IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

KARLA BEAVERS-GABRIEL, Plaintiff, vs. MEDTRONIC, INC. and MEDTRONIC SOFAMORE DANEK USA, INC., Defendants.	CIV. NO. 13-00686 JMS-RLP ORDER GRANTING DEFENDANTS MEDTRONIC, INC. AND MEDTRONIC SOFAMOR DANEK USA, INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

ORDER GRANTING DEFENDANTS MEDTRONIC, INC. AND MEDTRONIC SOFAMOR DANEK USA, INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

I. INTRODUCTION

On December 16, 2013, Plaintiff Karla Beavers-Gabriel ("Plaintiff") filed this action against Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic" or "Defendants"), asserting state law claims based on injuries she sustained after undergoing spinal surgery in which her surgeon used Defendants' Infuse® Bone Graft (the "Infuse Device" or "Infuse®"), a Class III prescription medical device, in an off-label manner not approved by the Food and Drug Administration ("FDA").

Currently before the court is Defendants' Motion to Dismiss, in which they argue that Plaintiff's claims are expressly preempted by the Medical Device Amendments ("MDA") of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), impliedly preempted by the "no private right of action clause" of the FDCA, 21 U.S.C. § 337(a), and in any event fail to assert plausible claims for relief or comply with Federal Rule of Civil Procedure 9(b). Based on the following, the court finds that Plaintiff's claims are preempted in part and otherwise fail to assert a plausible claim for relief and/or comply with Rule 9(b). The court therefore GRANTS Defendants' Motion to Dismiss, with leave for Plaintiff to amend as to certain claims.

II. BACKGROUND

A. Factual Background

To properly frame the issues presented in Defendant's Motion to Dismiss, the court provides the following factual background based on the allegations of the Complaint, the judicially-noticed facts,[1] as well as the statutes

[1] Both parties submitted Requests for Judicial Notice. *See* Doc. Nos. 15, 23. Defendants request the court to take judicial notice of certain public documents available on the FDA's public website regarding premarket approval of the Infuse Device. The court grants Defendants' request -- matters of public record such as records and reports of administrative bodies are proper subjects of judicial notice. *See Eidson v. Medtronic, Inc.*, --- F. Supp. 2d ----, 2013 WL 5533081, at *6 (N.D. Cal. Oct. 3, 2013) (collecting caselaw for the proposition that documents on the FDA's public website may be judicially noticed, and taking judicial notice (continued...)

and caselaw explaining the FDA's approval process of Class III medical devices such as the Infuse Device.

1. FDA Approval and Oversight of Class III Medical Devices

Class III medical devices such as the Infuse Device are regulated by the FDA pursuant to the Medical Device Amendments of 1976 (the "MDA") of the FDCA. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 316-17 (2008). Of the three classes of medical devices, Class III medical devices pose the greatest risk of death or complications -- "a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance

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[1](...continued)
of the same documents Defendants present in this action).

Plaintiff requests the court to take judicial notice of the Staff Report on Medtronic's Influence on Infuse Clinical Studies, which was prepared by the Staff of the Committee on Finance for the United States Senate, and is publicly available online (Plaintiff also submits two exhibits without requesting that the court take judicial notice, which the court ignores for the purposes of the Motion to Dismiss). Doc. No. 23. Defendants object to the extent Plaintiff submits the Report to establish the assertions and opinions provided in the Report, and not merely the fact of its existence. Doc. No. 28, Defs.' Obj. To the extent Plaintiff submits her Exhibit 1 for the validity of its contents, they are not the proper subject for judicial notice. *See, e.g.*, *Ramirez v. Medtronic, Inc*., 961 F. Supp. 2d 977, 984 (D. Ariz. 2013), *clarified on denial of reconsideration* (Oct. 24, 2013) (declining to take judicial notice of same exhibit as in this action). And in any event, the contents of this exhibit are not relevant to the issues presented in the Motion to Dismiss. *Id.*

in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

Class III medical devices are subjected to a "rigorous regime" of premarket approval ("PMA"). *Id.* To obtain PMA, a manufacturer must submit a multi-volume application outlining, among other things, all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation;" "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;" samples or device components required by the FDA; and a specimen of the proposed labeling. *Id.* at 318 (citing 21 U.S.C. § 360e(c)(1)). The FDA will spend an average of 1,200 hours per application, and will grant PMA "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" after weighing "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* (quoting 21 U.S.C. §§ 360e(d) & 360c(a)(2)(C)).

FDA approval of a Class III medical device does not end oversight -- "[o]nce 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." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). As a result, "[i]f the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). The manufacturer also has continuing reporting duties to the FDA of any new studies of the device or incidents of adverse affects, and "[t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Id.* at 319-20 (citing 21 U.S.C. § 360e(e)(1)).

2. FDA Approval of the Infuse Device

On July 2, 2002, the FDA approved the Infuse Device "to treat degenerative disk disease, but only by means on one specific procedure, namely, anterior lumbar interbody fusion ("ALIF") surgeries on a single level between L4 and S1." Doc. No. 1, Compl. ¶ 74; *see also* Doc. No. 15-1, Defs.' Ex. A.[2] The

[2] The FDA has subsequently approved forty-seven supplements to the PMA for the Infuse Device (neither party argues that these supplements address the use of the Infuse Device at issue in this action). *See* Doc. No. 15-1, Defs.' Ex. A.

Infuse Device is approved only for use with the ALIF procedure, and is not approved for use in cervical spine surgery, any lumber surgery performed through the back or side of the body, or any back surgeries that use Infuse Bone Graft Component without the LT-Cage. Doc. No. 1, Compl. ¶ 4.

The Infuse Device consists of (1) a metallic cylindrical spacer used to keep the two vertebrae in place and to direct the development of new bone growth (the "LT-Cage"); and (2) the Bone Graft Component, which includes a collagen sponge that acts as a carrier and scaffold for the active ingredient, rhBMP-2 protein, which promotes bone growth. *Id.* ¶ 72. The labeling for the Infuse Device, as approved by the FDA, provides: "These components must be used as a system. The Infuse® Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device Component." *Id.* ¶ 75; *see also* Doc. No. 15-7, Defs.' Ex. G at 1.

The labeling further warns against using the Infuse Device in spinal surgeries beyond what is approved by the FDA:

> The safety and effectiveness of the InFUSE Bone Graft component with other spinal implants, implanted at locations other than the lower lumbar spine, or used in surgical techniques other than anterior open or anterior laparoscopic approaches have not been established. When degenerative disc disease was treated by a posterior lumber interbody fusion procedure with

> cylindrical threaded cages, posterior bone formation was observed in some instances.

Doc. No. 15-7, Defs.' Ex. G at 4. An earlier Medtronic trial using rhBMP-2 in a posterior lumbar interbody fusion was halted in December 1999 when uncontrolled bone growth developed, *see* Doc. No. 1, Compl. ¶¶ 81-82, and the FDA Advisory Committee Panel voiced concerns regarding the potential for off-label use and admonished Medtronic to guard against procedures beyond the specific ALIF procedure approved by the FDA. *Id.* ¶¶ 84-86.

3. Off-Label Use of the Infuse Device

Although the Infuse Device is approved only for the ALIF procedure and by using both of its components together, Medtronic sells the Bone Graft Component separately from the LT-Cage, and physicians may use FDA-approved medical devices "in any way they see fit" so long as the patient is fully informed of the off-label use. *Id.* ¶¶ 76, 79. Off-label uses of the Infuse Device account for 85 to 90 percent of all spine surgeries using the Infuse Device, *id.* ¶ 133, even though these off-label uses have resulted in many more reported adverse events than on-label uses. *Id.* ¶ 110. Adverse effects include severe uncontrolled or ectopic bone growth, severe inflammatory reaction, adverse back and leg pain events, radiculits, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement. *Id.* ¶ 115.

The Complaint asserts that Medtronic, aware of the heightened risks of off-label uses, nonetheless engaged in an aggressive campaign to promote off-label uses of the Infuse Device. For example, Medtronic funded studies which failed to accurately describe the adverse side effects of off-label uses, *id.* ¶¶ 115, 143, and ensured that adverse side effects were under-reported by writing and editing the published medical literature. *Id.* ¶¶ 153(d), 189-90, 253-54. The Complaint further asserts that Medtronic (1) used its sales representatives to promote off-label uses by assisting physicians during surgery, distributing false and misleading medical literature that was written and/or edited by Medtronic, recommending dosages, and referring physicians to paid Medtronic physicians; (2) used its distributors to purchase gifts for physicians and facilities to induce them to use the Infuse Device off-label; (3) and used "opinion leaders" and other paid physician consultants to promote off-label uses of the Infuse Device at conferences, VIP meetings, demonstrations, and to serve as resources for other physicians seeking information on off-label uses. *Id.* ¶ 153.[3]

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[3] The Complaint further outlines that Medtronic has been criticized for its off-label promotion of the Infuse Device, and as a result has been investigated and the subject of two whistleblower actions. *See* Doc. No. 1, Compl. ¶¶ 125-27, 255-60, 284-98.

4. Plaintiff's Surgery

On April 17, 2008, Plaintiff underwent a transforaminal lumbar interbody fusion and posterolateral fusion at L5-S1 in Honolulu, Hawaii. *Id.* ¶ 299. To achieve this fusion, Plaintiff's surgeon used the Infuse Device in an off-label manner by using a transforaminal and posterolateral approach as well as by placing rhBMP-2 both inside and outside of non-LT-Cages. *Id.* The Complaint asserts that Plaintiff's surgeon was encouraged to engage in this off-label procedure by Medtronic's sales representatives and paid key opinion leaders. *Id.* ¶ 300. After the surgery, Plaintiff was diagnosed with heterotopic bone growth, secondary to rhBMP-2 at the right neuroforamen of the S1 nerve root, requiring extensive medical treatment and additional surgery, and causing significant injuries to Plaintiff. *Id.* ¶¶ 301-02.

B. Procedural History

Plaintiff's December 16, 2013 Complaint, containing 414 paragraphs, alleges eight causes of action titled (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; (5) Products Liability -- Negligence; (6) Breach of Express Warranty; (7) Breach of Hawaii's Consumer Protection Statutes; and (8) Punitive Damages.

On February 4, 2014, Defendants filed their Motion to Dismiss. Doc. No. 14. On March 13, 2014, the parties stipulated to dismissal of Count 7 of the Complaint for Breach of Hawaii's Consumer Protection Statutes. Doc. No. 21. On March 14, 2014, Plaintiff filed her Opposition, Doc. No. 22, and Defendants filed their Reply on March 24, 2014. Doc. Nos. 26, 28.[4] A hearing was held on April 7, 2014. At the April 7, 2014 hearing, Plaintiff's counsel conceded to dismissal of the "Strict Products Liability -- Misrepresentation" claim.

III. STANDARDS OF REVIEW

A. Rule 12(b)(6): Failure to State a Claim

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss a claim for "failure to state a claim upon which relief can be granted[.]"

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Weber v. Dep't of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir. 2008). This tenet -- that the court must accept as true all of the allegations contained in the complaint -- "is inapplicable to legal

[4] After filing the Reply, Defendants filed various Notices of Supplemental Authority. Doc. Nos. 29, 30.

conclusions." *Iqbal*, 556 U.S. at 678. Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555); *see also Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011) ("[A]llegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively.").

Rather, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). In other words, "the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr*, 652 F.3d at 1216. Factual allegations that only permit the court to infer "the mere possibility of misconduct" do not show that the pleader is entitled to relief as required by Rule 8. *Iqbal*, 556 U.S. at 679.

B. Federal Rule of Civil Procedure 9(b)

Federal Rule of Civil Procedure 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated

with particularity." "Rule 9(b) requires particularized allegations of the circumstances *constituting* fraud." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-48 (9th Cir. 1994) (en banc), *superseded on other grounds by* 15 U.S.C. § 78u-4.

In their pleadings, Plaintiffs must include the time, place, and nature of the alleged fraud; "mere conclusory allegations of fraud are insufficient" to satisfy this requirement. *Id*. at 1548 (citation and quotation signals omitted). However, "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b); *see also In re GlenFed, Inc. Sec. Litig*, 42 F.3d at 1547 ("We conclude that plaintiffs may aver scienter . . . simply by saying that scienter existed."); *Walling v. Beverly Enter.*, 476 F.2d 393, 397 (9th Cir. 1973) (Rule 9(b) "only requires the identification of the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations." (citations omitted)).

A motion to dismiss for failure to plead with particularity is the functional equivalent of a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003). In considering a motion to dismiss, the court is not deciding the issue of "whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support

claims." *Jackson v. Carey*, 353 F.3d 750, 755 (9th Cir. 2003) (*quoting Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

IV. ANALYSIS

Defendants argue that Plaintiff's state law claims are expressly preempted and/or impliedly preempted, and in any event fail to assert plausible claims for relief and/or comply with Rule 9(b). The court first outlines the basic principles of express and implied preemption, addresses the parties' preemption arguments that apply to all claims, and then addresses each of the claims in this action.

A. Express and Implied Preemption

1. Framework

The MDA outlines two different forms of preemption -- express preemption and implied preemption.

The express preemption provision of the MDA provides, 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); *see also* 21 C.F.R. § 808.1(d) (implementing regulation). The implied preemption statute, 21 U.S.C. § 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).

Three Supreme Court cases address MDA preemption -- *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), with *Lohr* and *Riegel* addressing express preemption, and *Buckman* addressing implied preemption.

In *Lohr*, the plaintiff asserted negligence claims after her pacemaker failed, alleging that the defendant failed to warn the "plaintiff or her physicians of the tendency of the pacemaker to fail, despite knowledge of other earlier failures." 518 U.S. at 481. *Lohr* held that these claims were not preempted -- "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties *when those duties parallel federal requirements*." *Id.* at 495 (emphasis added). *Lohr* reasoned that the general duty to inform users of potentially dangerous aspects of a product is "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention

regulations and zoning codes, or to use due care in the training and supervision of a work force." *Id.* at 501-02. Thus, the state-law duties underpinning the negligence claim were not preempted "because their generality leaves them outside the category of requirements that § 360(k) envisioned to be 'with respect to' specific devices such as pacemakers." *Id.* at 502. *See also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228-29 (9th Cir. 2013) (en banc) (discussing *Lohr*).

Riegel clarified the contours of express preemption. Unlike in *Lohr*, *Riegel* held that claims alleging that a catheter was defective when inflated to a higher pressure than recommended were preempted because they were based on violations of state law despite compliance with the MDA, and would therefore allow state law to impose a more stringent safety requirement than federal law. *Riegel*, 552 U.S. at 323. *Riegel* also cast some doubt on *Lohr's* emphasis on the generality of the state law claims as providing a basis for avoiding preemption -- *Riegel* pointed out that in *Lohr* "five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Id.* at 323-24 (citing *Lohr*, 518 U.S. at 512 (opinion of O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ.); *id*. at 503-05 (opinion of Breyer, J.)). *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), subsequently relied on this language to explain

that according to *Riegel*, "[i]t did not matter that the common-law claims involved general tort duties of care applicable to other products besides medical devices." *Id.* at 1118 (discussing *Lohr* and *Riegel*).

Riegel outlined that a state-law claim is expressly preempted by the MDA where (1) the FDA has established requirements applicable to the particular medical device at issue; and (2) the state common law claims seek to impose requirements that are "different from, or in addition to" the federal requirements, and that relate to safety and effectiveness. 552 U.S. at 321-22. In other words, any claim that a medical device "violated state tort law notwithstanding compliance with the relevant federal requirements" is expressly preempted. *Id*. at 330. The MDA does not, however, "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." *Id.* (citations omitted); *see also Stengel*, 704 F.3d at 1228 ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

Finally, *Buckman* determined that implied preemption applied where the plaintiffs asserted state-law negligence claims against a consulting company that allegedly made fraudulent misrepresentations to the FDA in the course of obtaining premarket approval for the manufacturer. 531 U.S. at 343, 348.

Although these "fraud-on-the-FDA" claims were framed in terms of negligence, *Buckman* distinguished these claims from those alleged in *Lohr*:

> Notwithstanding the fact that [*Lohr*] did not squarely address the question of implied pre-emption, it is clear that the [*Lohr*] claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S. at 481, 116 S. Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although [*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.

Id. at 352-53. Where the claims are premised solely on violations of the FDCA or MDA, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. Thus, to avoid implied preemption, a cause of action must rely on traditional state tort law and not be based solely on a violation of federal law. *Id.* at 353.

Together, express preemption and implied preemption 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*)." *Id.* (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig*., 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis in both)). Thus, to avoid preemption, a plaintiff must assert a state-law claim that is premised on a violation of law, but that is not based solely on such violation.

2. The Parties' General Preemption Arguments

This court is hardly the first to address preemption as applied to off-label use of Infuse Device -- the allegations in the Complaint mirror those asserted in other actions, and numerous courts have already addressed the issues presented in the parties' briefing. The caselaw provides fertile ground for both parties' arguments -- courts have taken differing views in applying *Lohr*, *Buckman*, and *Riegel* to determine whether a plaintiff's claims for off-label use of the Infuse Device are preempted. Although most of the preemption arguments are best addressed in terms of particular claims, the court first addresses those arguments raising more general questions as to whether claims based on off-label promotion of a medical device can be preempted.

a. First step of Riegel

Riegel's first step in applying express preemption is to determine whether the FDA has established requirements applicable to the Infuse Device.

This step appears to be plainly met -- the Infuse Device is a Class III medical device approved by the FDA. Plaintiff nonetheless argues that this step is not met in this case because the only "requirements" the FDA established were for the Infuse Device when both components are used in a single-level ALIF procedure, and the FDA established no requirements where only a component of the Infuse Device is used and in an off-label manner. *See* Doc. No. 22, Pl.'s Opp'n at 23-24.

Plaintiff fails to cite any authority that supports this proposition,[5] and courts have uniformly found that using the Infuse Device off-label does not prevent a finding of *Riegel's* first step that the FDA has established requirements applicable to the Infuse Device. *See, e.g.*, *Schouest v. Medtronic, Inc*., 2014 WL 1213243, at *5 (S.D. Tex. Mar. 24, 2014) (stating that courts "uniformly agree that the PMA process imposes requirements on the Infuse device"). And courts have rejected Plaintiff's argument given the broad language of § 360k(a) providing that preemption applies "with respect to a device," as opposed to a particular *use* of the device. For example, *Houston v. Medtronic, Inc*., 957 F. Supp. 2d 1166 (C.D. Cal. 2013) ("*Houston I*"), held that given this broad language, "even though Plaintiff

[5] Although Plaintiff cites to *Ramirez v. Medtronic*, 961 F. Supp. 2d 977 (D. Ariz. 2013), *Ramirez* determined that express preemption did not apply based on other grounds (addressed below). Indeed, *Ramirez* specifically found that "[b]ecause the FDA regulates Infuse for at least some purposes, Ramirez's claims regarding Infuse are subject to potential preemption under § 360k." *Id.* at 987.

was not implanted with the Infuse Device in an approved manner, her state claims are oriented 'with respect to' the off-label promotion and use of a device that is covered by federal requirements." *Id.* at 1176.[6] *Houston v. Medtronic, Inc.*, 2014 WL 1364455 (C.D. Cal. Apr. 2, 2014) ("*Houston II*"), further explained that "[b]ecause Infuse passed Class III premarket approval, federal requirements apply to Infuse even if it is later used in an off-label manner." *See id.* at *4. The court finds this reasoning persuasive -- even though off-label use of only a component of the Infuse Device is at issue, the FDA approval applies "with respect to" the Infuse Device generally and therefore such approval includes its components. Plaintiff's claims meet the first step of *Riegel*.

[6] *See also, e.g., Hawkins v. Medtronic, Inc*., 2014 WL 346622, at *6 (E.D. Cal. Jan. 30, 2014) (explaining that "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)."); *Eidson v. Medtronic, Inc.*, 2013 WL 5533081, at *8 (N.D. Cal. Oct. 3, 2013) (rejecting same argument and collecting cases for the proposition that "the preemption analysis should not be applied differently to the component parts of a medical device and the medical device that received PMA"); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013) (determining that first prong of *Riegel* analysis was met even though only one component of Infuse Device was used because the "preemption analysis is not applied differently to the component parts of a medical device and the medical device itself that has received premarket approval"); *see also Bass v. Stryker Corp*., 669 F.3d 501 (5th Cir. 2012) (affirming that PMA granted for a medical device also established specific federal requirements applicable to a component of the medical device at issue); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779-80 (D. Minn. 2009) (holding that components of a PMA-approved device "work together as a single medical device" and thus "it makes no sense . . . to pick apart the components of a medical device and apply different preemption analyses to different components"); *Duggan v. Medtronic, Inc*., 840 F. Supp. 2d 466, 471 (D. Mass. 2012) ("Once premarket approval is granted, all claims relating to all components of the device are preempted.").

b. Second step of Riegel

The second step of *Riegel* requires the court to determine whether the state-law claims seek to impose requirements that are "different from, or in addition to" the federal requirements. In theory, the federal "requirements" should be easy enough to determine -- they are defined by the MDA, FDCA, and the implementing regulations. But courts have struggled in addressing state-law claims asserting injuries from off-label uses, and in particular whether there are federal requirements directed to off-label promotion that allow such claims to survive express preemption. Defendants cite cases outside this Circuit to argue that there is no "federal law that expressly prohibits off-label promotion," Doc. No. 26, Defs.' Reply at 11, while Plaintiff argues that this court should follow *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013), *clarified on denial of reconsideration* (Oct. 24, 2013), which took a more policy-based approach to hold any claim based on off-label promotion and/or use is not expressly preempted.[7]

[7] Without citing any specific holding, Plaintiffs also argue that the court should generally follow *Alton Medtronic, Inc*., --- F. Supp. 2d ----, 2013 WL 4786381 (D. Or. Sept. 6, 2013). *See* Doc. No. 22, Pl.'s Opp'n at 20. *Alton* determined that the plaintiff's claims were not expressly preempted by largely relying on *Lohr's* recognition that a claim escapes preemption where is it "premised on conduct that contravenes state-law duties of such generality as not to present any risk of interference with the federal medical-device regulatory scheme." 2013 WL 4786381, at *24. As explained above, this state law "generality" theory has been called into question by subsequent caselaw. *See Riegel*, 522 U.S. at 323-24 stressing that in *Lohr*, "five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical (continued...)

See Doc. No. 22, Pl.'s Opp'n at 20. The court rejects both parties' arguments and joins the majority of courts in this Circuit which have determined that the FDCA prohibits off-label promotion such that a state-law claim for off-label promotion survives express preemption.

i. Off-label promotion of the Infuse Device

Contrary to Defendants' argument, there are ample "requirements" in both the FDCA and its regulations establishing that off-label promotion is prohibited. In particular, the FDCA makes unlawful "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. §§ 331(a), 333. The FDCA defines that an article may be "misbranded" where "the labeling *or advertising* is misleading," and such finding is determined by considering, among other things, "representations made or suggested by statement, word, design, device, or any combination thereof." 21 U.S.C. § 321(n) (emphasis added). Thus, the FDCA prohibits a manufacturer from engaging in misleading

[7](...continued)
device"); *Perez*, 711 F.3d at 1118 (explaining that in *Riegel*, "[i]t did not matter that the common-law claims involved general tort duties of care applicable to other products besides medical devices"). The court is not aware of any other court in this circuit to have relied on the generality of the state-law duties at issue as a basis for rejecting express preemption, and declines to do so here.

advertising regarding Class III medical devices, because such advertising is a form of misbranding.

The FDCA regulations further define that a manufacturer cannot engage in advertising off-label uses. In particular, the FDCA regulations provide that "[a] device may not be manufactured, packaged, stored, labeled, distributed, *or advertised* in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80 (emphasis added). The PMA approval letter for the Infuse Device provides that the Infuse Device "is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1," and the "Bone Graft/LT-Cage devices are to be implanted via an anterior open or an anterior laparscopic approach." Doc. No. 15-2, Defs.' Ex. B. The approved labeling for the Infuse Device reiterates these indications and further stresses that the Bone Growth Component and LT Cage must be used as a system. *See* Doc. No. 15-7, Defs.' Ex. G.

In sum, 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. Given these

federal "requirements," the court finds that a claim based on off-label promotion survives express preemption. *See*, *e.g.*, *Eidson*, 2013 WL 5533081, at *10 n.4 (adopting similar reasoning); *Houston I*, 957 F. Supp. 2d at 1179 ("[F]ederal law forbids device manufacturers to promote any off-label uses, and certainly prohibits false or misleading off-label promotion."); *In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1287 (C.D. Cal. 2008) ("Under FDA regulations, drug manufacturers are prohibited from promoting off-label uses of prescription drugs."); *see also Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815 (9th Cir. 2010) ("[T]he marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA.").

ii. *Ramirez*

Plaintiff argues that the court should follow *Ramirez*, which read *Riegel* narrowly to determine that the second step for express preemption -- that the state common law claims seek to impose requirements that are "different from, or in addition to" the federal requirements -- is not met where the Infuse Device is used in an off-label manner. *Ramirez* started with the premise that "the FDA reviewed Infuse's safety and effectiveness only for the uses Medtronic specified in its PMA application, and the regulations are premised on that review." 961 F. Supp. 2d at 988. Although *Ramirez* recognized that off-label promotion of a

medical device is prohibited by the FDA (which would presumably provide a basis to assert a parallel state law claim), *id.* at 990, *Ramirez* reasoned that when a manufacturer engages in off-label promotion, "there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection." *Id.* at 991. In other words, Medtronic's off-label promotion "departed the realm of federal regulation and returned to the area of traditional state law remedies." *Id.* Thus, according to *Ramirez*, claims based on off-label use are not preempted because "[s]ection 360k protects manufacturers who adhere to the federal regulatory program, but it does not expand federal law into heretofore unregulated areas" like off-label promotion. *Id*. at 996.

Ramirez has been rejected -- for good reason -- by numerous courts.[8] The court finds particularly persuasive *Houston II*, which explains that *Ramirez* "is not consistent with the text of § 360(k), the scope of federal requirements imposed on Class III devices, or Ninth Circuit precedent." *Houston II*, 2014 WL 1364455, at *5. *Houston II* explains that off-label promotion is in fact regulated by the FDA -- § 360(k) applies broadly to "devices" as opposed to particular "uses" of such devices, and the MDA prohibits off-label promotion through its statutes and

[8] *See, e.g.*, *Scovil v. Medtronic, Inc*., 2014 WL 502923, at *10 n.12 (D. Ariz. Feb. 7, 2014); *Alton v. Medtronic, Inc*., 2013 WL 4786381, at *22 (D. Or. Sept. 6, 2013); *Schouest*, 2014 WL 1213243, at *5; *Coleman v. Medtronic, Inc*., 167 Cal. Rptr. 3d 300, 314 (Cal. App. 2014), *as modified* (Feb. 3, 2014), *review filed* (Mar. 10, 2014).

regulations prohibiting misbranded devices. *Id.* In other words, contrary to *Ramirez*' suggestion that manufacturers could "escape[] federal requirements by promoting an off-label use, a device manufacturer's off-label promotion [is] itself [] subject to specific MDA provisions." *Id.*

Houston II further explains that *Ramirez* is contrary to *Perez*, which "implicitly held that the MDA imposes requirements on devices that are used in off-label manners, even when the off-label uses are promoted by the device manufacturer." *Id.* (citing *Perez*, 711 F.3d at 1112-13, 1118-19). *Houston II* reasons that *Perez*, in addressing claims for off-label use and promotion, held that "the [medical device at issue] was subject to device-specific requirements" as a result of the MDA's premarket approval regulations. *Id.* (citing *Perez*, 711 F.3d at 1118).

The court agrees with this reasoning and rejects *Ramirez* to the extent it suggests that the preemption analysis does not apply to claims based on off-label promotion. The court now addresses each of Plaintiff's claims.

B. Plaintiff's Claims

1. Fraudulent Misrepresentation and Fraud in the Inducement (Count I)

The Complaint asserts that Medtronic fraudulently concealed and misrepresented (1) the health and safety hazards associated with off-label use of

the Infuse Device, (2) its practice of promoting and marketing the practice of using the Infuse Device in off-label manners, and (3) information about the known comparative risks and benefits of the off-label use of the Infuse Device and other alternate treatments. Doc. No. 1, Compl. ¶ 309. The Complaint further asserts that Medtronic intended to cause Plaintiff and Plaintiff's physicians to rely on Defendants' concealment and misrepresentations, that Plaintiff and Plaintiff's physicians were justified in relying on Medtronic's actions and would not have decided to use the Infuse Device in an off-label manner had they known of the safety risks, and that Plaintiff was injured as a result of Medtronic's fraudulent concealment and/or misrepresentations. *Id.* ¶¶ 307-15.

Reading these allegations in context of the entire Complaint, this claim appears to be based on misrepresentations and omissions (1) contained in the labeling of the Infuse Device, and/or (2) made in promoting off-label use of the Infuse Device. *See, e.g.*, *Eidson*, 2013 WL 5533081, at *9 (addressing similar allegations). As to the first theory -- that Defendants made misrepresentations and omissions in the labeling of the Infuse Device -- the court joins the majority of courts finding that such claims are expressly preempted. As *Caplinger v. Medtronic*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013), explains: "allowing [such a] claim to proceed would permit a finding that defendants were required to alter the

Infuse Device's warning and label and to provide additional warnings above and beyond those on the Infuse Device's label and accompanying the device -- a label and warnings that were specifically approved by the FDA as part of the PMA process." *Id.* at 1219. Such claim is expressly preempted because it seeks to impose different and/or additional written warnings and labeling beyond those approved by the FDA through the PMA process. *Id.*; *See Eidson*, 2013 WL 5533081, at *9; *Hawkins v. Medtronic, Inc*., 2014 WL 346622, at *9 (E.D. Cal. Jan. 30, 2014); *Kashani-Matts v. Medtronic, Inc*., 2013 WL 6147032, at *5 (C.D. Cal. Nov. 22, 2013); *see also Perez*, 711 F.3d at 1118.

As to the second theory -- that Defendants made misrepresentations and omissions in promoting off-label use of the Infuse Device -- the court joins those courts determining that such claim is neither expressly preempted nor impliedly preempted. *Houston I* explains:

> Leaving aside Rule 9(b) for the moment, the Court concludes that Plaintiff's fraud-based claims could escape both express and implied preemption. As an initial matter, Plaintiff's fraudulent advertising claims are not impliedly preempted under *Buckman* because they are moored in traditional state common law that exists independently from the FDCA. With respect to express preemption, Plaintiff's claim that Defendants made fraudulent statements to promote off-label uses of the Infuse Device lies "parallel" to federal requirements. First, although federal law permits Defendants to engage in advertising beyond the subject device's label, it

> requires that such representations not be false or misleading. Second, federal regulations prohibit device manufacturers from promoting off-label uses of medical devices. In sum, federal law forbids device manufacturers to promote any off-label uses, and certainly prohibits false or misleading off-label promotion. Against this backdrop, Plaintiff's fraud claims are parallel or "genuinely equivalent" to federal law because there is no likelihood that Defendants could be held liable under state law without having violated the federal law.

957 F. Supp. 2d at 1179-80 (citations omitted); *See also Blankenship v. Medtronic*, 2014 WL 1226491, at *10 (E.D. Mo. March 25, 2014) (adopting reasoning in *Houston I*); *Scovil v. Medtronic*, 2014 WL 502923, at *10 (D. Ariz. Feb. 7, 2014); *Eidson*, 2013 WL 5533081, at *10; *Hawkins*, 2014 WL 346622, at *11-12; *cf. Kashani-Matts*, 2013 WL 6147032, at *5 (explaining that "[t]o the extent that Plaintiff's fraud claims are based on alleged misrepresentations and omissions Medtronic made while promoting and marketing the Infuse Device, such claims could survive preemption," but dismissing claim where the pleading "fails to identify what specific misrepresentations or omissions form the basis for Plaintiff's claims"). The court finds this reasoning persuasive and adopts it here. Plaintiff's fraud claim based on promotion and/or marketing is not preempted.

In opposition, Defendants argue that Plaintiff's claims, to the extent based on a concealment theory (as opposed to an affirmative misrepresentation),

are preempted pursuant to *Perez*. In *Perez*, the plaintiff alleged that the manufacturer was aware that its device was being used in an off-label manner and should have affirmatively provided certain warnings about the off-label nature of that use. 711 F.3d at 1112-13. *Perez* determined this claim was expressly preempted because the plaintiff "effectively seeks to write in a new provision to the FDCA: that physicians and medical device companies must affirmatively tell patients when medical devices have not been approved for a certain use." *Id.* at 1118-19. *Perez* further determined this claim was impliedly preempted because the plaintiff "cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval." *Id.* at 1119. The plaintiff had alleged no injury, and as a result, she could not "bring suit solely for failure to disclose lack of FDA approval." *Id.* at 1120.

Perez is distinguishable. As described above, although claims directed to the labeling and warnings provided with the Infuse Device are expressly preempted (as in *Perez*), this claim also alleges that Defendants concealed information that they were required to disclose to the FDA (*e.g.*, the studies of adverse effects of off-label testing). As a result, Plaintiff's fraud-by-omission claim is not expressly preempted. Nor does this claim exist solely as a result of the FDCA; rather, this claim is based on traditional state common law that Defendants

had a duty to disclose information regarding adverse side effects of their product, and instead concealed this information from individuals who they knew or had reason to know would use the Infuse Device in an off-label manner.

The court finds, however, that Plaintiff's claim must still be dismissed for failure to comply with the particularity requirements of Rule 9(b). The Complaint certainly details (in voluminous fashion) the numerous alleged omissions and misrepresentations made by Defendants, including, for example, that they (1) funded studies which failed to accurately describe the adverse side effects of off-label uses, Doc. No. 1, Compl. ¶¶ 115, 143, (2) ensured that adverse side effects were under-reported by writing and editing the published medical literature, *id.* ¶¶ 153(d), 189-90, 253-54; and (3) used "opinion leaders" and other paid physician consultants to promote off-label uses of the Infuse Device at conferences, VIP meetings, demonstrations, and to serve as resources for other physicians seeking information on off-label uses. *Id.* ¶ 153. The Complaint identifies the dates of many of these alleged bad acts, and describes as much as possible the individuals responsible for these actions. *Id.* ¶¶ 112-283.

Missing from the Complaint, however, is the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians -- *i.e.*, that Plaintiff and Plaintiff's physicians relied on these misrepresentations. *See Shoppe*

v. Gucci Am., Inc., 94 Haw. 368, 386, 14 P.3d 1049, 1067 (2000) (explaining that a fraud claim requires a plaintiff to establish that "(1) false representations were made by defendants, (2) with knowledge of their falsity (or without knowledge of their truth or falsity), (3) in contemplation of plaintiff's reliance upon these false representations, and (4) plaintiff did rely upon them." (internal quotation marks and citations omitted)). Although the Complaint generally asserts that "Plaintiff and Plaintiff's physicians . . . [relied] on MEDTRONIC's concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to use Infuse® in an off-label manner," *id.* ¶ 313, the Complaint fails to identify what particular misrepresentations and/or concealments were made to Plaintiff and Plaintiff's physicians (as opposed to the medical field generally), who made those particular representations and/or omissions, and when those events occurred.

The court therefore GRANTS Defendants' Motion to Dismiss Count I, with leave for Plaintiff to assert a fraud claim based on Defendants' off-label promotion of the Infuse Device.

2. Strict Products Liability -- Failure to Warn (Count II)

The Complaint alleges that Medtronic failed to warn Plaintiff and her physicians of the dangers of using the Infuse Device in an off-label manner. Doc.

No. 1, Compl. ¶ 322. In particular, the Complaint alleges that "the warnings accompanying the Infuse® product did not adequately warn Plaintiff and Plaintiff's physicians . . . of the dangers associated with Infuse® when used without an LT-Cage™ and placed transforaminally or posterolaterally in a lumbar spine fusion surgery," and "failed to provide the level of information that an ordinary physician or consumer would expect." *Id.* ¶¶ 326-27. The Complaint further asserts that Medtronic "failed to provide adequate warnings, instructions, guidelines, or admonitions to members of the consuming public, including Plaintiff and Plaintiff's physicians, of the problems with off-label use of Infuse® which Defendants knew" or should have known. *Id.* ¶ 328.

This claim is expressly preempted. As *Houston I* explains, "for Plaintiff to prevail, a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in an off-label manner. While FDA regulations permit Defendants to issue such post-sale warnings, those regulations do not require such warnings." 957 F. Supp. 2d at 1177 (citations omitted); *see also Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (noting that "any attempt to predicate the Stengels' claim on an alleged state law duty to warn doctors

directly would have been expressly preempted" where the FDA did not require such warnings). In other words, Plaintiff's claim seeks to impose on Defendants a duty to provide warnings beyond those already outlined by the FDA, which *Riegel* prohibits. *See also Scovil*, 2014 WL 502923, at *10; *Hawkins*, 2014 WL 346622, at *15.

In opposition, Plaintiff argues that this claim runs parallel to the federal prohibition on off-label promotion because Medtronic unilaterally changed the "intended use" of the Infuse Device by promoting off-label uses and then failed to notify the FDA or provide any warnings for this new "intended use." Doc. No. 22, Pl.'s Opp'n at 28; *see also* 21 C.F.R. § 801.4 (explaining that an "intended use" of a medical device refers "to the objective intent of the persons legally responsible for the labeling of devices"). Plaintiff asserts that Defendants' actions therefore simultaneously violate the FDA's prohibition of misbranding devices, 21 U.S.C. § 352, and the state law duty to warn. *Id.*

This argument was adopted in *Alton*, which determined that a failure to warn claim was not preempted to the extent the claim was parallel to the requirement that Medtronic update its label where it has adopted a new intended use for the Infuse Device. *See* 2013 WL 4786381, at *27. This court, however, finds *Hawkins* more persuasive, which rejects such argument:

> 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.

2014 WL 346622, at *15. Stated differently, "[a]lthough 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." *Id.* at *16. As a result, requiring a manufacturer engaging in prohibited off-label promotion to at the same time provide directions and warnings for such off-label uses would include an additional requirement not provided by the FDCA.

Plaintiff also argues that this failure to warn claim runs parallel to Medtronic's violations of the FDCA's requirements to submit reports of adverse events and include those events in its labeling. Doc. No. 22, Pl.'s Opp'n at 28. The court recognizes that *Eidson* found that a failure to warn claim based on this theory would not be expressly preempted. 2013 WL 5533081, at *12-13. Whether Plaintiff *can* assert such claim, however, is not before the court -- as alleged in the Complaint, Plaintiff's failure to warn claim asserts that Defendants failed to

provide warnings to Plaintiff and Plaintiff's physicians, not the FDA, and Plaintiffs provide no facts or argument tying the failure to submit reports of adverse events to the FDA to a failure to warn Plaintiff and Plaintiff's physicians.

The court therefore GRANTS Defendants' Motion to Dismiss Count II of the Complaint, with leave for Plaintiff to amend as to a failure to warn theory based on Defendants' alleged failure to submit reports of adverse events to the FDA. The parties have not briefed, and the court expresses no opinion at this time, as to whether such claim would survive a preemption analysis.

3. Strict Products Liability -- Design Defect (Count III)

The Complaint alleges that the Infuse Device "was defectively designed because the design was unsafe when used in the manner promoted by Defendants and/or in a manner reasonably foreseeable by Defendants," and that the Infuse Device "failed to perform as safely as an ordinary consumer would expect when used, as it was promoted by the MEDTRONIC Defendants for use off-label without an LT-Cage™ and placement transforaminally and posterolaterally in lumber spine fusion surgeries." Doc. No. 1, Compl. ¶ 340. The Complaint further asserts that the Infuse Device "was defectively designed because the risks of danger in the design outweigh the benefits of the design," and that an alternative

design would have resulted or avoided the foreseeable risks of harm. *Id.* ¶¶ 341-43.

The court joins the majority of courts finding that this claim is expressly preempted -- to prevail on this claim, Plaintiffs would need to establish that the Infuse Device should have been designed in a manner different than that approved by the FDA. *See, e.g.*, *Houston I*, 957 F. Supp. 2d at 1177 (finding claim expressly preempted because it "attacks the 'the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device'" (quoting *Bryant v. Medtronic*, Inc., 623 F.3d 1200, 1206 (8th Cir. 2010)); *Schouest*, 2014 WL 1213243, at *11 ("Schouest's strict liability claim based on design and manufacturing defect theories is also clearly barred by *Riegel* because it would require the Infuse device to be designed or manufactured differently than the FDA authorized.").

The court therefore GRANTS Defendants' Motion to Dismiss Count III of the Complaint without leave to amend.

4. Products Liability -- Negligence (Count V)

The Complaint alleges that 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 the Infuse Device, and to disclose their

practices of improperly promoting to physicians off-label uses of the Infuse Device. Doc. No. 1, Compl. ¶ 369. The Complaint further alleges that Defendants breached this duty by (1) improperly promoting the Infuse Device for off-label uses; (2) failing to warn of the dangers of off-label uses; (3) failing to comply with federal law and regulations; and (4) failing to exercise reasonable care to prevent the Infuse Device from creating an unreasonable risk of harm to Plaintiff and other consumers. *Id.* ¶ 372.

As explained above, this claim is expressly preempted to the extent it is based on a failure to provide warnings on the labeling of the Infuse Device, or based on any negligence in the design and manufacture of the Infuse Device, because such claim would seek to impose labeling and design requirements different, or in addition to, the FDA requirements. *See also Hawkins*, 2014 WL 346622, at *19; *Eidson*, 2013 WL 5533081, at *15. This claim also fails to the extent it vaguely asserts that Defendants violated federal law -- Plaintiff does not specify what federal laws were violated such that the court cannot determine whether Plaintiff is asserting a parallel state law claim. Plaintiff "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." *Eidson*, 2013 WL 5533081, at *16 (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)); *see also Houston I*, 957 F. Supp.

2d at 1178 (finding negligence claim based on "some other violation of federal law" expressly preempted because the "[p]laintiff must allege facts to substantiate that Defendants violated a particular federal requirement applicable to the subject device"); *Hawkins*, 2014 WL 346622, at *19 (same).

To the extent this claim is based on the theory that Defendants were negligent in promoting the Infuse Device for off-label uses, it is not expressly preempted, but is barred by implied preemption. As described above for Plaintiff's fraud and strict liability/misrepresentation claims, this claim is not expressly preempted because it is based on a violation of federal law banning off-label promotion. *See also Hawkins*, 2014 WL 346622, at *19; *Eidson*, 2013 WL 5533081, at *15. This claim is, however, impliedly preempted pursuant to *Buckman* -- Defendants' duty (as an element of the negligence claim) to abstain from off-label promotion exists solely by virtue of the federal prohibition of off-label promotion and finds no independent source from traditional state law. *See Hawkins*, 2014 WL 346622, at *19 (determining that negligence claim is impliedly preempted because "Defendants' conduct is only allegedly 'negligent' because the FDCA bans off-label promotion.'" (quoting *Eidson*, 2013 WL 5533081, at *15)); *Houston I*, 957 F. Supp. 2d at 1178 ("Permitting this claim to proceed would essentially allow a private litigant to attempt to enforce the FDCA."). In other

words, absent the FDCA's prohibition of off-label promotion, Defendants have no duty based on state law to abstain from promoting the Infuse Device for off-label purposes.[9]

Finally, to the extent Plaintiff bases this claim on Defendant's failure to report adverse events to the FDA, the court recognizes that some courts have found that such a claim may survive preemption. *See, e.g.*, *Eidson*, 2013 WL 5533081, at *15; *Schouest*, 2014 WL 1213243, at *10. As explained above, however, the Complaint asserts that Defendants failed to provide warnings to Plaintiff and Plaintiff's physicians, not the FDA, and Plaintiffs provide no facts or argument tying the failure to submit reports of adverse events to the FDA to a failure to warn Plaintiff and Plaintiff's physicians. Without such allegations, the court cannot determine whether Plaintiff can indeed assert a state law claim that runs parallel to any federal law.

The court therefore GRANTS Defendants' Motion to Dismiss Count V of the Complaint, with leave for Plaintiff to assert a negligence claim based on the failure to report adverse events to the FDA.

[9] This claim appears to be based on off-label promotion generally; the Complaint does not assert that Defendants were negligent in making a particular statement to Plaintiff or Plaintiff's physicians.

5. Breach of Express Warranty (Count VI)

Count VI alleges that Defendants "utilized journal articles, advertising media, sales representatives/consultants and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse® Bone Graft and expressly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in lumbar fusion procedures, were safe and effective." Doc. No. 1, Compl. ¶ 339. Plaintiff further alleges that "her treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of off-label use of Infuse®, but such off-label uses, including uses in lumbar fusion procedures, were not effective, safe, and proper for the use as warranted in that Infuse® was dangerous when put to these promoted uses." *Id.* ¶ 384.

The court finds that this claim survives both express preemption and implied preemption. As *Houston I* persuasively explains, express preemption does not apply:

> [F]ederal law already prohibits false or misleading off-label promotion. Therefore, to the extent that Plaintiff seeks to impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff is not imposing any requirement different from or additional to what federal law already requires. In other words, to avoid state law liability on this claim, Defendants need only to refrain from making misleading

> warranties, which adds no burden beyond what federal law already imposes.

957 F. Supp. 2d at 1180-81; *see also Schouest*, 2014 WL 1213243, at *11 ("Schouest's express warranty claim can survive to the extent she seeks to recover based on false warranties that Medtronic voluntarily and falsely made beyond the federally approved warning because '[f]ederal law already requires [Medtronic] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.'" (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 788 (D. Minn. 2009)). Nor does implied preemption apply -- a breach of warranty claim is well-recognized under Hawaii law and requires a plaintiff to establish "that (1) Defendants made an affirmation of fact or promise regarding the product, (2) that statement became part of the basis of the bargain, and (3) the product failed to perform according to the statement." *Stoebner Motors, Inc. v. Automobili Lamborghini S.P.A.*, 459 F. Supp. 2d 1028, 1035 (D. Haw. 2006) (quoting *Neilsen v. Am. Honda Motor Co.*, 92 Haw. 180, 190-91, 989 P.2d 264, 274-75 (Haw. App. 1999)). This liability for a breach of warranty exists independently of the FDCA -- Plaintiff's breach of warranty claim would exist even absent federal law.

The court finds, however, that Plaintiff has failed to allege sufficient facts to assert a plausible breach of warranty claim. Although the Complaint

details Medtronic's alleged representations regarding off-label use of the Infuse Device, it fails to include any facts suggesting that those representations became the "basis of the bargain" for Plaintiff and her physicians. Indeed, the Complaint fails to describe what specific warranties Medtronic made to Plaintiff and/or her physicians. *See also Houston I*, 957 F. Supp. 2d at 1181; *Schouest*, 2014 WL 1213243, at *11.

The court therefore GRANTS Defendant's Motion to Dismiss Count VI, with leave for Plaintiff to assert a breach of warranty claim based on alleged false warranties made beyond the federally-approved labeling of the Infuse Device.

6. Punitive Damages (Count VIII)

Defendants argue that Plaintiff's punitive damages claim must be dismissed where none of the other claims asserts a plausible basis for relief. Doc. No. 14-1, Defs.' Mot. at 31-32. The court agrees -- punitive damages is a remedy, and not a substantive claim for relief. Punitive damages may be realleged in an amended complaint as a remedy sought by Plaintiff.

V. CONCLUSION

For the foregoing reasons, the court GRANTS Defendants' Motion to Dismiss, with leave for Plaintiff to amend (1) Count I to assert a fraud claim based on Defendants' off-label promotion; (2) Count II to assert a strict liability -- failure

to warn claim based on Defendants' alleged failure to submit reports of adverse events to the FDA; (3) Count V to assert a negligence claim based on the failure to report adverse events to the FDA; and (4) Count VI to assert a breach of warranty claim based on alleged false warranties made beyond the federally-approved labeling of the Infuse Device.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, April 10, 2014.

/s/ J. Michael Seabright
J. Michael Seabright
United States District Judge