UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:13-cv-01679-SVW-SHx	Date	April 2, 2014
Title	Jennifer Houston v. Medtronic, Inc. et al.		

Present: The Honorable	STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz	N/A
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: IN CHAMBERS ORDER Re: Defendants' Motion to Dismiss Plaintiff's First Amended Complaint [39]

I. INTRODUCTION

On March 8, 2013, plaintiff Jennifer Houston commenced this action against defendants Medtronic Inc., and Medtronic Sofamor Danek USA. (Dkt. 1). Houston alleges that she suffered harmful side effects after undergoing a lumbar back surgery in which her surgeon used Medtronic's product, the Infuse device, in an off-label manner. (FAC ¶¶ 250-51). She asserts a variety of state law claims against Medtronic, asserting that the Infuse device was defective, that Medtronic failed to warn about Infuse's risks, and that Medtronic misleadingly promoted off-label uses of Infuse.

On July 30, 2013, the Court granted Medtronic's motion to dismiss Houston's original complaint, with leave to amend. (Dkt. 36). The Court held that some of Houston's claims were expressly preempted, other claims were impliedly preempted, and that Houston had failed to plead sufficient facts to state plausible claims for those causes of action that were not preempted. (Dkt. 36); Houston v. Medtronic, Inc., — F. Supp. 2d ----, 2013 WL 3927839 (C.D. Cal. 2013). Now before the Court is Medtronic's motion to dismiss Houston's First Amendment Complaint. (Dkt. 39). For the reasons stated below, the Court GRANTS in part and DENIES in part Medtronic's motion.

II. FACTUAL BACKGROUND

The Court reviewed the background of Houston's case at length in its July 30, 2013 order. (Dkt. 36). Here, the Court briefly reviews the relevant facts: Infuse is used in spinal fusion surgeries. (FAC ¶¶ 24-36). Its active ingredient, a liquid rhBMP-2 protein, stimulates bone growth near diseased

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vertebrae. (Id.). In 2002, the FDA approved Infuse as a Class III medical device. (Id.). The FDA's approval was limited to the use of Infuse in anterior (front) abdomen implants, and instances where Infuse was used in conjunction with the "LT-Cage", a component that keeps Infuse's liquid protein in place. (Id.).

In October 2008, Houston underwent lumbar fusion surgery with the Infuse device. (FAC ¶¶ 250-68). Her physician performed the surgery using Infuse in an off-label manner; the device was implanted by means of a posterior, rather than anterior approach, and an LT-Cage was not used. (Id.).[1] After her surgery, Houston developed uncontrolled bone growth, nerve compression, and radiculitis near where the Infuse Device was implanted. (Id.).

Houston alleges that the Infuse device, as it was used in her surgery, was defective. She also alleges that Medtronic failed to warn her or her physician of the true incidence of side effects associated with the off-label use of Infuse. Finally, she contends that Medtronic engaged in a lengthy campaign of off-label promotion of Infuse, while minimizing and/or concealing the increased safety risks associated with the device.

III. JUDICIAL STANDARD

A complaint must "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 697 (2009). When a party fails to state a claim upon which relief can be granted, a defendant may move to dismiss that claim. Fed. R. Civ. P. 12(b)(6). In deciding a 12(b)(6) motion, the Court must assume that allegations in the challenged complaint are true and construe the complaint in the light most favorable to the non-moving party. Cahill v. Liberty Mut. Ins. Co., 80 F.3d 336, 337-38 (9th Cir. 1996).
The court must then address whether the well-pleaded facts, and reasonable inferences therefrom, give rise to a plausible claim for relief. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). The

[1] Physicians are permitted to use Class III devices in off-label manners. See 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349-50 (2001) ("[O]ff-label usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." (internal quotation marks omitted)).

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court may not dismiss "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Russell v. Landrieu, 621 F.2d 1037, 1039 (9th Cir. 1980).

IV. DISCUSSION

Houston advances six claims against Medtronic related to the injuries she suffered from her physician's use of the Infuse device: (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; and (6) breach of express warranty.

In the Court's July 30, 2013 order dismissing Houston's original complaint, the Court made the following holdings related to these claims:

- Claim (2), Houston's strict products liability—failure to warn claim, was expressly preempted by 21 U.S.C. § 360k(a) of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act of 1938 ("FDCA") to the extent that the claim was premised on Medtronic's failure to provide Houston or her physician with post-sale warnings, or warnings in addition to those required by MDA labeling requirements.

- Claim (3), Houston's strict products liability—design defect claim was expressly preempted by § 360k(a).

- Claim (5), Houston's products liability—negligence claim, was expressly preempted under § 360k(a) to the extent it relied on Medtronic's failure to warn Houston or her physician, and impliedly preempted by 21 U.S.C. § 337(a) and Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) to the extent it relied exclusively on non-compliance with FDA promotion regulations.

- Claims (1), (4) and (6), Houston's fraudulent misrepresentation and fraudulent inducement claim; strict products liability—misrepresentation claim; and breach of express warranty claim were not expressly or impliedly preempted. However, Houston's complaint did not include sufficient allegations to support these claims.

(Dkt. 36); Houston, 2013 WL 3927839, at *7-8.

On August 29, 2013, Houston filed an amended complaint. (Dkt. 39). Her opposition to

Medtronic's motion to dismiss her amended complaint proceeds as follows: First, Houston asks the Court to reconsider its express preemption holding for her (2), (3), and (5) claims in light of Ramirez v. Medtronic, Inc., --- F. Supp.2d ----, 2013 WL 4446913 (D. Ariz. Aug. 21, 2013). In Ramirez, the district court held that identical claims were not expressly preempted in a similar factual scenario.[2] Second, even if her failure-to-warn claim premised on Medtronic's failure to provide additional warnings to Houston or her physician is preempted, Houston contends that her amended complaint includes a failure-to-warn claim that escapes preemption, premised on Medtronic's failure to warn the FDA about Infuse's adverse effects. Finally, Houston asserts that her amended complaint includes additional factual allegations to support plausible claims for fraudulent misrepresentation and fraudulent inducement, strict products liability—misrepresentation, and breach of an express warranty. The Court considers Houston's arguments in turn below.

A. Claims Expressly Preempted Under 21 U.S.C. § 360k(a)

1. The Court's Prior Holdings

The Court previously held that Houston's strict products liability—failure to warn claim, negligent failure to warn claim, and strict products liability—design defect claims were expressly preempted by 21 U.S.C. § 360k(a) of the MDA. (Dkt. 36); Houston, 2013 WL 3927839, at *7-8. Under § 360k(a),

> [N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device; and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

[2] A district court has "the inherent power to reconsider and modify its interlocutory orders prior to the entry of judgment." Smith v. Massachusetts, 543 U.S. 462 (2005) (internal quotation marks and citations omitted). In the instant case, the Court chooses to reexamine its express preemption holding in light of Ramirez in order to clarify its holding.

The Supreme Court has applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). First, a court must determine whether the MDA has established federal "requirements" applicable to the particular medical device at issue. Id. at 321. If the MDA does establish federal requirements, a court must then determine whether the state law claims are based on state requirements that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. Id. at 321-22.

As a Class III FDA approved device, the Court previously held that Infuse was clearly subject to MDA "requirements." (Dkt. 36); Houston, 2013 WL 3927839, at *6-7. Class III devices are subjected to a rigorous premarket approval regime, and the Supreme Court clearly stated in Riegel that "[p]remarket approval . . . imposes 'requirements' under the MDA." See 552 U.S. at 323.

This Court also held in its previous order that Houston's strict liability and negligent failure to warn claims imposed requirements "different from, or in addition to" the MDA's requirements, and thus violated the second prong of Riegel. Houston's failure to warn claims were based on allegations that Medtronic failed to warn Houston or her physician of the incidence of certain side effects related to the off-label use of Infuse. For Houston to prevail on these claims, the Court held that she would have to establish that Medtronic was either required to include warnings beyond those on the FDA-approved label for Infuse, or that Medtronic was obligated to issue post-sale warnings about the potential adverse effects from using Infuse in an off-label manner. These additional warnings are not required by the MDA and thus would impose state requirements that are "different from, or in addition to" federal requirements. See Houston, 2013 WL 3927839, at *7-9 (citing Stengel v. Medtronic, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring)). Similarly, the Court held that Houston's design defect claim attacked the risk/benefit analysis that led the FDA to approve the device, and as such also imposed requirements that were "different from, or in addition to" the MDA's requirements. Houston, 2013 WL 3927839, at *8.

2. Houston's Request for Reconsideration

Houston now requests that the Court reconsider its holding under the first prong of Riegel: that federal requirements apply to the Infuse device that was used in her surgery. Specifically, Houston contends that because Medtronic *promoted off-label* uses of Infuse, Medtronic in effect avoided Class III premarket approval for certain unapproved uses of Infuse, and should not be able to shield itself from state tort law by relying on MDA requirements that it intentionally avoided. This was the holding of Ramirez v. Medtronic, Inc., --- F. Supp.2d ----, 2013 WL 4446913 (D. Ariz. Aug. 21, 2013).

Putting aside for the moment whether promoting a device impacts the preemption analysis under § 360k(a), as a preliminary matter the Court notes that Class III safety review imposes federal "requirements" on Infuse, even when the device is used in an off-label manner. While Class III safety review focuses primarily on the intended uses of a device, rather than off-label uses, § 360k(a) applies if federal requirements are applicable "to the *device*," rather than a particular *use* of a device. See § 360k(a)(1) ("No State may establish . . . any requirement which is different from, or in addition to, any requirement applicable under this chapter to the *device*."). Because Infuse passed Class III premarket approval, federal requirements apply to Infuse even if it is later used in an off-label manner. Supreme Court and Ninth Circuit precedent support this holding. See Riegel, 552 U.S. at 318, 320, 322-33 (holding that Class III premarket approval imposed federal requirements on a catheter, even though the catheter was used in an off-label manner); Perez v. Nidek Co., 711 F.3d 1109, 1112, 1118 (9th Cir. 2013) (holding that Class III premarket approval imposed requirements on a device that was used in an off-label manner).

The district court in Ramirez did not contend otherwise. However, it held that even though the MDA imposes "requirements" on Class III devices that are used in off-label manners, the MDA does not impose requirements on off-label uses that are actively *promoted* by device companies. Ramirez, 2013 WL 4446913, at *9-10. In Ramirez, the court addressed allegations similar to the instant case: Medtronic had allegedly promoted the off-label use of Infuse, and the plaintiff suffered serious side effects after Infuse was used in an off-label manner during her spinal surgery. Id. at *1. The Ramirez court noted that under the MDA physicians are free to use Class III devices in off-label manners. See 21 U.S.C. § 396. But that when a manufacturer promotes an off-label use they are in effect circumventing Class III premarket approval for the off-label uses. Id. The court reasoned that by avoiding premarket approval, a manufacturer escapes safety review for particular uses of a device, and should not be permitted to avoid state tort liability by relying on FDA "requirements" that it intentionally avoided. Id. at *9-10. As a result, the Ramirez court held that none of the plaintiff's state law claims were expressly preempted by § 360k(a).

Houston asserts that this Court should follow Ramirez, and find that § 360k(a) does not apply where a manufacturer actually promotes off-label uses of a device. The Court finds, however, that the Ramirez holding is not consistent with the text of § 360k(a), the scope of federal requirements imposed on Class III devices, or Ninth Circuit precedent. First, as noted above, § 360k(a) applies when the FDA imposes requirements on a "*device*." The scope of the provision is not limited to particular "uses" of a device. See Riegel, 552 U.S. at 320-33; Perez, 711 F.3d at 1112, 1118. If § 360k(a) does not distinguish between uses of a device, it surely does not distinguish between whether a particular use of a device was promoted by the manufacturer. See Gavin v. Medtronic, Inc., No. 12-0851, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013) (holding that "nothing in § 360k(a) or Riegel suggests that

applicability of the preemption analysis depends on how the device is being *promoted* to be used" (emphasis added)); Hawkins v. Medtronic, Inc., No. 13-cv-0499 AWI SKOx, 2014 WL 346622, at *5-6 (E.D. Cal. Jan. 30, 2014) (holding that "premarket approval imposes federal requirements on the Infuse device regardless of off-label *promotion* or use" (emphasis added)); Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1218 (W.D. Okla. 2013) (same).

Further, even if Medtronic had to show that MDA requirements applied to a particular use of the device, there are multiple MDA requirements that apply to devices, even when they are used in an off-label manner and the off-label use is promoted by the manufacturer. For example, after premarket approval a device manufacturer is required to report to the FDA any information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). This reporting requirement applies regardless of how a device is used. The MDA also prohibits manufacturers from making changes in "design specifications, manufacturing processes, [or the] labeling" of devices without FDA approval, regardless of use. Riegel, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). And importantly, the MDA prohibits the very activity the Ramirez court focused on—off-label promotion. Off-label promotion amounts to misbranding, see Carson v. Depuy Spine, Inc., 365 Fed. App'x 812, 815 (9th Cir. 2010) (citing 21 U.S.C. § 331), and misbranding is subject to an extensive FDA enforcement scheme, providing for both civil and criminal penalties. See 21 U.S.C. § 333(a); Reeves v. AcroMed Corp., 44 F.3d 300, 307 (5th Cir. 1995). Thus, rather than escaping federal requirements by promoting an off-label use, a device manufacturer's off-label promotion itself is subject to specific MDA provisions. And like premarket approval, these requirements govern the safety of Class III.

Finally, the Ninth Circuit in Perez 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. See Perez v. Nidek Co., 711 F.3d 1109, 1112-13, 1118-19 (9th Cir. 2013). In Perez, the plaintiffs received LASIK eye surgery to correct their farsightedness. Id. at 1112. However, the device used was only FDA approved to correct nearsightedness. Id. The plaintiffs alleged that despite warnings from the FDA, their physicians, certain medical centers, and the manufacturer of the device "continued to sell, distribute, lease, use, service, and *market* the Lasers" with the capacity to perform off-label procedures. Id. at 1113 (emphasis added). Despite the fact that the device was used for an off-label purpose, and that the manufacturer had marketed the off-label use, the Ninth Circuit held that "the Laser was subject to device-specific requirements" under § 360k(a) as a result of the MDA's premarket approval regulations. Id. at 1118. Other district courts have also interpreted Perez to implicitly establish that MDA requirements apply to off-label uses of devices promoted by manufacturers. See, e.g., Alton v. Medtronic, Inc., — F. Supp.2d —, 2013 WL 4786381, at *22 (D. Ore. Sept. 6, 2013) (holding that Ramirez "cannot be reconciled with the Ninth Circuit's holding in Perez that claims arising

out of a manufacturer-promoted off-label application of a [MDA]-approved medical device were preempted under section 360k(a)").

In sum, given the text of § 360k(a), the fact that the MDA includes a number of requirements that clearly apply to even off-label device uses, and the Ninth Circuit's holding in Perez, the Court declines to follow the reasoning in Ramirez. Instead, the Court reaffirms its July 30, 2013 holding that Houston's strict products liability and negligent failure-to-warn claims are expressly preempted under § 360k(a) to the extent they rely on the theory that Medtronic failed to provide Houston or her physician with warnings in addition to those required by the MDA. Similarly, Houston's design defect claim remains expressly preempted.

B. Houston's New Claim: Failure to Warn the FDA Claim

Although Houston's claim that Medtronic failed to warn Houston or her physician is expressly preempted, her amended complaint includes a new failure-to-warn claim, alleging that Medtronic failed to warn the *FDA* of certain adverse events associated with the off-label use of Infuse. (FAC ¶¶ 134-36). Specifically, Houston contends that Medtronic knew that the off-label use of Infuse had caused death and serious injuries, but failed to report these adverse events to the FDA. She asserts that had Medtronic reported these adverse events to the FDA, the FDA would have issued warnings, and Houston's physician would have relied on these warnings and consequently not used Infuse in Houston's surgery.

The Ninth Circuit has held that such a claim for failure to warn the FDA may escape preemption. See Stengel v. Medtronic, Inc., 704 F.3d 1224, 1233-34 (9th Cir. 2013). Such a claim escapes express preemption under § 360k(a) because MDA regulations require device manufacturers to report to the FDA certain post-sale adverse events. Specifically, a manufacturer must report whenever a Class III device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred. See 21 C.F.R. § 803.50(a). Thus, a state law claim premised on a manufacturer's failure to warn the FDA does not impose state law requirements "different from, or in addition to" federal requirements.

However, a claim based on failure to warn the FDA must also escape implied preemption under 21 U.S.C. § 337(a). Under § 337(a), all claims to enforce MDA requirements must be brought by the Federal Government rather than by private litigants. Thus, the Supreme Court held in Buckman that for a claim premised on a violation of the MDA to survive implied preemption under § 337(a), the claim must also be moored in traditional state tort law. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); see also Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009) ("[T]he

conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the [MDA] had never been enacted.").

In Stengel, the Ninth Circuit held that a claim based on failure to warn the FDA escaped implied preemption (at least under Arizona law), because it was moored in the State's traditional negligence law. Stengel, 704 F.3d at 1232-33. Arizona negligence law imposes a duty on manufacturers "to warn of dangers which the [manufacturer] knows or should know are inherent in its use. This duty may be a continuing one applying to dangers the manufacturer discovers after sale." Id. (quoting Rodriguez v. Besser Co., 115 Ariz. 454 (Ariz. Ct. App. 1977)). And importantly, this duty can be satisfied by warning a third party, such as the FDA, if there is "reasonable assurance that the information will reach those whose safety depends on their having it." Id. (citation omitted).

The questions in the instant case are (1) is a claim based on failure to warn the FDA also moored in California tort law (as is the case under Arizona law); and if so, (2) does Houston plead sufficient facts to support such a claim. The Court concludes that the answer to both questions is yes.

Like Arizona law, California law also imposes a duty to warn on manufacturers. Under California law, a device manufacturer can be found strictly liable if it "[does] not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of distribution." Anderson v. Owens-Corning, 53 Cal.3d 987, 1002 (1991); see also Carlin v. Superior Court, 13 Cal. 4th 1104, 1110-12 (1996). And this duty can be satisfied by conveying warnings to a third party "[w]hen a manufacturer or distributor has no effective way to convey a product warning to the ultimate consumer." Persons v. Salomon N. Am., Inc., 217 Cal. App. 3d 168, 178 (1990). Such a claim is similar to the Arizona law which the Ninth Circuit discussed in Stengel. See Coleman v. Medtronic, Inc., 223 Cal. App. 4th 413, 428-29 (2014) (holding that as in Arizona, California imposes a state tort duty to warn on manufactures, which can require the manufacturer to warn a particular third-party if that is the only available method to warn doctors and consumers).

Houston's amended complaint also includes allegations that are sufficient to state a claim of failure to warn the FDA. The amended complaint alleges that from Infuse's premarket approval in 2002, until 2011, Medtronic systematically manipulated the medical literature on Infuse by paying substantial sums of money to surgeon "Opinion Leaders" who conducted studies and authored journal articles that favorably reported the benefits of using Infuse in spinal fusion surgeries, while concealing and downplaying known dangers and risks. (FAC ¶¶ 51-52). Some of these studies and journal articles directly examined the posterior use of Infuse, and reported no adverse incidents related to this use.

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(FAC ¶¶ 91-103). However, in 2011 a physician and professor at Stanford University, Dr. Carragee, reviewed Medtronic's sponsored studies, as well as related FDA documents, and discovered specific instances of unreported adverse events. (FAC ¶¶ 107, 136). Dr. Carragee also estimated that the actual incidence rate of adverse events related to Infuse likely ranged from 10 percent to 50 percent, depending on the approach used in the spinal surgery rather than the near zero number cited by Medtronic. (FAC ¶ 136). At even the low end of this spectrum, Houston argues that Medtronic has significantly underreported to the FDA adverse events related to the off-label use of Infuse, based on the total number of off-label Infuse procedures performed during the same time period and the total number of adverse events actually reported to the FDA. (See FAC ¶¶ 135-36 ("Approximately 844 adverse events involving Infuse in spinal surgeries have been reported to the FDA from July 2, 2002 to August 31, 2011;" while the use of "genetically modified bone growth protein in inpatient procedures increased "from 23,900 to 103,194" per year between October 2002 and December 2007; and "spinal fusion surgeries accounted for 92.8 percent of these procedures," the "vast majority of which were off-label uses")).

At the pleading stage, these allegations are sufficient to support a claim of failure to warn the FDA. Cf. Coleman, 223 Cal. App. 4th at 420, 428-29 (holding in a case with near identical facts that the plaintiff there adequately stated a claim for failure to warn the FDA where the plaintiff alleged that Medtronic had failed to report known adverse events associated with Infuse to the FDA). As the litigation proceeds, however, Houston will ultimately have to prove that if Medtronic had properly reported these adverse events to the FDA as required under federal law, that this information would have reached Houston's doctors in time to prevent her injuries. See Stengel, 704 F.3d at 1234 ("Because [the plaintiffs] predicate their claim on Medtronic's reporting duty to the FDA, as they must to avoid express preemption, the [plaintiffs] face a causation hurdle that would not otherwise exist."); Hughes v. Boston Scientific Corp., 631 F.3d 762, 770 & n.5, 776 (5th Cir. 2011) (examining causation evidence on a motion for summary judgment involving a claim of failure to warn the FDA, but ultimately remanding the matter for determination by the district court). Medtronic's motion to dismiss Houston's claim for failure to warn the FDA though is DENIED.[3]

[3] Medtronic argues that because Infuse's label already warned that bone overgrowth was a potential adverse side effect, that Houston cannot state a claim for failure to warn because the FDA (and physicians who rely on FDA warnings) were already aware of this risk. (Mot., at 14). The Court rejects this argument. At issue is not Medtronic's failure to warn of a particular side effect, but rather Medtronic's alleged failure to warn of the incidence rate of certain serious side effects. It is reasonable to conclude on a motion to dismiss that an increased incidence of a dangerous side effect would be the type of risk that would require warnings by a manufacturer under California's failure to warn law.

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C. Fraud-Based Claims—Fraudulent Misrepresentation, Fraud in the Inducement, Strict Products Liability (Misrepresentation)

Houston also alleges that Medtronic fraudulently and intentionally misrepresented the health and safety hazards associated with the off-label use of Infuse to Houston and her physician. (Id. ¶ 272). In its prior order, the Court held that Houston's fraud-based claims escaped both express or implied preemption.[4] See Houston, 2013 WL 3927839, at *10-11. However, the Court also held that Houston had failed to plead her fraud claims with the particularity required by Federal Rule of Civil Procedure 9(b). The Court reasoned that Houston had only "alleged generally that Defendants misrepresented the safety of the Infuse Device to physicians and patients. But the Complaint fail[ed] to alleged the specific contents of those representations, when and where Defendants allegedly made them, and to whom they were made." Id. at *11.

Houston's amended complaint has added the following specific allegations. As early as 1999, Houston alleges that Medtronic had knowledge that the use of Infuse in posterior fusion procedures led to uncontrolled bone growth. (FAC ¶ 144). That year, Medtronic sponsored a study that it halted prematurely after early results demonstrated an approximately 70 percent rate of bone overgrowth. (Id.). Despite this knowledge, over the course of the next decade Medtronic paid consultant physicians to perform studies, write journal articles, and give presentations that promoted Infuse, while concealing or downplaying the risks of bone overgrowth associated with the off-label use of Infuse. (FAC ¶¶ 51-52). Houston contends that her physician attended some of these presentations and read certain articles authored by Medtronic consultants where Infuse was promoted but the risks of bone overgrowth and other serious side effects were concealed. Specifically, Houston states that:

[4] Houston also includes a cause of action for strict products liability—misrepresentation. (FAC ¶¶ 86-88). In California, strict liability has been imposed for three types of product defects: "manufacturing defects, design defects, and warning defects." O'Neil v. Crane Co., 53 Cal. 4th 335, 347 (2012) (citation and internal quotation marks omitted). None of these claims is based on misrepresentations, and Houston has not provided any authority to support a strict products liability claim based on misrepresentations. Other courts have also questioned the existence of such a claim. See Harris v. Medtronic, Inc., No. RG12-636341, 2013 WL 4011624, at *6 (Cal. Super. Aug. 1, 2013) ("The court knows of no state law claim such as that captioned as [strict liability–misrepresentation]."). Given the lack of authority for such a claim, the Court GRANTS Medtronic's motion to dismiss on this claim.

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> (1) Prior to conducting [Houston's] 2008 off-label Infuse surgery, Dr. Perri [Houston's physician] listened to Medtronic consultant, Dr. Boden, speak several times regarding Infuse at Cedar Sinai Hospital in Los Angeles. During these presentations, Dr. Boden did not mention anything regarding bone overgrowth or radiculitis;
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> (2) Prior to conducting [Houston's] 2008 off-label Infuse surgery, Dr. Perri also believes that he read articles by Medtronic consultants Dr. Burkus and Dr. Haid endorsing the use of Infuse as safe and effective, while failing to warn of the true risks of bone overgrowth and inflammatory reactions; and
>
> (3) Dr. Perri attended several professional society meetings, including meetings of the North American Spine Society, in which the off-label use of Infuse was discussed without warnings regarding the problems associated with bone morphogenic, radiculitis or other problems. Dr. Boden, Dr. Burkus or Dr. Zdeblick presented at one or more of these NASS meetings.

(FAC ¶¶ 251-54). Houston contends that her doctor relied on these representations about Infuse, and that had her doctor known what he knows now regarding the true rate of uncontrolled bone growth resulting from the off-label use of Infuse, and other associated risks, he would have used another bone graft material in Houston's surgery, or would have warned Houston of the specific dangers. (Id. ¶ 254).

The Court finds these specific allegations sufficient to satisfy Rule 9(b)'s particularity requirement. Houston's second and third allegations support claims of fraudulent misrepresentation and fraud in the inducement.[5] In addition to the allegations cited above, the complaint includes allegations that Dr. Burkus and Dr. Haid received significant consulting fees from Medtronic between 2000 and 2008. (FAC, Ex. C). Additionally, the complaint cites to multiple articles written by Drs. Burkus and Haid during the relevant time period that were supportive of off-label uses of Infuse, including the

[5] The first of Houston's specific allegations fails because it broadly states that her doctor listened to Medtronic consultant Dr. Boden speak "regarding Infuse." However, there are no allegations that Dr. Boden spoke about off-label uses of Infuse. And it is only the fraudulent promotion of off-label uses of an FDA approved device that escapes preemption. See Houston, 2013 WL 3927839, at *10 (stating that fraud claims escape express preemption if they related to the misleading promotion of off-label uses because federal regulations prohibit device manufactures from false or misleading off-label promotion, and thus the fraud claim is parallel to federal requirements under § 360k(a)).

posterior use of Infuse. (Id. ¶¶ 79, 93-94). These articles allegedly did not warn of the risks of bone overgrowth and inflammatory reactions, even though the complaint includes allegations that Medtronic knew of these adverse effects at the time the articles were published. (Id. ¶¶ 79, 93-94).

Houston's allegations that either Dr. Boden, Dr. Burkus, or Dr. Zdeblick discussed off-label uses of Infuse at North American Spine Society meetings, without disclosing various adverse side effects, also supports Houston's fraud claims. Like Dr. Burkus, the complaint includes allegations that Drs. Boden and Zdeblick received substantial consulting fees from Medtronic from 2000 to 2008. By discussing off-label uses of Infuse without revealing certain dangerous side effects, Medtronic's consulting physicians may have both fraudulently misrepresented the safety of off-label uses of Infuse, and may have violated the FDA's prohibition against off-label promotion.

Together, Houston's factual allegations are sufficient to support cognizable fraudulent misrepresentation and fraudulent inducement claims under Federal Rule of Civil Procedure 12(b)(6). Further, Houston's amended allegations identify the "time, place, and specific content of the false representations as well as the identifies of the parties to the misrepresentations," as required under Federal Rule of Civil Procedure 9(b). Edwards v. Marin Park, Inc., 356 F.3d 1058, 1066 (9th Cir. 2004). Therfore, Medtronic's motion to dismiss these claims is DENIED.

D. Breach of Express Warranty Claim

Houston's final claim is for breach of an express warranty. Her allegations here are nearly identical to those supporting her fraud claims. Namely, she alleges that through its paid physician-consultants, Medtronic endorsed the use of Infuse as safe and effective, while failing to warn of the true risks of bone overgrowth and inflammatory reactions. (FAC ¶¶ 251-54). She also alleges that these affirmative misrepresentations formed the basis of her physician's decision to use Infuse in an off-label manner.

In its prior order, the Court held that Houston's breach of an express warranty claim was neither expressly nor impliedly preempted. Houston, 2013 WL 3927839, at *10-11; see also Alton v. Medtronic, Inc., — F. Supp. 2d ----, 2013 WL 4786381, at *30 (D. Or. Sept. 6, 2013) (holding that a similar breach of express warranty claim against Medtronic was neither expressly nor impliedly preempted). However, the Court dismissed Houston's express warranty claim because her original complaint did not allege sufficient facts for the claim to survive dismissal under Federal Rule of Civil Procedure 8. Houston, at *11.

Under California law, to state a claim for breach of an express warranty, Houston must alleged

that Medtronic: (1) made an affirmation of fact or promise, or provided a description of its goods; (2) that the promise or description formed part of the basis of the bargain; (3) that the express warranty was breached; and (4) that the breach caused injury to the plaintiff." Keegan v. Am. Honda Motor Co., 838 F. Supp. 2d 929, 949 (C.D. Cal. 2012) (internal quotation marks omitted); see also Cal. Com. Code § 2313.

Regarding the first element—an affirmation of fact or promise—a seller does not need to use formal words such as "warrant" or "guarantee," or have a specific intention to make a warranty. See Cal. Com. Code § 2313(2). Rather, "[c]ourts have liberally construed affirmations of quality made by sellers in favor of injured consumers." Keith v. Buchanan, 173 Cal. App. 3d 13, 21 (1985) (citing Hauter v. Zogarts, 14 Cal. 3d 104, 112 (1975)). In fact, "[i]t has even been suggested that in an age of consumerism all seller's statements, except the most blatant sales pitch, may give rise to an express warranty." Id. (citation and internal quotation marks omitted).

As noted in the Court's discussion of Houston's fraud claim above, Houston's amended complaint alleges that prior to her surgery, her physician, Dr. Perri, believes he read articles by Medtronic consultants Dr. Burkus and Dr. Haid endorsing the use of Infuse as safe and effective, while failing to warn of the true risks of bone overgrowth and inflammatory reactions. (FAC ¶¶ 251-54). Drs. Burkus and Haid's statements amount to affirmations as to the quality of the Infuse device, and California courts have held that similar affirmations that products are effective and free from defects have amounted to express warranties. See, e.g., Rose v. Chrysler Motors Corp., 212 Cal. App 2d 755, 758 (1963) (holding that an auto dealer's statement that "each new motor vehicle [would be] free from defects in material and workmanship" amounted to an express warranty).

Further, although the affirmations pled by Houston were made by Drs. Burkus and Haid rather than directly by Medtronic, the amended complaint includes allegations that these two physicians acted as Medtronic's agents. It is established that a principal may be bound by warranties made by his agent. See Alvarez v. Felker Mfg. Co., 230 Cal. App. 2d 987, 997 (1964) (citing Cal. Civ. Code § 2323)). Here, the complaint alleges that Drs. Burkus and Haid received significant consulting fees from Medtronic during the time period when the articles were written. (FAC, Ex. C). Further, the complaint alleges that Medtronic employees actually edited draft manuscripts of the articles in order to include comments supporting the use of Infuse in an off-label posterior approach. (FAC ¶¶ 93-94). For purposes of a motion to dismiss, these allegations are sufficient to establish that Drs. Burkus and Haid's statements amounted to an affirmation of fact made by Medtronic.

Houston's amended complaint also adequately alleges that her physician relied on Medtronic's affirmations by deciding to use Infuse in Houston's surgery. The amended complaint also adequately

alleges that the Infuse device did not perform as warranted, and that Houston was injured as a result of the breach. Together, these allegations support a breach of an express warranty claim that satisfies Rule 8. Therefore, Medtronic's motion to dismiss Houston's breach of express warranty claim is DENIED.[6]

V. CONCLUSION

For the reasons stated above, the Court reaffirms its prior holding that Houston's strict products liability and negligent failure to warn claims, premised on Medtronic's failure to provide Houston or her physician with warnings in addition to those required by the MDA, are expressly preempted. Houston's design defect claim is similarly expressly preempted. However, the Court concludes that Houston's amended complaint adequately alleges a claim for failure to warn based on Medtronic's failure to warn the FDA of certain adverse incidents. The Court also concludes that Houston's amended complaint adequately states claims for fraudulent misrepresentation and fraudulent inducement, as well as breach of an express warranty. As a result, Medtronic's motion is GRANTED in part and DENIED in part.

[6] To support a breach of express warranty claim, a buyer must generally plead that notice of the alleged breach was provided to the seller within a reasonable time after discovery of the breach. See Alvarez v. Chevron Corp., 656 F.3d 925, 932 (9th Cir. 2011). However, this rule does not apply where a consumer does not purchase a product directly from the manufacturer, but rather from a third-party. See Keegan, 838 F. Supp. 2d at 949-51 (holding that a consumer who purchases goods through a dealer, rather than directly from a manufacturer, is not required to give the manufacturer notice before filing suit); Sanders v. Apple, Inc., 672 F. Supp. 2d 978 (N.D. Cal. 2009) ("[A]t least until [the plaintiff] has had legal advice it will not occur to him to give notice to one with whom he has had no dealings."). Here, Houston's amended complaint states that she purchased Infuse from her healthcare provider rather than directly from Medtronic. (FAC ¶ 350). As such, she does not need to show that she provided notice of the alleged breach to Medtronic.

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