogarts,14 Cal.3d 104, 111, fn. 3 (1975). Unlike the first cause of action for fraudulent misrepresentation and fraud in the inducement, this cause of action does not require that

Defendants intended to defraud or induce reliance by their misrepresentations. It is enough that 1) Defendants made a misrepresentation of material fact, 2) Plaintiff justifiably relied on the misrepresentation, and 3) that caused Plaintiff's injuries.

The complaint alleges the following:

> 322. At all relevant times, Defendants were engaged in the business of selling INFUSE® for resale or use, and in fact did sell the INFUSE® device used by Plaintiff's implanting surgeon. In the course of marketing INFUSE®, the MEDTRONIC Defendants made untrue representations of material facts and omitted material information to Plaintiff, Plaintiff's physicians, and the public at large. The MEDTRONIC Defendants sponsored biased medical trials, reports, and articles that wrongfully and inaccurately claimed that the dangers inherent to off-label use of INFUSE® did not exist or were significantly less than the actual dangers. The MEDTRONIC Defendants made these misrepresentations and omissions to guide doctors and physicians in their purchase and use of INFUSE®.
>
> 323. Plaintiff and Plaintiff's physicians would not have purchased and made off-label use of INFUSE® by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA.
>
> * * *
>
> 326. Plaintiff and Plaintiffs' physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to INFUSE® in deciding to make off-label use of INFUSE® by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA.
>
> 327. As the direct, proximate and legal result of the Defendants' misrepresentations, Plaintiff has suffered and will severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

The allegations support a cause of action for strict products liability for misrepresentation and thus survive implied preemption.

Plaintiff's cause of action for strict products liability for misrepresentation must be construed as being based on misrepresentations made during the off-label promotion of INFUSE®. To that extent, it escapes express preemption for the same reasons as the first cause of action. This cause of action is based on misrepresentations made by Defendants during the off-label promotion of INFUSE® which is in violation of the FDCA. A sufficient parallel claim has been stated to survive preemption.

Like the first cause of action, this cause of action also fails the particularity requirements of Rule 9(b). The discussion above concerning the generalized pleadings and lack of specific content equally applies to this cause of action.

Therefore, Plaintiff's fourth cause of action is for strict products liability for misrepresentation will be DISMISSED.

5. Products Liability-Negligence

Plaintiff's fifth cause of action is for products liability for negligence. The complaint alleges the following:

> 330. Defendants marketed their INFUSE® product to and for the benefit of Plaintiff, and additionally marketed it to Plaintiff's physicians, and these Defendants knew or should have known that Plaintiff and Plaintiff's physicians would use their product, including for the off-label use of INFUSE® without an LT-Cage® and the placement of INFUSE® medially and laterally to a non-FDA approved cage in lumbar spine fusion.
>
> 331. Defendants owed Plaintiff and Plaintiff's physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.
>
> * * *
>
> 333. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff and Plaintiff's physicians of the true health and safety risks related to the off-label use of INFUSE®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of INFUSE® without an LT-Cage® and the placement of INFUSE® medially and laterally to a non-FDA approved cage for lumbar spine surgeries. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of INFUSE® to Plaintiff and Plaintiff's physicians.
>
> 334. Misrepresentations made by Defendants about the health and safety of INFUSE® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and Plaintiff's physicians the true health and safety risks related to INFUSE®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.
>
> 335. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff and to Plaintiff's physicians.

336. The following sub-paragraphs summarize, inter alia, Defendants' breaches of duties to Plaintiff and Plaintiff's physicians and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

> a. The defendants were at all times negligent and careless in and about their design, testing, distribution, manufacture, advertising, sale and marketing of the above-described INFUSE® product.
>
> * * *
>
> d. Defendants negligently promoted and marketed INFUSE® to physicians, including for off-label use in lumbar spine fusion surgeries;
>
> e. Defendants negligently failed to warn physicians and Plaintiff of the dangers associated with INFUSE® when used off-label by utilizing a posterior approach, by using INFUSE® in at least six locations, by using INFUSE® without an LT cage, and by otherwise using it in a manner not approved by the FDA including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments;
>
> f. Defendants negligently failed to recall or retrofit INFUSE®.
>
> g. Defendants negligently failed to exercise reasonable care in that they failed to comply with federal law and regulations applicable to the sale and marketing of INFUSE®; and
>
> h. Defendants failed to exercise reasonable care to prevent INFUSE® from creating an unreasonable risk of harm to Plaintiff and other consumers who might reasonably be expected to be harmed by INFUSE® while it was being used in the manner the MEDTRONIC Defendants should have reasonably expected.
>
> * * *

338. As the direct, proximate and legal result of the Defendants' misrepresentations, Plaintiff has suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

As alleged in the complaint, Plaintiff's cause of action for products liability for negligence must be construed as being based on the negligent failure to warn of the dangers associated with INFUSE® when used off-label. All other bases for this cause of action are expressly preempted. As discussed in Part IV.B.2.iii., supra, any state law duties that would require deviation from the

FDA-approved label will be preempted absent an allegation that Defendants did in fact deviate from the federal standards. The same reasoning is applicable to allegations of negligence based on the device's design and manufacture. Plaintiff makes no allegation that Defendants failed to comply with those federal standards. Additionally, as discussed in Part IV.B.2.iv., supra, Plaintiff does not specify which federal laws or regulations were violated to support a parallel state law claim. To that extent, Plaintiff's claims are expressly preempted.

The general allegation that Defendants were negligent for promoting INFUSE® off-label must fail as impliedly preempted because the state law claim "exist[s] solely by virtue of the FDCA . . . requirements." Buckman, 531 U.S. at 353. The court in Eidson noted that "Defendants' conduct is only allegedly 'negligent' because the FDCA bans off-label promotion." Eidson, 2013 WL 5533081 at *15. Off-label promotion itself exists only as a creation of the FDCA scheme. A state law cause of action cannot rest solely on the off-label promotion of INFUSE®. See Perez, 711 F.3d at 1119-20.

A negligent failure to warn claim does exist independently of the FDCA and would survive implied preemption. "Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." Anderson v. Owens-Corning Fiberglas Corp., 53 Cal.3d 987, 1002 (1991). Such a claim, however, is expressly preempted for the reasons set forth in the discussion concerning the second cause of action. Part IV.C.2., supra. Permitting a negligent failure to warn claim, as discussed above, would result in different or additional warning requirements for the INFUSE® device not required by the FDCA.

Therefore, Plaintiff's fifth cause of action for products liability for negligence will be DISMISSED.

V. ORDER

For the foregoing reasons, Defendants' motion to dismiss is GRANTED. Plaintiff's third cause of action for strict products liability for design defect is DISMISSED with prejudice; all other causes

of action are DISMISSED without prejudice. Plaintiff may file an amended complaint within thirty (30) days of the date of this order. Failure to file an amended complaint by this deadline will result in dismissal of the action without prejudice.

IT IS SO ORDERED.

Dated: January 30, 2014

SENIOR DISTRICT JUDGE