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FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Cristina Ramirez, Plaintiff, v. Medtronic Incorporated, a Minnesota corporation; and Medtronic Sofamor Danek USA Incorporated, Defendants.	No. CV-13-00512-PHX-GMS **ORDER**

Defendants Medtronic Inc. and Medtronic Sofamor Danek USA Inc. move to dismiss the Complaint filed by Plaintiff Cristina Ramirez. (Doc. 24.) The briefing on that Motion has also produced a Motion to Strike. (Doc. 37.) The Court held oral argument on August 13, 2013. For reasons discussed below, the Court grants in part and denies in part both Motions.

BACKGROUND[1]

Ramirez has brought several tort claims against Medtronic that challenge how Medtronic has produced and promoted its Infuse device. Ramirez underwent a lumbar fusion procedure to alleviate her back pain on March 2, 2009. (Doc. 1 ¶ 246.) Her surgeon, Dr. Wang, used Infuse, a bio-engineered liquid bone graft substitute, during the procedure. (*Id.* ¶¶ 1, 246.)

Infuse is one of Medtronic's products. (*Id.* ¶ 2.) Its purpose is to "foster fusion

[1] The Court takes as true the allegations contained in Ramirez's Complaint at this stage of the litigation. *Smith v. Jackson*, 84 F.3d 1213, 1217 (9th Cir. 1996)

between the vertebrae without implanting a patient's own bone or cadaver bone between the vertebrae in the spine, obviating the necessity of harvesting bone from the patient's own hip or risking rejection of cadaver bone." (*Id.*) The Infuse device consists of three components: (1) a metallic spinal fusion cage (the LT-Cage), (2) the bone graft substitute, which consists of liquid rhBMP-2, and (3) a spongy carrier or scaffold for the protein that resides in the fusion cage. (*Id.* ¶ 56.) During surgery, the doctor attaches the fusion cage to the diseased spinal region to stabilize the area, soaks the collagen sponge with the rhBMP-2, and applies it to the diseased region. (*Id.* ¶¶ 57–59.) In time, the sponge dissolves while the rhBMP-2 stimulates the spinal cells to grow new bone in place of the diseased area. (*Id.*)

Infuse is a Class III device under the Medical Device Amendments of 1976 (MDA), which updated the Food, Drug, and Cosmetic Act of 1938 (FDCA). (*Id.* ¶ 64.) A Class III device poses the highest level of risk and consequently receives the highest level of regulatory scrutiny before marketing. *See* 21 U.S.C. §§ 360c, 360e. A major aspect of that scrutiny is the Premarket Approval Application (PMA) that a manufacturer of a Class III device must submit to the FDA prior to distribution and marketing. *See id.* Among other things, the application must specify the "intended use" of the product. *Id.* § 360e(c)(2)(A)(iv). The FDA then analyzes studies and data to measure the safety and effectiveness of the device for that use. *See id.* § 360e(c).

Medtronic submitted a PMA to the FDA for Infuse on January 12, 2001. (Doc. 1 ¶ 70.) Infuse was intended for a single-level anterior lumbar interbody fusion performed with all three components in a specific spinal region. (*Id.* ¶¶ 72–74.) On July 2, 2002, the FDA approved Infuse to treat degenerative disc disease in the procedure specified by Medtronic. (*Id.* ¶ 73.) With the exception of two non-spinal uses not relevant here, the FDA has never approved any other use of Infuse, including the posterior approach used on Ramirez.[2] (*Id.* ¶¶ 72, 76–77.) The FDA was concerned about the potential adverse

[2] There have been subsequent PMA Supplements approved by the FDA that allow use of different cage configurations with the Infuse bone graft product. (Doc. 25-1, Exs. D–F.) The Court has taken judicial notice of these subsequent FDA actions.

effects, such as bone overgrowth, that occurred when Infuse was used in posterior procedures. (*Id.* ¶¶ 79–86.) Despite the limited nature of the FDA's approval of Infuse, physicians are free to use FDA-approved medical devices either "on-label" (in accordance with the FDA approval) or "off-label" (for other uses). (*Id.* ¶ 78.)

Off-label uses of Infuse by physicians made up close to 90% of the $800 million dollars in revenue that Infuse generated in 2011. (*Id.* ¶¶ 126–30.) Medtronic allegedly promoted those off-label uses through its sales personnel and by establishing consulting/royalty agreements with physicians who advocated off-label uses to fellow surgeons. (*Id.* ¶¶ 131–32, 136–40, 166–71.) Yet Medtronic knew a number of studies showed that off-label use of Infuse often produced severe side effects. (*Id.* ¶¶ 87–125.) Medtronic allegedly tried to conceal these risks by funding biased studies and articles by opinion leaders in key medical journals that showed a lower incidence of off-label adverse effects. (*Id.* ¶¶ 113, 131–32, 136–40, 172–214.) In addition, Medtronic allegedly failed to report certain adverse events to the FDA. (*Id.* ¶¶ 28, 112, 147–49, 166q, 224, 228, 245, 355.)

These activities (or lack thereof) have produced litigation with private parties and the federal government, and also resulted in significant media coverage in outlets like the *Wall Street Journal* and *New York Times*. (*Id.* ¶¶ 133, 151–71, 178–97.) A few Senators have initiated investigations into Medtronic's promotion and marketing of Infuse. (*Id.* ¶¶ 215–31, 239–42.) In addition, a recent issue of *The Spine Journal* focused on the "serious patient safety and ethical concerns related to the use of rhBMP-2 (Infuse®) in the spine." (*Id.* ¶ 232.) These articles questioned the accuracy of previous Medtronic-sponsored trials and studies that showed a far lower incidence of adverse effects. (*Id.* ¶¶ 232–38.)

The Complaint alleges that Medtronic's aggressive promotion of Infuse's off-label uses and obfuscation of the true risks has led to widespread acceptance among spinal surgeons of such uses. (*Id.* ¶¶ 245.) These surgeons—including Dr. Wang, who was a

paid Medtronic consultant[3] and used Infuse in an off-label manner with Ramirez—were unaware of the serious risks that off-label use entailed. (*Id.* ¶ 252.) When Dr. Wang performed Ramirez's lumbar fusion operation, he used only the rhBMP-2 bone graft component of the Infuse device and employed a posterior approach. (*Id.* ¶ 246.) Dr. Wang did not use the other components of the Infuse device. (*Id.*) At the time of the procedure, Ramirez and her doctor were unaware of the true incidence of certain side effects that appear when Infuse was used in this manner. (*Id.* ¶ 247.)

Ramirez began experiencing severe pain after surgery and later discovered that she had developed uncontrolled bone growth in the area where her surgeon had implanted Infuse. (*Id.* ¶¶ 248–49.) The pain she experienced resulted from nerve impingement caused by the bone overgrowth. (*Id.*) Her pain has significantly disrupted her life. (*Id.* ¶¶ 254–56.)

Ramirez brought suit against Medtronic on March 11, 2013, on the basis of diversity jurisdiction. She asserts six causes of action against Medtronic that arise out of state law: fraudulent misrepresentation/fraud in the inducement, failure to warn, defective design, misrepresentation, negligence, and breach of express warranty. (*Id.* ¶¶ 264–349.) Medtronic has moved to dismiss the Complaint in its entirety. (Doc. 24.) Both Parties have submitted lengthy Requests for Judicial Notice. (Docs. 25, 32.) Medtronic has moved to strike Ramirez's Request. (Doc. 37.) The Court has also reviewed the several Notices of Supplemental Authority filed by the Parties. (Docs. 40, 41, 43, 45, 46.)

DISCUSSION

I. MOTION TO STRIKE

Ramirez filed a Request for Judicial Notice that contains letters from four Senators, a Senate committee staff report, the FDA-approved label for Infuse, and a series of court decisions. (Doc. 32.) The general rule that a court may not consider evidence or

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[3] Ramirez's counsel represented to the Court at oral argument that Dr. Wang was a paid Medtronic consultant, and Medtronic's counsel acknowledged as much. The Court therefore assumes the truth of this representation for purposes of deciding the Motion to Dismiss.

documents beyond the complaint in the context of a Rule 12(b)(6) Motion to Dismiss has two exceptions. First, a court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading," *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005) (alteration in original). Second, a court may take judicial notice of "matters of public record outside the pleadings." *Mack v. S. Bay Beer Distribs., Inc.*, 798 F.2d 1279, 1282 (9th Cir. 1986), *overruled on other grounds by Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991). While matters of public record, such as prior court proceedings, are proper subjects of judicial notice, a court may take notice only of the authenticity and existence of a particular order or pleading, not the veracity or validity of its contents. *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001); *Walker v. Woodford*, 454 F. Supp. 2d 1007, 1022 (S.D. Cal. 2006), *aff'd in part*, 393 Fed. App'x 513 (9th Cir. 2010). Even when considering a public record, however, judicial notice is limited to those facts that are "not subject to reasonable dispute." Fed. R. Evid. 201(b).

Thus the Court can properly take judicial notice of the FDA-approved label. It is a matter of public record and there is no dispute between the Parties about its authenticity. *See In re Epogen & Aranesp Off-Label-Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (taking judicial notice of FDA label). As to the remaining documents, the Court takes judicial notice of their authenticity and existence, but not the validity of the allegations or claims made therein. To the extent Ramirez seeks to rely on those documents for the validity of their contents, the Motion to Strike is granted. In any event, the contents of those documents have no bearing on the issues presented by Medtronic's Motion. Moreover, any relevant content alleged through Ramirez's Complaint is taken as true at this point in the litigation, including allegations that Medtronic promoted Infuse for off-label use. The Motion consequently has little bearing on the decision here.

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II. MOTION TO DISMISS

A. Legal Standard

Rule 12(b)(6) is designed to "test the legal sufficiency of a claim." *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). To survive dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must contain more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action"; it must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While "a complaint need not contain detailed factual allegations . . . it must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1022 (9th Cir. 2008) (quoting *Twombly*, 550 U.S. at 570). "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." *Twombly*, 550 U.S. at 555. Accordingly, a plaintiff must do more than employ "labels," "conclusions," or a "formulaic recitation of the elements of a cause of action." *Id.*

When analyzing a complaint for failure to state a claim under Rule 12(b)(6), "[a]ll allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." *Smith v. Jackson*, 84 F.3d 1213, 1217 (9th Cir. 1996). However, legal conclusions couched as factual allegations are not given a presumption of truthfulness, and "conclusory allegations of law and unwarranted inferences are not sufficient to defeat a motion to dismiss." *Pareto v. FDIC*, 139 F.3d 696, 699 (9th Cir. 1998).

When a plaintiff like Ramirez alleges that a defendant has committed fraud, the Federal Rules deploy a heightened pleading requirement: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged

generally." Fed. R. Civ. P. 9(b). Under this rule, a plaintiff "must state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Schreiber Distrib. Co. v. ServWell Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986); *see also Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) ("Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." (internal quotation marks omitted)).

"To allege fraud with particularity, a [claimant] . . . must set forth an explanation as to why the statement or omission complained of was false or misleading." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994). Falsity may be established through inconsistent contemporaneous statements or information made by or available to the defendants, but such statements are not required. *Id.* at 1549. Falsity may also be established through allegations of circumstantial evidence. *See Cooper v. Pickett*, 137 F.3d 616, 625 (9th Cir. 1997).

B. The MDA and Preemption

Medtronic's chief contention is that Ramirez's common law claims are preempted under the MDA and FDCA.

1. The MDA

Prior to the passage of the MDA, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008). But in 1976, Congress responded to concerns about device safety "with passage of the [MDA], which swept back some state obligations and imposed a regime of detailed federal oversight." *Id.* The MDA created three categories of devices, each to receive an increasing level of regulatory scrutiny. As discussed above, Infuse is a Class III medical device, which means that a less stringent classification would not provide sufficient assurance of safety and effectiveness, and Infuse is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

As a Class III device, Infuse endured the "rigorous" PMA process as the FDA conducted a comprehensive examination of the device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); *Riegel*, 552 U.S. at 317–18; *see generally* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. Nevertheless, the FDA's detailed safety and effectiveness evaluation is strictly tied to the manufacturer's intended use of the device. 21 U.S.C. § 360c(a)(2). The FDA looks only at the "safety and effectiveness of a device . . . with respect to the persons for whose use the device is represented or intended, with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* Thus the FDA looks at the use of a device within the parameters defined by the manufacturer. *See id.*; *id.* § 360e(c)(1) (describing how the Secretary can deny approval based on the safety and effectiveness of the device "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof").

As discussed above, Medtronic submitted Infuse to the FDA for use in a single-level anterior lumbar interbody fusion performed with all three components in a specific spinal region. (Doc. 1 ¶¶ 72–74.) Accordingly, the FDA's premarket review focused exclusively on the safety and effectiveness of Infuse for that use. *See* 21 U.S.C. §§ 360c(a)(2), 360e(c)(1). And when the FDA approved Infuse on July 2, 2002, the FDA approved Infuse to treat degenerative disc disease in the procedure defined by Medtronic, and only in that manner. (*Id.* ¶¶ 72–73, 76–77.)

Once a manufacturer has specified and the FDA has approved the device for the intended use, the FDA takes substantial control of how the manufacturer designs, manufactures, labels, and markets the device going forward—the MDA prohibits any unilateral "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer is further prohibited from promoting a use of the product that is not the specified use. 21 U.S.C. § 331(a); *see also* 21 C.F.R.

§ 814.80 (providing that a "device may not be . . . advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). A manufacturer who wishes to modify the labeling, packaging, design, or indications for use of its device has to comply with a supplemental PMA process. 21 C.F.R. § 814.39(a). The statute also subjects approved devices to reporting requirements. 21 U.S.C. § 360i. For example, the manufacturer must update the FDA when it learns of investigations or scientific studies concerning its device, 21 C.F.R. § 814.84(b)(2), or incidents where the device—used in any manner—"[m]ay have caused or contributed to a death or serious injury," either due to malfunction or normal operation, *id.* § 803.50(a). The FDA can revoke its approval based on these post-approval reports. 21 U.S.C. §§ 360e(e)(1), 360h(e).

In short, the FDA strictly regulates manufacturers based on the intended use of the device, and manufacturers can deviate from those specifications only with permission.

2. Preemption

Congress also provided a measure of protection for medical device manufacturers. It employed its power to preempt state laws that impose on a regulated device "any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device . . . ." *Id.* § 360k(a). This express preemption provision allows manufacturers to avoid having their devices subject to overlapping and conflicting requirements. Common-law causes of action qualify as state requirements for purposes of the preemption statute because they impose standards of conduct on manufacturers that could potentially differ from those set by the FDA. *See Riegel*, 552 U.S. at 323–24; *Lohr*, 518 U.S. at 512 (plurality op. of O'Connor, J.); *id.* at 503–05 (Breyer, J., concurring). Accordingly, where the federal government has approved the product for a specific use and set forth specific regulations, manufacturers need only worry about complying with those regulations. State law cannot force manufacturers to do anything more than or different from federal law.

The statute thus requires a two-part inquiry to determine whether a state law claim

is preempted. Has the federal government established requirements applicable to the device? And if so, do the plaintiff's state common-law claims require the manufacturer to do something "different from, or in addition to" those requirements imposed by the federal government? An affirmative answer to both leads to preemption. *Riegel*, 552 U.S. at 321–22. Consequently, any claim that a device "violated state tort law notwithstanding compliance with the relevant federal requirements" is expressly preempted. *Id.* at 330. And so § 360k generally shields a manufacturer from liability under state tort law so long as the manufacturer complies with federal law. *See, e.g.*, *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 767 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 549–50 (7th Cir. 2010).

In addition, state law claims that seek only to enforce federal law, nothing more, are impliedly preempted. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 344 (2001). Claims premised solely on violations of the FDCA or MDA are preempted because "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; *see also id.* at 349 (citing statutory provisions that enable the FDA to investigate fraud and seek appropriate civil and criminal relief). The FDCA places enforcement of its provisions in the hands of the government, not private plaintiffs: an action for "enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). To allow a private party to essentially enforce the FDCA through state law would upset the balance of objectives the FDA strives to maintain. *Buckman*, however, limited implied preemption to cases where the claim arises "solely from the violation of FDCA requirements." *Id.* at 352–53. In *Buckman*, the plaintiffs' claim was preempted because they did not rely on any independent state law theory and sought recovery only on the basis of the defendant's violation of the federal requirements.

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C. Applicability of § 360k to Ramirez's Claims

With a few exceptions, discussed below, Ramirez premises her state law claims on her physician's off-label use of the Infuse device, which she claims resulted from Medtronic's active promotion of that use. Her claims thus seek to hold Medtronic liable for injuries that trace back to its off-label promotion.[4] Ramirez has brought six state law causes of action against Medtronic. These include: fraudulent misrepresentation/fraud in the inducement, strict products liability—failure to warn, strict products liability—defective design, strict products liability—misrepresentation, negligence, and breach of express warranty. (Doc. 1 ¶¶ 264–349.) As an initial matter, Medtronic alleges that each and every one of Plaintiff's state law claims is preempted by the pervasive federal regulations that resulted from the FDA's approval of Infuse. The Court rejects that argument for the reasons set forth below.

1. "Different From, or in Addition to" Federal Requirements

Because the FDA regulates Infuse for at least some purposes, Ramirez's claims regarding Infuse are subject to potential preemption under § 360k. The primary inquiry for § 360k preemption is whether Ramirez seeks to enforce state law requirements that are "different from, or in addition to any requirement applicable under [the MDA] to [Infuse]."

a. Section 360k and Applicable Federal Requirements

There is no dispute that the federal government heavily regulates Infuse, and there are a number of federal requirements "applicable . . . to the device" for purposes of § 360k. These requirements include strict limitations on the ability of Medtronic to change the labeling for its device or alter its design. *See, e.g.*, 21 U.S.C. § 360e(d)(6)(A)(i) (prohibiting "any change to a device . . . that affects safety or effectiveness" outside of supplemental PMA process). These requirements are not "use-specific"; they do not purport to apply only to approved uses of Infuse. For example,

[4] The issue of causation is not before the Court on this Motion to Dismiss.

Infuse's FDA-approved label currently contains warnings regarding off-label use.[5]

Nevertheless, 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. *See id.* § 360c(a)(2) (stating that the FDA measures the "safety and effectiveness of a device . . . with respect to the persons for whose use the device is represented or intended, with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."); *id.* § 360e(c)(1) (describing how the Secretary can deny approval based on the safety and effectiveness of the device "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof"). Thus, while the requirements applicable to the device are not explicitly use-specific, they are premised on the manufacturer's intended use.

Still, because the requirements are not use-specific, a claim arising solely from the off-label use of a device could face preemption. The MDA does not seek to control how physicians use regulated devices; indeed, off-label use is expressly permitted as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350; *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

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[5] These warnings included:

- "**These components must be used as a system. The InFUSE™ Bone Graft component must not be used with the LT-CAGE ™ Lumbar Tapered Fusion Device Component**." (Doc. 25-1, Ex. G at 1.)
- "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 lumbar interbody fusion procedure with cylindrical threaded cages, posterior bone formation was observed in some instances." (*Id.* at 4.)

As described above, the Court has taken judicial notice of the label.

practitioner-patient relationship."). Neither can a manufacturer control how a physician chooses to use its device. When a plaintiff is injured because her doctor used an FDA-approved device for an unapproved use, and she brings state law tort claims against the manufacturer claiming that it should have provided additional warnings or designed the product differently in light of this unapproved use, the plaintiff is asking the manufacturer to do something "different from, or in addition to" federal law. The doctor's off-label use is not a result of the manufacturer's conduct; indeed, the manufacturer in this situation is adhering to federal law. Federal law does not require manufacturers to provide additional warnings regarding unapproved uses, and federal law forbids a manufacturer from changing the device's design without approval. *See* 21 C.F.R. § 814.39(d) (physicians are permitted, but not required, to issue post-sale warnings); 21 U.S.C. § 360e(d)(6)(A)(i) (no changes affecting safety or effectiveness outside of supplemental PMA process).

The Supreme Court arguably faced an off-label use claim in *Riegel*, and determined that certain claims against a manufacturer arising out of a physician's off-label use of the device were preempted by § 360k. Although the Supreme Court did not directly call the doctor's use of the product "off-label," the Court's description of the facts makes it clear that the case involved off-label use. *See* 552 U.S. at 320 ("Riegel's doctor inserted the Evergreen Balloon Catheter into his patient's coronary artery in an attempt to dilate the artery, although the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. The label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres. Riegel's doctor inflated the catheter five times, to a pressure of 10 atmospheres; on its fifth inflation, the catheter ruptured."). The plaintiffs had sued the manufacturer and claimed the device was "designed, labeled, and manufactured in a manner that violated New York common law." *Id.* The Supreme Court held the common law claims preempted because the plaintiffs had alleged "that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements." *Id.* at 330.

A similar situation appeared in *Perez v. v. Nidek Co*. 711 F.3d 1109 (9th Cir.

2013). There, 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. *Id.* at 1118–19. That fraud by omission claim was preempted, however, because, despite the manufacturer's awareness of the off-label use, the manufacturer was making the device only for use in a certain procedure and was not promoting the off-label use.[6] *Id.* ("Like the device in *Riegel*, the Laser was subject to device-specific requirements under the PMAs—including that it was not to be used for hyperopic corrections and was not permitted to be introduced into commerce for such corrections . . . ."). Federal law did not require the manufacturer to provide these additional warnings, which meant that a state law requirement that did require such warnings created a requirement "in addition to" federal law. *Id.* Both *Riegel* and *Perez* involved assumptions that the manufacturer in question, although aware of the off-label use of its product, was in compliance with the federal regulations applicable to the device. In other words, the manufacturer had done nothing to alter the status quo. In such a situation, state law claims that the manufacturer should have done something more with its device than was approved by the FDA are preempted because they conflict with the FDA's approval of the design and label of the device.

Ramirez's case presents a different scenario. The core of her claim is that she was injured due to an off-label use of Infuse that resulted from Medtronic's practice of

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[6] Medtronic claims that *Perez* is in fact an off-label promotion case. Because the plaintiffs in *Perez* sued doctors and health care centers in addition to the device manufacturer, a careful reading of *Perez* is required. For example, *Perez* states that plaintiffs alleged "that the defendants engaged in a nationwide scheme to modify the approved Laser to enable it to correct farsightedness before it was approved for that purpose" but that the manufacturer only "knew about the improper use of the [device]." 711 F.3d 1109, 1112 (9th Cir. 2013). There were also allegations that employees of the manufacturer had altered the design of the device to facilitate the off-label use and that the manufacturer had dragged its feet in reporting the tampering. *Id.* There was, however, no discussion about off-label promotion, nor was the alleged tampering cited at all in the court's discussion of the preemption issues. *See id.* at 1117–20. The preemption section proceeded based on the theory that both the manufacturer and the doctors "misled the proposed class by failing to disclose that the [device] was not FDA approved for [certain procedures] . . . ." *Id.* at 1117, but there was no discussion of the manufacturer's promotion of off-label uses in that section. According to this Court's reading of *Perez*, the Ninth Circuit has not yet addressed a claim premised on a manufacturer's off-label promotion.

promoting such uses. While permitting health care providers to use devices in ways other than those anticipated by the FDA, the FDA prohibits device manufacturers from promoting the off-label use of their product. By engaging in off-label promotion, the manufacturer may misbrand a device[7] and as such advertise it "in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 U.S.C. § 331(a); *see also* 21 C.F.R. § 814.80 (providing that a "device may not be . . . advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). The FDA forbids this practice because the FDA's review of a device's safety and effectiveness was not universal; it focused only on the intended use specified by a manufacturer. *See* 21 U.S.C. §§ 360c(a)(2), 360e(c)(1). The manufacturer may not tell the FDA that its device should be used only in a certain set of procedures, and then encourage physicians to use the device in other procedures. By advertising the device to physicians for a new, unapproved use, the manufacturer has shown that its intended use of the device has changed. Off-label promotion, then, violates federal law and may carry criminal penalties.[8] *Id.* § 333(a); *see Carson v. Depuy Spine, Inc.*, 365 Fed. App'x 812, 815 (9th Cir. 2010) (observing that "while doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA"); *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012) (noting that the "government has repeatedly prosecuted—and obtained convictions against—

[7] A device is misbranded if its labeling fails to bear "adequate directions for use," 21 U.S.C. § 352(f), which FDA regulations define as "directions under which the layman can use a device safely and for the purposes *for which it is intended*," 21 C.F.R. § 801.5 (emphasis added). The FDA then defines intended use by reference to "the objective intent of the persons legally responsible for the labeling of devices," which may be demonstrated by, among other evidence, "oral or written statements by such persons or their representatives . . . ." *Id.* § 801.4.

[8] The Court recognizes that the Second Circuit has determined that a prohibition on off-label promotion can raise First Amendment concerns. *United States v. Caronia*, 703 F.3d 149, 160–69 (2d Cir. 2012). The Ninth Circuit, however, has assumed that off-label promotion does violate federal law. *Carson v. Depuy Spine, Inc.*, 365 Fed. App'x 812, 815 (9th Cir. 2010). Medtronic has not directly attacked the constitutionality of such a ban in this preliminary proceeding, and the Court therefore assumes for purposes of this Motion that the ban on off-label promotion remains constitutionally viable.

pharmaceutical companies and their representatives for misbranding based on their off-label promotion").

If a manufacturer wants to change the intended use for a device, it must follow the FDA's established procedure. *See* 21 C.F.R. § 814.39(a) (specifying how a manufacturer can add new indications for use through the supplemental PMA process); 21 U.S.C. § 360e(d)(6) (same). When a manufacturer unilaterally attempts to specify a new use—through off-label promotion or otherwise—the manufacturer violates federal law by creating a new, heretofore unreviewed use of the medical device. To determine whether a manufacturer who alters the intended use of a device outside of the prescribed process can nevertheless avoid liability for injuries that are traceable back to that conduct requires examination of § 360k's premises.

The fundamental purpose of § 360k's express preemption provision is to avoid having another entity (jury, state regulators, or state legislatures) arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process. *See, e.g.*, 21 C.F.R. § 808.1(d) ("State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements."); *Stengel v. Medtronic Inc.*, 704 F.3d 1226, 1228–31 (9th Cir. 2013) (en banc). That concern vanishes when the plaintiff brings a claim against a manufacturer that arises out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer. As discussed above, the FDA approved Infuse based on Medtronic's representations regarding how the device would be used. *See* 21 U.S.C. §§ 360c(a)(2), 360e(c)(1). Ramirez has alleged that Medtronic has now sought to establish a new use for Infuse outside of the appointed process.

Thus Medtronic's Motion presents the following question: can Medtronic with one hand violate federal law by establishing a new use, a use that the FDA has not examined,

and with the other hand put forth as justification for preemption the federal regulations that admittedly govern Infuse, but were nonetheless premised on Medtronic's initial representations that Infuse would only be used in certain procedures? Medtronic would answer the question in the affirmative and have the Court hold that, despite any violation of federal law by Medtronic, it nonetheless retains protection of § 360k even for state law claims that arise out of that violation. Medtronic thus cites the existence of federal regulations it is allegedly circumventing to justify dismissal of Ramirez's claims. The Court rejects that interpretation of § 360k.

Ramirez's allegations regarding Medtronic's off-label promotion suffice to allow the majority of her claims to escape preemption. When the device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection. It is true that federal requirements are still applicable to the device, including requirements that Medtronic not alter the design or label of the device without FDA consent. But when Medtronic allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device,[9] it departed the realm of federal regulation and returned to the area of traditional state law remedies. Medtronic claims that the FDA now acts as investigator, judge, and jury for all determinations regarding the safety of Class III medical devices. But federal courts "have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Lohr*, 518 U.S. at 485. This presumption against preemption is especially forceful when "Congress has 'legislated . . . in a field which the States have traditionally occupied,'"

[9] Federal regulations provide that misbranding can also be shown by "the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 801.4. According to the regulation, then, mere awareness of off-label use can potentially result in the creation of a new intended use. The Ninth Circuit did not address this issue in *Perez*, but its holding in that case may foreclose efforts to claim that merely alleging knowledge of off-label use in the absence of off-label promotion by the manufacturer can establish a new, unregulated intended use by the manufacturer and therefore subject the manufacturer to state law claims. *See* 711 F.3d at 1112 (reciting that the manufacturer "knew about the improper use" but still finding state law claims preempted).

and courts will "'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* (citations omitted). This longstanding presumption against preemption remains, even where the FDA has subjected a Class III medical device to the PMA process. *See Stengel*, 704 F.3d at 1227–28. States have always been concerned with protecting their consumers from harmful products, and their common law has served as method of recourse for those injured by such products. *Lohr*, 518 U.S. at 475.

While Congress observed a widespread problem with medical devices and created a nationwide approval process with the MDA, that incursion into traditional state domains did not displace wholesale the array of state remedies available to injured consumers. It certainly did not displace such remedies when physicians are making use of devices in a way the FDA has not approved and with the encouragement of the device's manufacturers. It would make little sense to allow Medtronic to receive the protection of preemption when it is actively promoting off-label uses that have not been reviewed by the FDA. The en banc Ninth Circuit has quoted with approval the Seventh Circuit's description of the fatal defect at the core of Medtronic's interpretation:

> The central issue in this appeal is whether federal law preempts product liability claims against manufacturers of Class III medical devices where a patient claims that she was harmed by the manufacturer's violation of federal law. That statement of the issue may be a little startling. The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.

Stengel, 704 F.3d at 1232 (quoting *Bausch*, 630 F.3d at 549).

Medtronic's reliance on *Riegel* and *Perez* is therefore misplaced. Those cases are distinguishable because Ramirez has premised her claims here not just on the fact that her surgeon used Infuse off-label—itself not an indication that Medtronic is violating federal law—but that he did so as a result of Medtronic's active promotion of Infuse's off-label merits. There is a crucial difference between a claim premised on a physician's use of a device that is unsanctioned by both the FDA and the manufacturer, and one based on a

use that still lacks FDA scrutiny but is actively promoted by the manufacturer. The safety and effectiveness of the former has been weighed and approved by the FDA, while the second "use" is essentially unregulated. The federal government's blanket prohibition on a manufacturer's off-label promotion does not amount to a regulation of use sufficient to pre-empt state tort law regulating the off-label use

To review, when the manufacturer has done nothing to alter the intended use of the product, or promote its use in an off-label manner, a claim based only the manufacturer's knowledge of an off-label use appears to be preempted under § 360k because it would seeks to require the manufacturer to depart from the FDA-approved design and label in order to make the separate, unapproved use more safe or effective when the manufacturer is not promoting that use. *See Riegel*, 552 U.S. at 330; *Perez*, 711 F.3d at 1117–19. By remaining in compliance with the federal scheme and promoting only the use anticipated by the regulations, the manufacturer has shielded itself from such state law claims.

The shield drops when the manufacturer violates federal law. "Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law." *Bausch*, 630 F.3d at 553. Medtronic offers no controlling authority suggesting that the federal government's extensive regulations concerning a medical device apply to off-label uses in cases in which the manufacturer promotes such uses. Allowance for state law claims premised on Medtronic's off-label promotion and consequent establishment of a new, unregulated use does not impose any requirement on Medtronic relating to Infuse "different from, or in addition to" the requirements set by the federal government. The thrust of Ramirez's claims, discussed in detail below, is that in light of Medtronic's promotion of off-label uses, the warning approved by the FDA for "on-label" use was inadequate and harmful to her when she underwent an off-label use promoted by Medtronic. Had Medtronic followed the established procedure and created a new use for Infuse under the MDA, there would be a number of applicable regulations with which the

state law might conflict. As it stands, however, a finding against Medtronic on Ramirez's claims does not entail a finding that Medtronic committed wrongdoing despite compliance with federal law. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321–22. To be preempted, Ramirez's claims must conflict with applicable federal law. In the absence of federal approval of the new use, there is nothing to preempt state law requirements. And in light of the limited breadth courts afford a preemption defense, § 360k should not be read as a broad assertion of exclusive federal power over all things having to do with medical devices. Section 360k does not foreclose Ramirez's state law theory.

b. Implied Preemption

A claim premised on an off-label use promoted by the manufacturer is also not impliedly preempted under *Buckman*. Medtronic is correct that Ramirez will have to establish that Medtronic violated the applicable MDA and FDCA requirements pertaining to off-label promotion as part of her claim. But the mere fact that a federal court will have to interpret the MDA and FDCA at some point in evaluating a plaintiff's claim does not give rise to implied preemption. The en banc Ninth Circuit did not read *Buckman* to preempt any claim that would require a court to interpret the MDA. In *Stengel*, the plaintiffs' claim was that the manufacturer had a duty under federal law to warn the FDA and that its failure to do so resulted in the plaintiff's injuries. 704 F.3d at 1232–33. That the claim would require parsing the applicable federal regulations that govern reporting of adverse events did not result in implied preemption. *Id.* (holding "under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*"). Judge Watford, writing for seven judges of the en banc panel in *Stengel*, expressly rejected a broad interpretation of *Buckman* that would preempt any state law claim that was premised, at least in part, on a federal violation. *See* 704 F.3d at 1235 ("In my view, accepting that argument would require an unwarranted expansion of *Buckman*'s rationale.")

Perez did not hold otherwise. In an abbreviated discussion at the conclusion of the

opinion, the court held that the plaintiff's claim that the manufacturer should have provided additional warnings about the device's off-label use was impliedly preempted. 711 F.3d at 1119–20. Although *Perez* excerpted language from the district court's decision that is susceptible to a broader interpretation, see *id.* at 1120, it cannot be read in light of *Stengel* to preempt any claim that would require interpreting the federal regulations. The majority opinion and Judge Watford's concurrence—and *Perez*, for that matter—all limited *Buckman* to its terms—state law claims that "'exist *solely* by virtue' of the federal enactment" are preempted, while those that have a separate state law origin are not. 704 F.3d at 1235 (Watford, J., concurring) (quoting *Buckman*, 531 U.S. at 353) (emphasis in original); *id.* at 1233; *Perez*, 711 F.3d at 1119. The author of *Perez* joined both the majority and concurring opinions in *Stengel* and the Court will not read *Perez* to overrule *Stengel sub silentio* on the issue of implied preemption.

Furthermore, Medtronic's reading of *Perez* raises serious issues regarding the appropriate scope of preemption. As discussed at length above, the assumption in medical device cases is no preemption. *Buckman* disposed of that presumption only because the plaintiff's claim was wholly derivative of federal law. 531 U.S. at 347–48. The equivalent here would be if Ramirez's only claim was that Medtronic promoted Infuse off-label. Instead, she brings a host of state law theories that have separate and independent origins. That the Court will have to determine as a threshold matter whether Medtronic violated the provisions of the FDCA and MDA regulating off-label promotion to ensure that Ramirez's claims are not preempted under § 360k does not make her claims impliedly preempted under *Buckman*. If the Court accepted Medtronic's view, then almost all state law claims with respect to medical devices would be foreclosed because almost all of those claims require some measurement of whether the manufacturer violated federal law. Indeed § 360k mandates that kind of review. Justice Stevens's observations regarding Medtronic's aggressive interpretation of preemption are on point:

Under Medtronic's view of the statute, Congress effectively precluded state

> courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction . . . would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use.'

Lohr, 518 U.S. at 487 (citation and footnote omitted) (plurality op.). *Buckman* does not foreclose claims that would require a court to interpret federal law.

The state law claims here exists independent of federal law. Put another way, all things being equal, Ramirez could bring a claim against Medtronic, for example, for knowingly concealing information in off-label promotion even if off-label promotion was legal under federal law. The core of her claim under state law does not turn on the existence of a federal infraction, and is therefore permissible under *Buckman*.

Medtronic's interpretation of § 360k and *Buckman* adds a layer of protection for manufacturers that is not required by case law or statute and runs counter to the public policy of a state that seeks to protect the safety and health of its citizens. As Chief Judge Hamilton on the Southern District of Indiana put it, "some medical device manufacturers . . . have tried recently to stretch [preemption] beyond recognition by transforming its protection for FDA-approved devices that comply with federal law into a grant of civil immunity for FDA-approved devices that violate federal law." *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009). Accordingly, claims based on off-label promotion escape preemption.

c. "Parallel Claims"

The Parties have assumed that Ramirez must show that her state law claims qualify as "parallel claims" to escape preemption. That term, however, is not entirely appropriate for claims premised on off-label use promoted by a manufacturer. No controlling case has ever discussed the need to show a parallel claim when the injuries

resulted from off-label use promoted by the manufacturer. The term originated in *Lohr*, where the Supreme Court examined a claim that a manufacturer defectively designed, manufactured, and labeled a device. 518 U.S. at 480–81. The plaintiffs' claims were premised on the on-label (or standard) use/promotion/design of the product at issue. *Id.*; *see also Stengel*, 704 F.3d at 1227 (injuries arising from on-label use). And as discussed above, *Riegel* and *Perez* dealt with off-label uses that were not promoted by the manufacturer. Where a plaintiff seeks to hold a manufacturer liable for injuries that result from the manufacturer's off-label promotion, however, the FDA has not approved that new use and there are no applicable federal regulations and therefore no need to establish a parallel claim.[10]

Nevertheless, a number of district courts across the country have applied the parallel claim framework to claims based on off-label use promoted by the manufacturer. *See, e.g., Caplinger v. Medtronic, Inc.*, --- F. Supp. 2d ---, ---, CIV-12-630-M, 2013 WL 453133 at *10 n.4 (W.D. Okla. Feb. 6, 2013); *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, --- F. Supp. 2d ---, 2013 WL 3214714 (D. Vt. June 25, 2013); *Gavin v. Medtronic, Inc.*, No. 12-0851, 2013 WL 3791612 (E.D. La. July 19, 2013); *Houston v. Medtronic, Inc.*, --- F. Supp. 2d --- , 2013 WL 3927839 (C.D. Cal. July 30, 2013); *Dawson v. Medtronic, Inc.*, No. 3:13-cv-00663-JFA (D.S.C. Aug. 9, 2013). Some courts even require the state law requirement to be "genuinely equivalent" to the federal law. *See also Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011). Others have a

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[10] Even if Ramirez had to show that her claims of off-label use promoted by Medtronic somehow parallel federal requirements, she has done so. Her claims are premised on Medtronic's off-label promotion of Infuse and the resulting injury. Off-label promotion violates federal law. 21 U.S.C. § 331(a); 21 C.F.R. § 814.80; *Carson*, 365 Fed. App'x at 815; *Caronia*, 703 F.3d at 154. Medtronic violated federal law by establishing a new use whose label and design had not been reviewed by the FDA. Accordingly, claims that Medtronic fraudulently concealed information, made material misrepresentations, was negligent, defectively designed Infuse, or failed to warn about the risks of off-label use of Infuse while engaged in off-label promotion are premised on violations of federal law. All of those state law theories exist independently of federal law as well and thus avoid implied preemption. Because those claims are not candidates for either express or implied preemption, they are, by definition, parallel claims.

less stringent definition of parallel.[11] *See Riley*, 625 F. Supp. 2d at 783–84; *see also Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012) (incorporating a similar theory and holding that to the extent "plaintiffs' failure-to-warn claim is founded on promotion by defendants of off-label uses of the device beyond the safe harbor, the claim is not preempted").

However the term "parallel" is analyzed, it does not apply to claims based on the off-label use of a device that was promoted by its manufacturer. Those cases did not recognize that the manufacturer's conduct has established a new, unregulated use. The absence of FDA approval means that are no federal determinations that conflict with a potential jury verdict on the safety or adequacy of a device and its labels. Section 360k protects manufacturers who adhere to the federal regulatory program, but it does not expand federal law into heretofore unregulated areas. Accordingly, there is no need for Ramirez to establish that her state law claims parallel federal requirements. Medtronic's alleged off-label promotion has relieved her of that responsibility.

2. Claims Premised on Off-Label Promotion

The first category of claims involves those Ramirez premises on Medtronic's off-label promotion of Infuse.

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[11] To the extent Ramirez needs to show a parallel claim, the Court rejects an interpretation of the term "parallel" that requires the plaintiff's state law theories to mirror applicable federal requirements in all respects in order to avoid preemption. That interpretation does not comport with the statute, the presumption against preemption, or the rulings on this subject that have emerged from the Supreme Court and the Ninth Circuit. *Lohr*, *Riegel*, and *Stengel* did not take such a miserly view of claims that could survive preemption. *See Lohr*, 518 U.S. at 495 ("Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule."); *Riegel*, 552 U.S. at 330 (describing a parallel claim is one "premised on"—not identical to—"a violation of FDA regulations," and one that does not "add to[ ] federal requirements"); *Stengel*, 704 F.3d at 1233–34 (Watford, J., concurring) (allowing state failure-to-warn claim even where there was not a perfect identity between the federal and state violation).

a. Fraud

1) Preemption

Ramirez alleges that Medtronic committed fraud by concealing and/or making fraudulent representations during its promotional practices concerning the off-label use of Infuse and concealing its practice of off-label promotion. (Doc. 1 ¶¶ 264–77.) To prevail on a fraud claim under Arizona law, Ramirez has to show:

> 1) a representation (or an omission); 2) its falsity; 3) its materiality; 4) the speaker's knowledge of the representation's falsity or ignorance of its truth; 5) the speaker's intent that it be acted upon by the recipient in the manner reasonably contemplated; 6) the hearer's ignorance of its falsity; 7) the hearer's reliance on its truth; 8) the right to rely on it; and 9) his consequent and proximate injury.

Echols v. Beauty Built Homes, 647 P.2d 629, 631 (Ariz. 1982); *see Haisch v. Allstate Ins. Co.*, 5 P.3d 940, 944 (Ariz. Ct. App. 2000) (citing *Echols*).

Assuming that Ramirez has stated a valid state law theory of fraud, she must show that her various theories of recovery do not require the manufacturer to do something "different from, or in addition to" the requirements set by the federal government. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321–22. The core of Ramirez's fraud claim is that Medtronic fraudulently concealed information relating to a use of Infuse that the FDA has not approved. By sidestepping the FDA-approved channel, Medtronic opened itself to state law claims based on its off-label promotion. The absence of federal approval of the specific use and the absence of federal regulations that govern how a manufacturer promotes the off-label use of its device means that traditional state-law standards of conduct remain and govern manufacturers' conduct. Section 360k does not apply by its terms to those claims. It is true that § 360k might preempt fraud claims (or failure to warn or design defect claims, as discussed below) in other contexts. But in light of the presumption against preemption, the Court looks at Ramirez's claims in the specific factual context of off-label promotion and not at fraud claims in general. Within the specific scenario that Ramirez has presented, the state law prohibition on fraud will not require Medtronic to do anything different from or in addition to the federal

requirements.

In addition, Ramirez's fraud claim is not impliedly preempted under *Buckman*, because the state law fraud claim exists independent of any federal regulations. Accordingly, Ramirez can bring a claim for fraud based on Medtronic's representations during its off-label promotion efforts.

2) Rule 9

Although Ramirez's fraud theories survive preemption, they must also survive the heightened pleading requirements of Rule 9. Ramirez sufficiently alleges why statements made by Medtronic representatives were false or misleading. She describes how Medtronic assured the medical community that off-label use of Infuse was safe and effective, despite Medtronic's knowledge of the true effects of off-label use. (Doc. 1 ¶¶ 87–171.) That shows the specific content of the allegedly false statements.

Ramirez must also "state the time [and] place . . . of the false representations as well as the identities of the parties to the misrepresentation." *Schreiber Distrib. Co.*, 806 F.2d at 1401; *see also Vess*, 317 F.3d at 1106 (9th Cir. 2003) ("Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." (internal quotations omitted)). At oral argument Ramirez alleged and Medtronic did not contest that Dr. Wang was a paid consultant for Medtronic. In light of that allegation, Ramirez has established all that is necessary for Rule 9. The Court may reasonably infer that Dr. Wang, as a result of being a paid consultant for Medtronic, was a recipient of Medtronic's alleged off-label promotion. That factual detail "brings home" the fraud to Ramirez. Her fraud allegations are in compliance with Rule 9.

b. Failure to Warn

Ramirez's second cause of action is for failure to warn. She supports this count with the following allegations: (1) Medtronic failed to sufficiently warn Ramirez and her physicians about the dangers of the off-label use that it was promoting, and (2) the warnings accompanying Infuse regarding off-label use were inadequate. (Doc. 1 ¶¶ 278–96.) Although Ramirez references a design defect as a premise for this claim, the Court

addresses only the failure-to-warn claims here and discusses all claims predicated on a design defect in the following section.

Ramirez's theory that Medtronic failed to provide proper warnings while engaged in off-label promotion survives preemption for the reasons described above. Arizona law requires manufacturers to provide adequate warnings, and the Court assumes that Medtronic's conduct allegedly violates state law. *See Stengel*, 704 F.3d at 1233 (citing Arizona cases on failure to warn). Moreover, Medtronic allegedly violated federal law by engaging in misleading off-label promotion, and therefore forfeited § 360k protection. The failure-to-warn claim exists independent of any federal enactment and therefore is not impliedly preempted. Ramirez's failure-to-warn claim consequently survives preemption.

In addition, Ramirez's claim that the labeling and information provided with Infuse was incomplete in light of Medtronic's off-label promotion also survives. Normally, a claim that the labeling and information provided with a medical device were incomplete is an attack on the FDA approval process and suffers preemption. *See Riegel*, 552 U.S. at 317–20; *Caplinger*, 2013 WL 453133 at *10. Ramirez argues that she does not desire to change or in any way vary from the warning required by Medtronic for on-label uses. She merely wishes, as a consequence of the injuries that she suffered due to Medtronic's promotion of off-label uses, to be reimbursed for the injuries she suffered due to the inadequacy of the warnings when the use was off-label, not reviewed by the FDA, and caused her damage.

As discussed above, Medtronic changed the calculus when it began promoting Infuse for a use that differed from the approved uses. In light of the new, unapproved use of Infuse, Ramirez may not have received appropriate warnings about the use of the device in an off-label manner. The FDA has not expressed any opinion on the adequacy of Infuse's warnings for the use at issue in this case, and there is consequently no potential conflict with state law. In some sense, Ramirez's claim would require Medtronic to change that label and information, but that is nothing "different from, or in

addition to" what federal law would require. Federal law requires a device manufacturer to update labeling and information for a device when there has been a change in use. *See* 21 C.F.R. § 814.39(a) (specifying how a manufacturer can add new indications for use through the supplemental PMA process); 21 U.S.C. § 360e(d)(6) (same). Medtronic cannot both violate federal law by unilaterally changing the indicated use for Infuse and then use § 360k as a shield to deflect liability and claim that any lawsuit under state law that seeks to hold it accountable for Infuse's now-misleading label is preempted. Unless and until Medtronic brings its new use of Infuse within the federal regulatory scheme, state law claims based on that new use survive § 360k, and are not based solely on federal law.

c. Design Defect

Ramirez's third claim is that Infuse was defectively designed. (Doc. 1 ¶¶ 282, 297–310.) This claim is not preempted. "For a prima facie case of strict product liability, the plaintiff must demonstrate that the product was in a defective condition that made it unreasonably dangerous, that the defective condition existed when the product left the defendant's control, and that the defective condition proximately caused the plaintiff's injuries." *Dillon v. Zeneca Corp.*, 42 P.3d 598, 603 (Ariz. Ct. App. 2002) (citing *Gosewisch v. Am. Honda Motor Co.*, 737 P.2d 376 (Ariz. 1987)). Again, normally a successful design defect claim requires a finding that Medtronic should have manufactured, designed, or labeled Infuse in a manner different from what the FDA required. If the claim was based on the on-label use of Infuse, or the off-label use of Infuse that had not been promoted by Medtronic, it would be an "attack[ ] on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such [on-label] claims are expressly preempted by § 360k." *In re Medtronic, Inc.*, 623 F.3d at 1206.

But the fact that Medtronic is alleged to have actively promoted the use of Infuse outside of the prescribed federal approval process has opened up state law claims premised on the new, unapproved use of Infuse. Infuse may indeed be defectively

designed for the off-label uses that Medtronic may have actively promoted. Certainly the FDA has not made a finding one way or the other. Because there are no applicable federal regulations that govern the product for this new use, there is no conflict for preemption purposes. Moreover, the absence of federal approval makes *Buckman* inapplicable. Ramirez's design defect claim remains.

d. Misrepresentation

Ramirez alleges a claim of misrepresentation against Medtronic. She alleges that there were specific defects in the Infuse product and that Medtronic sponsored false studies and made assurances that concealed the true risks of using Medtronic in an off-label manner. (Doc. 1 ¶¶ 311–23.) For the reasons discussed in relation to Ramirez's fraud and failure-to-warn claims, a claim for misrepresentation premised on allegations of misleading or fraudulent statements made through off-label promotion is not preempted. A finding that Medtronic misled doctors and patients while engaged in impermissible off-label promotion does not impose on Medtronic any requirements different from or in addition to applicable federal law.

e. Negligence

Ramirez claims that Medtronic breached its duty of care by (1) unreasonably promoting Infuse for off-label use, (2) failing to warn of the dangers of off-label use while engaged in off-label promotion, (3) failing to properly design Infuse, and (4) failing to comply with federal law. (Doc. 1 ¶¶ 324–39.) Three of these theories are resolved based on principles discussed above that will not be repeated here. To the extent Ramirez claims that Medtronic breached a duty of care by promoting Infuse in an unreasonable or fraudulent manner, failing to give proper warnings regarding the dangers of off-label use of Infuse, or improperly designed Infuse for the new use, her negligence claim is not preempted.

The remaining theory is that Medtronic failed "to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse® . . . ." (*Id.* ¶ 331c.) This allegation appears to assert a claim for negligence per se,

or at least a negligence claim based solely on Medtronic's alleged violations of federal law. The standard of reasonable care in a negligence action may be established by statute or regulation or adopted by the Court from a statute or regulation. Restatement (Second) of Torts § 285 (1965). A court may adopt as the standard of care the requirements of a statute or regulation whose purpose is exclusively or in part:

> (a) to protect a class of persons which includes the one whose interest is invaded, and
> (b) to protect the particular interest which is invaded, and
> (c) to protect that interest against the kind of harm which has resulted, and
> (d) to protect that interest against the particular hazard from which the harm results.

Restatement § 286; *see Tellez v. Saban*, 933 P.2d 1233, 1237 (Ariz. Ct. App. 1996) (citing the Restatement elements). "A person who violates a statute enacted for the protection and safety of the public is guilty of negligence per se." *Alaface v. Nat'l Inv. Co.*, 892 P.2d 1375, 1385 (Ariz. Ct. App. 1994). Under either an adopted negligence or negligence per se theory, Medtronic's alleged negligence was its failure to comply with federal law.

Section 360k does not expressly preempt this theory because Ramirez seeks only to hold Medtronic accountable for violations of federal law. By its very nature, a negligence theory that revolves around a violation of federal law does not force Medtronic to do anything "different from, or in addition to" the requirements set by the federal government. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321–22.

Nevertheless, a claim for negligence that is premised solely on a manufacturer's violation of a federal standard—here the FDCA and MDA—is impliedly preempted. This type of claim presents the exact difficulties that produced implied preemption in *Buckman*. *Buckman* dealt with a plaintiff who wanted to sue the defendant under state tort law for defrauding the FDA. 531 U.S. at 346–47. The Court scrutinized plaintiff's fraud-on-the-FDA theory and concluded that allowing a plaintiff to use state law to police fraud on the FDA would "skew" the "balance sought be the Administration" to "achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The Court honed in on

"the relationship between a federal agency and the entity it regulates," and described that relationship as "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. The FDA has numerous statutory weapons at its disposal and retains the discretion to deploy them in whatever manner it sees to fit to achieve "a measured response" to suspected violations of its requirements. *Id.* at 349–50. The responsibility for enforcing the FDCA and MDA lies exclusively with the federal government. 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 352.

Accordingly, federal regulations cannot be hijacked by private plaintiffs. As a practical matter, manufacturers that have to comply with the FDA's detailed regulatory requirements knowing that they have to answer to the FDA for any violations would also face the knowledge that any of the 50 states could also be policing the manufacturer's compliance with those laws under the guise of negligence actions. *Id.* at 350–51. That regime might produce a situation where "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. That was the problem in *Buckman*. Negligence claims where the duty and breach are imported from the FDCA and MDA produce those very same concerns.

Ramirez's negligence per se claim is premised wholly on violations of the FDCA and MDA. That is the entirety of this claim, and like the fraud claim premised solely on the violations of the FDCA in *Buckman*, is impliedly preempted.

f. Breach of Express Warranty

Ramirez's final claim is for a breach of express warranty. She alleges that Medtronic used journal articles, ads, sales reps, and opinion leaders to vigorously promote the off-label use of Infuse and expressly warranted that such uses were safe and effective. (Doc. 1 ¶¶ 340–49.)

1) Preemption

Ramirez bases her express warranty claim on voluntary statements during off-label promotion, and it survives preemption. First, Medtronic was engaged in off-label promotion, which violates federal law and establishes a new, unregulated use of the

product. It therefore loses the protection of § 360k for activities it undertook in relation to that new use. Second, federal 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." *Riley*, 625 F. Supp. 2d at 788; 21 U.S.C. § 331(b). Accordingly, a state law requirement that holds manufacturers to voluntary warranties made during off-label representations does not require something "different from, or in addition to" applicable federal requirements. And Ramirez's theory is not wholly dependent on federal law—her breach of express warranty claim would exist in the absence of the FDCA and MDA. The claim is therefore not impliedly preempted.

2) Affirmation by the Seller to the Buyer

Nevertheless, Ramirez's fails to state a claim under Arizona law. "[A] seller can create an express warranty in . . . [a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." *Dillon v. Zeneca Corp.*, 42 P.3d 598, 602 (Ariz. Ct. App. 2002) (citing Ariz. Rev. Stat. § 47-2313(A)). Arizona law has recognized that a claim for breach of express warranty can arise out of an advertisement. *Eck v. Helene Curtis Indus., Inc.*, 453 P.2d 366, 369 (Ariz. Ct. App. 1969) ("[A] manufacturer's liability for breach of express warranty regarding a cosmetic or similar product may arise out of statements made by the manufacturer in his advertisements of the product." (internal quotation marks omitted)).

But any affirmation that forms the basis of an express warranty must be between the seller and the buyer. The relevant parties here would be Medtronic and Ramirez. But Ramirez does not allege (in anything other than the most conclusory manner) that Medtronic targeted her with its guarantees of safety in off-label use of Infuse; instead, her Complaint provides a causal connection between Medtronic's off-label promotion, *her doctor*, and her doctor's decision to use Infuse with her. She does not allege that Medtronic advertised Infuse in an off-label manner to her through its scientific journals, studies, and so forth. Her claim for breach of express warranty that is premised on Medtronic's statements during off-label promotion is therefore insufficiently pleaded and

dismissed without prejudice.

3. Claims Not Premised on Off-label Promotion

Portions of each of Ramirez's claims contain allegations that, although reasonably read to be based on off-label use promoted by Medtronic, nevertheless may also be construed to allege harm resulting from off-label use alone. (Doc. 1 ¶¶ 265, 267, 280, 284, 286, 298, 299, 313, 331.) To the extent Ramirez asserts any claims that are premised solely on her doctor's off-label use of Infuse divorced from any connection to Infuse's off-label promotion, they are preempted for the reasons discussed above. *Riegel* and *Perez* foreclose those claims. Without the core allegation of off-label promotion, Ramirez's claims that the labeling and information provided with Infuse were incomplete and should have contained additional health or safety information amount to attacks on the FDA approval process. Similar principles apply to any design defect claims that are premised only on the off-label use, without more, of Infuse. Any such claims are dismissed with prejudice.

There is, however, one exception. Ramirez claims in her Response that she is also alleging a theory of recovery that is identical to *Stengel*. She claims that Medtronic should have warned the FDA of the adverse reports it was receiving about the dangers of using Infuse off-label and that the FDA's subsequent action would have then prevented her doctor from using Infuse in an off-label manner to treat her back problems. Because this claim is not premised on a new use for the product that has been established through off-label promotion, Ramirez must show that the claim falls within the traditional parallel claim framework.

The Ninth Circuit has succinctly described what a parallel claim must be: "'The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).'" *Perez*, 711 F.3d at 1120 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). Here, there is an applicable federal regulation.

Federal law requires manufacturers to report to the FDA if they learn of information "reasonably suggest[ing]" that one of their devices "[m]ay have caused or contributed to a death or serious injury . . . ." 21 C.F.R. § 803.50(a). Manufacturers must provide these reports ostensibly for all uses of a product, and therefore a manufacturer who learns of an adverse event that resulted from an off-label use must report that event to the FDA.

As Judge Watford, writing for seven judges on the en banc panel, explained in *Stengel*, a failure-to-warn claim based on a failure to report adverse events to the FDA survives preemption as a parallel claim:

> [T]he Stengels have not predicated their failure-to-warn claim on a duty to warn doctors directly. They have instead alleged that Medtronic breached its duty of reasonable care under Arizona negligence law by failing to report adverse events to the FDA. That requirement is not "different from, or in addition to" the requirements imposed by federal law, because FDA regulations required Medtronic to file an adverse event report with the FDA if it learned of information "reasonably suggest[ing]" that one of its devices "[m]ay have caused or contributed to a death or serious injury," as the Stengels have alleged here. 21 C.F.R. § 803.50(a). Framed in this fashion, the Stengels' negligence claim is not expressly preempted because it seeks to hold Medtronic accountable only for failing to do what federal law mandated. . . .

704 F.3d at 1234.

Such a claim also avoids implied preemption:

> In this case, Medtronic's failure to report was more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law. There is no question that state law has an important and legitimate role to play in regulating the adequacy of post-sale warnings for products already on the market. That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption.

Id. at 1235. Accordingly, Ramirez has established a parallel claim.

Unlike her other failure-to-warn theories, Ramirez does not spell these facts out in the count describing her theories for relief under a failure to warn cause of action. Nevertheless, she does allege in her Complaint that Medtronic failed to warn the FDA

about adverse events and that such a failure led to her doctor's decision to use Infuse. (Doc. 1 ¶¶ 112, 166q, 245.) Given the presence of those factual allegations in the Complaint and Ramirez's desire to pursue that theory, her failure-to-warn-the-FDA theory survives preemption.

CONCLUSION

To the extent she has based her claims only on the fact that her doctor used Infuse in an off-label matter, Ramirez's claims are preempted and dismissed with prejudice, with the exception of her *Stengel* claim. The majority of Ramirez's claims, however, trace her doctor's off-label use of Infuse back to Medtronic's off-label promotion and are therefore not preempted. Nevertheless, Ramirez's breach of warranty claim is dismissed without prejudice. She may amend her complaint to provide the necessary allegations to survive under Arizona law. Her negligence per se claim is dismissed with prejudice.

IT IS THEREFORE ORDERED that Medtronic's Motion to Dismiss is **granted in part and denied in part**. (Doc. 24.)

IT IS FURTHER ORDERED that Medtronic's Motion to Strike is **granted in part and denied in part**. (Doc. 37.)

Dated this 21st day of August, 2013.

G. Murray Snow
United States District Judge