UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MICHAEL MARTIN,

Plaintiff,

v.

MEDTRONIC, INC., et al.,

Defendants.

No. 1:15-cv-00994-DAD-MJS

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

(Doc. No. 25)

This matter came before the court on May 3, 2016, for hearing of defendants' motion to dismiss plaintiff's claims pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Attorneys Philip C. Bourdette and Gale D. Pearson appeared on behalf of plaintiff Michael Martin, and attorneys Stephen J. Mackey and Rami N. Fakhouri appeared on behalf of defendants Medtronic, Inc., Medtronic Puerto Rico Operations, Co., and Medtronic Logistics, LLC (collectively "Medtronic"). Having considered the briefing of the parties and their oral arguments, for the reasons stated below, the court will grant defendants' motion to dismiss while also granting plaintiff leave to amend.

FACTUAL BACKGROUND

In his complaint plaintiff alleges as follows. In 2004, plaintiff was diagnosed with Lumbar Spondylosis and Lumbar Degenerative Disc Disease. (Doc. No. 18 at 3, ¶ 14.) After several years of taking medication for his condition, plaintiff was referred by his doctor for a pain

pump trial. (*Id.*) He was admitted for the first trial of intrathecal opioid on January 17, 2008, and underwent a second trial on January 31, 2008. (*Id.* at 3–4, ¶¶ 14–15.) On February 4, 2008, plaintiff was implanted with medical devices for administering medication, the Medtronic Synchromed II Implantable Infusion System ("SynchroMed Device"), model # 8637-20, pump serial # NGP315748H, and the 8709SC Catheter, serial # N132467011. (*Id.* at 4–5, ¶¶ 15, 21.)

The SynchroMed Device is a programmable drug infusion system implanted in the human body for drug delivery. (*Id.* at 8, ¶ 31.) It is comprised of an infusion pump connected to a flexible catheter, which stores and delivers medication into a patient's spinal canal. (*Id.*) The device is manufactured by defendants, who received premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA") to market the SynchroMed Device in March 1988, and who later received supplemental PMA to market the device for use with the medications taken by plaintiff. (*Id.* at 2–3, 8–9, ¶¶ 2–10, 31–34.)

In November of 2008, plaintiff began experiencing health complications. (*Id.* at 4, ¶ 16.) These complications included "severe hot flashes [that] then progressed to abdominal cramping, nausea, severe malaise, fatigue, and blurred vision." (*Id.*) Plaintiff sought medical attention for these complications, but his physician was unable to identify their causes. (*Id.*)

In 2010, plaintiff's doctors removed the morphine from his medical pump, replacing it with another substance, "Hydromorphone (Dilaudid) or Fentanyl." (*Id.* at 5, ¶ 18.) Following the replacement, plaintiff began suffering from symptoms "like a withdrawal/overdose cycle." (*Id.*)

On July 12, 2013, plaintiff underwent a pump replacement procedure. (*Id.* at 5, ¶ 20.) The new implanted pump was a SynchroMed® II, model # 8637-20, pump serial # NGP385091H, and the new catheter was model # 8578 connection, serial # H880266403. (*Id.* at 5, ¶ 21.) During the procedure, the operating doctor discovered disintegration of the prior connector, noting broken pieces around the connector site of the pump, and slight leakage of fluids around the connection site. (*Id.* at 6, ¶ 23.) The doctor postulated that the leakage would have caused the medication in the pump to flow into the scar pocket where the pump was located, allowing medication to build up in the scar pocket for short periods without entering plaintiff's system, causing withdrawal symptoms, and then allowing fluid to leak periodically into plaintiff's

system in larger quantities than intended, causing him to experience the symptoms of an overdose. (*Id.*) Plaintiff alleges that he suffered "serious and permanent personal injuries" as a result of defects in the SynchroMed devices. (*Id.* at 7, ¶ 27.)

Beyond the specific defect in Martin's own device, plaintiff alleges that defendants have "shown a pattern of delayed responses to known safety issues concerning the SynchroMed II Implantable Infusion System." (*Id.* at 7, ¶ 27.) In his FAC, plaintiff cites a series of FDA Warning Letters from 2006, 2007, 2009, and 2012, all regarding defendants' device. (*Id.* at 15–22, ¶¶ 52, 55, 58, 59, 63). The FAC also notes that the FDA had inspected defendants' manufacturing facilities in 2006, 2007, 2011, 2012, and 2013, and had issued "Form 483" reports after each inspection session revealing potential violations of federal regulations discovered during the visit. (*Id.* at 26, ¶ 79.) According to plaintiff, defendants have issued over fifty recalls since 2004 relating to SynchroMed devices. (*Id.* at 23, ¶ 69.) Plaintiff suggests that defendants were also aware of an August 2011 recall issued by the FDA for the SynchroMed II Device due to "the potential for reduced battery performance that can lead to sudden loss of therapy." (*Id.* at 6, ¶ 25.) Plaintiff claims that, in May 2013, Medtronic issued a letter to customers implanted with SynchroMed II Devices that noted a redesign and suggested that certain models, including the one implanted in plaintiff, were to be removed from the market. (*Id.* at 6, ¶ 26.) Plaintiff alleges, however, that he did not receive any such letter. (*Id.*)

In 2015, the United States Department of Justice filed a complaint against Medtronic in the United States District Court for the District of Minnesota on behalf of the United States of America, alleging violations of federal law with respect to Medtronic's manufacturing practices for the Device. (*Id.* at 25–27, ¶¶ 77–84.) On April 27, 2015, that court issued a Consent Decree of Permanent Injunction against Medtronic, preventing the manufacture and distribution of Medtronic's Device. (*Id.* at 27, ¶ 85.)

PROCEDURAL BACKGROUND

Plaintiff Michael Martin initiated this action against the Medtronic defendants on June 29, 2014. (Doc. No. 2.) Plaintiff filed his First Amended Complaint ("FAC") on December 14, 2015. (Doc. No. 18.)

In his FAC, plaintiff presents eight causes of action, bringing claims for: (i) strict liability premised on a manufacturing defect, (*Id.* at 28–31, ¶¶ 87–101); (ii) negligence based on a failure to warn, (*Id.* at 31–34, ¶¶ 102–116); (iii) breach of express warranty, (*Id.* at 34–35, ¶¶ 117–22); (iv) breach of implied warranty, (*Id.* at 36–37, ¶¶ 123–29); (v) fraud based on intentional or negligent misrepresentation and concealment, (*Id.* at 37–38, ¶¶ 130–34); (vi) negligent failure to instruct and train medical providers, (*Id.* at 39–41, ¶¶ 135–39); (vii) violation of California's Unfair Competition Law ("UCL"), California Business & Professionals Code § 17200, (*Id.* at 40–41, ¶¶ 140–46); (viii) and violation of Minnesota consumer protection statutes, (*Id.* at 42–45, ¶¶ 147–69).

On January 13, 2016, defendants filed a motion to dismiss plaintiff's FAC. (Doc. No. 25.) Plaintiff filed his opposition on April 18, 2016. (Doc. No. 36.) Defendants filed their reply on April 26, 2016. (Doc. No. 37.) Following the hearing on defendants' motion to dismiss, both parties have filed notices of supplemental authority in support of their respective arguments. (Doc. Nos. 45–48.)

STANDARDS

The purpose of a motion to dismiss pursuant to Rule 12(b)(6) is to test the legal sufficiency of the complaint. *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Though Rule 8(a) does not require detailed factual allegations, a plaintiff is required to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

In determining whether a complaint states a claim on which relief may be granted, the court accepts as true the allegations in the complaint and construes the allegations in the light

most favorable to the plaintiff. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Novak v. United States*, 795 F.3d 1012, 1017 (9th Cir. 2015). It is inappropriate to assume that the plaintiff "can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

A district court should provide leave to amend upon granting a motion to dismiss unless it is clear that the complaint could not be saved by any amendment. *Mueller v. Auker*, 700 F.3d 1180, 1191 (9th Cir. 2012) (citing *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008)). Leave to amend is properly denied, however, if amendment would be futile. *Thinket Ink Information Resources, In. v. Sun Microsystems, Inc.*, 368 F.3d 1053, 1061 (9th Cir. 2004).

ANALYSIS

Defendants advance three arguments in moving to dismiss plaintiff's FAC. (Doc. No. 25-1.) First, defendants contend that plaintiff's claims are preempted by the Medical Device Amendment ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). (*Id.* at 13–16.) Second, defendants argue that, to the extent his claims are not preempted, plaintiff has not satisfied federal pleading standards for claims concerning manufacturing defects, failure to warn, failure to train, breach of express and implied warranty, and fraud. (*Id.* at 22–24.) Third, defendants assert that there are state law grounds for dismissing plaintiff's claims—specifically, that the claims are barred by California's two year statute of limitations for personal injury actions and that plaintiff's UCL claim is barred under California law. (*Id.* at 24–26.) The court analyzes each of defendants' arguments below.

I. Federal Preemption

Under the Supremacy Clause, Congress has the power to pre-empt state law. U.S. Const. art. VI, cl. 2. "Pre-emption may be either express or implied." *Shaw v. Delta Airlines*, 463 U.S. 85, 97 (1983) (citations omitted); *see also Montalvo v. Spirit Airlines*, 508 F.3d 464, 470 (9th Cir. 2007). Express preemption occurs if a federal statute explicitly indicates that federal law is to supersede state law. *Easterwood*, 507 U.S. at 664 (observing that "the task of statutory

construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent"); *Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2008). Implied preemption, in contrast, occurs if congressional intent to preempt is "implicitly contained in [the] structure and purpose" of a federal law." *Montalvo*, 508 F.3d at 470 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1997)).

There are two types of implied preemption—field and conflict preemption. *California v. ARC Am. Corp.*, 490 U.S. 93, 100–01 (1989); *Gingery v. City of Glendale*, 831 F.3d 1222, 1228 (9th Cir. 2016); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc). Field preemption "is applied when Congress intends federal law to 'occupy the field,'" with the result being that "all state law in that area is preempted." *ARC Am. Corp.*, 490 U.S. at 100; *Bank of America v. City and Cty. of San Francisco*, 309 F.3d 551, 560 (9th Cir. 2002) ("Field preemption is implied when the scheme of federal regulation in a particular field is so pervasive as to leave no room for the States to supplement it."). Conflict preemption exists when "the state law makes it either impossible to follow the federal law or provides a significant obstacle to adhering to the federal law." *Freightliner Corp v. Myrick*, 514 U.S. 280, 287 (1995); *see also CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (explaining that a state statute is preempted where it conflicts with or frustrates federal law); *Gingery*, 831 F.3d at 1229 ("Under the doctrine of conflict preemption, a state action must yield to federal executive authority where 'there is evidence of clear conflict between the policies adopted by the two.'"); *Puente Arizona v. Arpaio*, 821 F.3d 1098, (9th Cir. 2016) ("A law is field preempted where (1) the 'regulatory framework is so pervasive' that there is no room for state regulation, or (2) where the 'federal interest [is] so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'"). Regardless of the type, however, preemption only applies if it is "the clear and manifest purpose of Congress."[1] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

[1] Indeed, "[t]here is a presumption against federal preemption of state laws that operate in traditional state domains." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013) (en banc); *see also Hillman v. Maretta*, ___U.S.___, ___, 133 S. Ct. 1943, 1950 (2013).

In their pending motion, defendants argue that plaintiff's claims are preempted by the MDA and should therefore be dismissed.

To determine whether the MDA was passed with preemptive intent, the first point of inquiry is the language of the statute. *Easterwood*, 507 U.S. at 664; *see also Puerto Rico v. Franklin California Tax-Free Trust,* ___U.S.___, ___, 136 S. Ct. 1938, 1946 (2016); *Dilts v. Penske Logistics, LLC,* 769 F.3d 637, 643 (9th Cir. 2014); *Montalvo*, 508 F.3d at 470. The MDA establishes a regime of regulation over medical devices, and contains an express pre-emption provision. This provision states:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

Thus, under the language of the statute, two conditions must be met in order for express preemption to occur. First, an applicable federal requirement must exist. Under FDA regulations, an applicable federal requirement exists for purposes of preemption only when the FDA has established regulations specific to the particular medical device at issue. 21 C.F.R. § 808.1(d); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (noting that state law will be preempted "only to the extent that the FDA has promulgated a federal 'requirement'"); *Perez v. Nidek Co., Ltd*., 711 F.3d 1109, 1117 (9th Cir. 2013). Second, the state law must be different from or additional to that federal requirement, and must relate to safety or effectiveness. *Id.* Such laws are not limited to state statutes—state common law claims can also impose "requirements" for preemption purposes "to the extent that their recognition would impose requirements different from, or additional to, FDA requirements applicable to the device." *Papike v. Tambrands Inc*, 107 F.3d 737, 741 (9th Cir. 1997) (citing *Lohr*, 518 U.S. at 512) (Breyer, J., concurring in part). However, state law requirements that are "equal to, or substantially identical to, requirements imposed by or under the [MDA]" are not preempted." 21 C.F.R. § 808.1(d)(2). State law requirements of "general applicability" are also not expressly

preempted unless they have "the effect of establishing substantive requirements for a specific device." *Lohr*, 518 U.S. at 500; *see also Do Sung Hum v. Humana, Inc.*, 620 F.3d 1134, 1149 n.25 (9th Cir. 2010).

The MDA thus has an exception to express preemption for claims that "parallel" rather than add to federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *see also Stengel*, 704 F.3d at 1228. To state a parallel claim, a plaintiff must allege the violation of a specific federal requirement applicable to the device, and the violation of an identical state law duty. *See Wolicki-Gables v. Arrow International, Inc*., 634 F.3d 1296, 1300–01 (11th Cir. 2011); *Frere v. Medtronic, Inc.*, No. EDCV 15-02338-BRO (DTBx), 2016 WL 1533524, at *7 (C.D. Cal. Apr. 6, 2016). Violations of the FDA's Current Good Manufacturing Practices ("CGMPs") may rise to the level of specific federal violations that could support a parallel claim, but CGMP violations are not conclusive in this regard. *See Frere*, 2016 WL 1533524, at *7 (finding that "alleged violations of CGMPs alone may be insufficient to establish a parallel claim that can avoid express preemption . . . . [but that] that is not the case here"). The MDA also does not prohibit states from providing remedies for state law claims premised on violations of FDA regulations. *See Frere*, 2016 WL 1533524, at *5.

Even if a claim is not expressly preempted, it may be impliedly preempted. The MDA impliedly preempts claims that are based solely on violations of federal requirements, and not on state law requirements that could exist independently of any federal rules. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 352–53 (2001); *see also Frere*, 2016 WL 1533524, at *6; *cf. Lohr*, 518 U.S. at 500–502 (finding that there was no preemption of plaintiff's state law claims because they arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements); *Stengel*, 704 F.3d at 1230–33 (finding that a state law negligence claim escaped implied preemption because the state law cause of action was "independent of the FDA's pre-market approval process," and could exist separately from any federal requirement to report adverse events to the FDA). The basis for such implied preemption is that the MDA explicitly prohibits lawsuits by private litigants to enforce the FDCA's provisions, instead requiring that all such actions "shall be by and

in the name of the United States." 21 U.S.C. § 337(a). Ultimately, it has been recognized that there is a "narrow gap" through which a plaintiff's state law claim must fit in order to escape preemption by the FDCA: "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 Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)).

In their motion to dismiss, defendants contend that each of plaintiff's claims are preempted by the MDA. (Doc. No. 25-1 at 13–22.) Defendants make three arguments in support of this contention. First, defendants argue that the MDA's PMA process establishes federal requirements for the SynchroMed devices, and that plaintiff, by bringing a state law-based action, seeks to impose new standards for safety and effectiveness that go beyond those federal requirements. (*Id.* at 14–15.) As such, according to defendants, plaintiff's claims are expressly preempted. (*Id.*) Second, defendants argue that even if products liability causes of action are not always expressly preempted, such claims are expressly preempted here because plaintiff has not alleged specific federal law violations supporting a parallel claim. (*Id.* at 16–18.) Defendants contend that plaintiff's claims are premised on alleged breaches of the FDA's CGMPs, which "set forth open-ended standards, not concrete requirements" of federal law. (*Id.* at 17.) Defendants also assert that "state-law claims predicated on plaintiff's particular interpretation of the CGMPs would necessarily be enforcing requirements 'different from, or in addition to' any actual requirements that exist under federal law, and are therefore expressly preempted." (*Id.*) Third, and in the alternative, defendants argue that plaintiff's claims are impliedly preempted because they are entirely based on alleged federal violations. (*Id.* at 21–22.)

In opposing the pending motion to dismiss, plaintiff argues that his claims against defendants are not preempted under the MDA for three reasons. First, plaintiff notes that there is a general presumption against federal preemption. (Doc. No. 36 at 7–8.) Second, plaintiff argues that his claims are based on state law that does not impose requirements additional to or different from federal requirements. (*Id.* at 7–8.) Plaintiff notes in this regard that his claims are indeed

premised on violations of federal rules, and not on violations of independent state law rules. (*Id.* at 26–27.) Third, plaintiff argues that the absence of preemption is confirmed by FDA regulations, which provide that the MDA "[d]oes not preempt remedies created by States or Territories." (*Id.* at 25); *see also* 21 C.F.R. Part 820.

The court considers defendants' preemption arguments with respect to each of plaintiff's claims below.

a. Manufacturing Defect Claim

Plaintiff's first cause of action is a strict products liability claim based on an alleged manufacturing defect. (Doc. No. 18 at 28.)

The MDA creates a federal PMA process that imposes comprehensive safety requirements applicable to Class III medical devices[2] such as the one implanted into plaintiff. *Riegel*, 552 U.S. at 322; *Houston v. Medtronic, Inc.*, No. 2:13-cv-01679-SVW-SHx, 2014 WL 1364455, at *3 (C.D. Cal. Apr. 2, 2014) (finding that "a Class III FDA approved device . . . was clearly subject to MDA 'requirements'" for the purposes of Riegel's two step preemption analysis); *cf. Lohr*, 518 U.S. at 493 (finding that a law providing exemption from federal safety review for products that were substantially equivalent to federally approved products did not impose any requirements, and therefore did not preempt state law claims). The PMA process is rigorous, and requires full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. § 360e(c)(1); *see also Riegel*, 552 U.S. at 318, 323.

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[2] Under the MDA, Class III devices are those used "in supporting or sustaining human life or for a use [that] is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360(c)(a)(1).

California law also imposes requirements intended to protect consumers from harm caused by manufacturers' unreasonable behavior. *See, e.g*., *Greenman v. Yuba Power Products Inc*., 59 Cal. 2d 57, 62 (1963) ("A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."); *County of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 318 (2006) (describing the elements of a strict products liability cause of action); *Res-Care, Inc. v. Roto-Rooter Services Co*., 753 F. Supp. 2d 970, 988 (N.D. Cal. 2010). Under California law, a plaintiff may bring a strict products liability cause of action by alleging a defect in manufacture of a product, causation, and injury. *See County of Santa Clara*, 137 Cal. App. 4th at 318.

The MDA sets out manufacturing requirements applicable to the SynchroMed device through the PMA process. *See Riegel*, 552 U.S. at 322 (2008). California law, meanwhile, imposes a general duty on manufacturers of medical devices to use reasonable care in manufacturing their products. *See Finn v. G.D. Serle & Co.*, 35 Cal. 3d 691 (1984). Here, plaintiff alleges, as a violation of California law, defendants' failure to properly manufacture SynchroMed devices in accordance with federal requirements. (Doc. No. 18 at 28, ¶ 87.) Because plaintiff's state law claim is based on violation of federal law, rather than on state law requirements that are additional to or different from federal requirements, it is not subject to express preemption. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (stating that plaintiff's state law negligence claim was not preempted by the MDA "insofar as the state-law duty parallels a federal-law duty under the MDA"); *see also Beavers-Gabriel v. Medtronic, Inc.*, Civ. No. 13-00686 JMS-RLP, 2015 WL 143944, at *11–12 (D. Haw. Jan. 9, 2015) ("Contrary to Defendants' argument, Plaintiff is not challenging the labeling of the Infuse Device (a claim the court dismissed without leave to amend), but rather is asserting a straightforward *Stengel* claim—that Defendants failed to provide required information to the FDA, which, if [plaintiff's doctor] was aware of, would have affected his decision to use the [medical device] for Plaintiff's surgery."). Accordingly, the court concludes that plaintiff's manufacturing defect claim is not expressly preempted by federal laws concerning the manufacture of medical devices.

The court also finds that plaintiff has plausibly alleged violation of specific federal requirements applicable to the SynchroMed devices sufficient to support a parallel claim. Plaintiff's FAC alleges facts supporting the existence of specific evidence indicating that the SynchroMed device was implanted in plaintiff during a time when defendants were not in compliance with CGMPs. (Doc. No. 18 at 15–25.) The FAC notes that defendants had been cited by the FDA for manufacturing adulterated and misbranded products in breach of the FDCA as a result of these alleged violations. (*Id.*) Thus, while alleged violations of CGMPs alone are not by themselves conclusive of an FDA violation, plaintiff's allegations provide plausible support for the inference that defendants manufactured SynchroMed devices in violation of federal requirements. *See, e.g.*, *Frere*, 2016 WL 1533524, at *7 (finding that CGMP violations, while not conclusive, may be sufficient to establish a specific federal violation that would support a parallel claim); *De La Paz v. Bayer Healthcare LLC*, No. C 15–03995 WHA, 2016 WL 392972, at *7 (N.D. Cal. Feb. 2, 2016) ("The Form 483s offer plausible support for the inference that [defendant] produced some adulterated devices, even if not conclusive.").

However, the court also concludes that plaintiff's manufacturing defect claims are impliedly preempted by the MDA because it appears those claims rest entirely on defendants' alleged violation of federal requirements. In the FAC, plaintiff alleges that defendant "was under a duty to conform to and manufacture their products in accordance with federal law and in particular with the provisions of the FDCA and the . . . GCMP requirements of the Quality System regulation found at" 21 CFR Part 820, et seq. (Doc. No. 18 at 29, ¶ 91.) Plaintiff also alleges the medical device in question was manufactured at a time when defendants were violating federal regulations related to manufacturing processes. (*Id.* at 29, ¶ 94; 36 at 34.) Plaintiff asserts that defendants were producing "adulterated" or 'misbranded' products because of these violations and manufactured a product that did not conform to specifications, as evidenced by the malfunction which plagued plaintiff's device. (*Id.* at 29–30, ¶¶ 94–97.) According to plaintiff's FAC, "these product failures were the result of violations of federal law that occurred during the manufacturing process of the devices." (*Id.* at 30, ¶ 98.) In the FAC plaintiff merely mentions Minnesota and California law without specificity and alleges in

conclusory fashion and without explanation that defendants "violated parallel state law by failing to use reasonable care in manufacturing" the device. (*Id.* at 29, ¶ 92; 30, ¶ 95.) In light of the nature of the allegations set forth in the FAC, the court concludes that plaintiff's manufacturing defect claims are impliedly preempted because they entirely rest on defendants' purported violations of the FDA's CGMPs, rather than on a state law cause of action that could exist independently of any federal requirements. *See Perez*, 711 F.3d at 1118; *Frere*, 2016 WL 1533524, at *7.

b. Failure to Warn Claim

Plaintiff's second cause of action also alleges a strict products liability claim, based on defendants' failure to warn of the dangers associated with the SynchroMed device implanted in plaintiff. (Doc. No. 18 at 31-34.)

The MDA requires medical device manufacturers seeking PMA to disclose certain safety risks to the FDA, and imposes a continuing duty on PMA holders to report individual adverse events associated with those medical devices. 21 U.S.C. § 301, et seq.; 21 C.F.R. § 803.10(c); *see also Stengel*, 704 F.3d at 1226–27 (explaining the PMA process and observing that, after approval, manufacturers are required to report adverse events to the FDA). California law also imposes a general duty of reasonable care on manufacturers, and provides a strict products liability cause of action for failure to warn. *Johnson v. American Standard, Inc.*, 43 Cal. 4th 56, 64–65 (2008); *see also Sanders v. City of Fresno*, No. CIV F 05-0469 AWI SMS, 2006 WL 1883394, at *14 (E.D. Cal. July 7, 2006); *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 13 (1992) (stating that a "manufacturer is strictly liable for injuries caused by a product that is . . . distributed without adequate instructions or warnings of its potential for harm"); Cal. Civ. Code § 1714.[3] "To state a claim for strict products liability for failure to warn, a plaintiff must allege that the defendant failed to adequately warn of a known or knowable risk where that failure caused the plaintiff's injuries." *Hawkins v. Medtronic, Inc.*, No. 1:13-cv-00499 AWI SKO, 2014 WL

[3] California Civil Code § 1714 provides: "Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself."

346622, at *13 (E.D. Cal. Jan. 30, 2014) **(**citing *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112 (1996)). A failure to warn claim brought under state law will not be expressly preempted by the FDA so long as it "demand[s] the same conduct of manufacturers that federal law [does]." *Frere*, 2016 WL 1533524, at *5; *see generally Stengel*, 704 F.3d at 1233 (holding that a state law negligence claim based on failure to warn was not expressly preempted because the "state-law duty parallel[ed the] federal-law duty" to report events to the FDA).

Here, however, plaintiff's failure to warn cause of action is expressly preempted. As noted above, the MDA imposes a duty on manufacturers such as defendants to report adverse events associated with the SynchroMed device to the FDA, a duty that plaintiff acknowledges. (Doc. No. 18 at 12–13, ¶¶ 50–51.) However, by way of his state law failure to warn claim, plaintiff seeks to impose liability on defendants for failing to provide warning of medical device risks not only to the FDA, but also to "medical providers, and consumers such as Plaintiff." (*Id.* at 32, 34, ¶¶ 108, 115) (asserting that defendants "failed to warn Plaintiff, his medical providers, and the FDA of [the devices'] defective nature"). Because plaintiff here seeks to impose a duty to warn onto defendants that is broader and in addition to those required by federal law, plaintiff's failure to warn cause of action is expressly preempted. *Perez*, 711 F.3d at 1118 (finding that claims based on failure to take actions not required by FDA regulations were preempted, and plaintiff's fraud by omission claim expressly preempted because it would "effectively see[k] to write in a new provision to the FDCA: that physicians and medical device companies must affirmatively tell patients when medical devices have not been approved for a certain use"); *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) ("[A]ny attempt to predicate the [plaintiff's] claim on an alleged state law duty to warn doctors directly would have been expressly preempted."); *Hawkins*, 2014 WL 346622, at *14 (finding plaintiff's failure to warn claims challenging the manufacturer's failure to warn plaintiff and his physicians of risks related to medical devices was expressly preempted, because "[d]efendants cannot be made to go beyond [federal] warning requirements"); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1177 (C.D. Cal. 2013) (finding that plaintiff's failure to warn claim challenging the medical device manufacturer's failure to provide plaintiff or her physician with post-sale warnings, or warnings

additional to those required by MDA labeling requirements, was expressly preempted because "[p]laintiff aims to foist upon Defendants labeling or warning requirements 'in addition to' what federal law requires"); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236–37 (6th Cir. 2000) ("[T]he information submitted to and approved by the FDA . . . comprise the specific federal requirements applicable to defendant's [Class III medical device]. Accordingly, to the extent that plaintiffs' claim is premised on the adequacy of warnings reviewed and approved by the FDA, . . . the claim is [expressly] preempted.").

c. Express Warranty Claim

Plaintiff's fourth cause of action is a breach of express warranty claim. (Doc. No. 18 at 34.)

The MDA, through its PMA process, establishes conditions for approval that prohibit false or misleading off-label promotion. 21 C.F.R § 814.80; *see also Hawkins*, 62 F. Supp. 3d at 1152 (noting that "the vast majority of the courts in this Circuit" have held that "the MDA prohibits false or misleading off-label promotion of a Class III FDA approved medical device"); *cf. Hawkins*, 62 F. Supp. 3d at 1151 ("Courts appear split on . . . whether off-label promotion—by itself—constitutes misbranding in violation of [federal law]."). State law claims based on breach of express warranty can survive preemption under the MDA only to the extent that they seek to impose liability for misleading warranties voluntarily made outside the label. *Houston*, 957 F. Supp. 2d at 1180–81 (noting that such express warranty breach claims are not preempted because in such cases a plaintiff "is not imposing any requirement different from or additional to what federal law already requires"); *see also De La Paz v. Bayer Healthcare LLC*, No. C 15–03995 WHA, 2016 WL 392972, at *10 (N.D. Cal. Feb. 2, 2016) (finding that "the only claims for breach of the express warranty that have survived preemption are those that went 'beyond' statements approved by the FDA").

The court concludes that here, plaintiff's breach of express warranty claim is expressly preempted because it would impose requirements different from or additional to those required under federal law. Plaintiff's FAC points to several "warranties," describing those made "by way of written literature, including but not limited to product labeling, patient package inserts, articles

in medical journals, advertising and/or other documents and/or promotional materials." (Doc. No. 18 at 34, ¶ 118.) However, with respect to product labeling and patient package inserts, plaintiff pleads no facts "that plausibly indicate that Defendants breached a warranty made beyond any statements approved by the FDA during the [PMA] process." *Frere*, 2016 WL 1533524, at *8; *see De La Paz*, 2016 WL 392972, at *10 ("Any claim for breach of express warranty based on [FDA-approved] statements would require a determination that [the device] did not conform to the descriptions approved by the FDA. Such claims are preempted."); *see also In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d at 1207–08. Accordingly, plaintiff's breach of express warranty cause of action is expressly preempted under the MDA.

d. Implied Warranty Claim

Plaintiff's fourth cause of action alleges that defendants breached an implied warranty of merchantability. (Doc. No. 18 at 36–37.)

The MDA's PMA process permits the FDA to determine whether medical devices are fit for ordinary use. *See Houston*, 957 F. Supp. 2d at 1176. Such PMA approval imposes federal requirements that are specific to the device and constitute "federal safety review." *Riegel*, 552 U.S. at 322–23. Under California law, a breach of the implied warranty of merchantability occurs if a product lacks "even the most basic degree of fitness for ordinary use." *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (2003) (citing Cal. Com. Code § 2314(2)); *see also Birdsong v. Apple, Inc.*, 590 F.3d 955, 958 (9th Cir. 2009) (same).

Because plaintiff is bringing a state law claim for conduct that allegedly violates the FDCA, and not a claim based on defendants' alleged failure to comply with different or additional state law requirements, (Doc. No. 18 at 36, ¶ 127), the plaintiff's implied warranty claim is not expressly preempted by federal law. However, the court finds that this claim is impliedly preempted by federal law. In his FAC, plaintiff alleges that the SynchroMed device, as approved by the FDA, had "the potential to malfunction and cause serious and permanent injuries." (Doc. No. 18 at 37, ¶ 128.) Plaintiff does not allege, however, that defendants marketed the device for an "off label purpose," or that the device was surgically implanted for a

purpose other than those approved by the FDA during the PMA process. Instead, plaintiff's implied warranty claim is based solely on the basis that defendants' alleged conduct violates the FDCA; this cause of action is therefore subject to implied preemption under *Buckman*. *See Perez*, 711 F.3d at 1120 ("[T]he plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)."); *Frere*, 2016 WL 1533524, at *9; *see generally Buckman Co.*, 531 U.S. at 352–53.

e. Fraud Claims

Plaintiff's fifth cause of action alleges that defendants engaged in fraud through intentional or negligent misrepresentation and concealment. (Doc. No. 18 at 37–38, ¶¶ 130–134.)

Federal law establishes specific requirements for disclosure of dangers relating to medical devices. In particular, the MDA's PMA process provides device-specific disclosure requirements for physicians and medical device companies. *See Perez*, 711 F.3d at 1118–1119. State law claims that depend on safety requirements "in addition to" those federal mandates are expressly preempted under federal law. *See id.* at 1118–1119 (finding that the FDCA expressly preempted plaintiff's fraud-by-omission claims, as plaintiff sought to enforce state law requirements that would have required defendants to give additional medical device disclosures than those required under federal law).

State law-based fraud claims are also impliedly preempted when those claims exist solely by virtue of the FDCA disclosure requirements. *See Buckman*, 531 U.S. at 352–53 (stating that "were plaintiffs to maintain their fraud-on-the-[FDA] claims here, they would not be relying on [state law that] has predated the federal enactments in question . . . [instead] the existence of these federal enactments is a critical element in their case"); *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040 (9th Cir. 2015) (citing *Buckman*, 531 U.S. at 347–48) ("Policing fraud against federal agencies is hardly 'a field [that] the States have traditionally occupied,' such as to warrant a presumption against preemption").

Here, the court concludes that plaintiff's fraud claims are also preempted. Plaintiff's FAC alleges that defendants carried out fraud through both misrepresentation and concealment. (Doc. No. 18 at 37–38.) The court will first address plaintiff's fraudulent misrepresentation claim.

In his FAC, plaintiff alleges that defendants "negligently or intentionally made representations of material facts" that "were in fact false," and did so "with the intent to defraud," pointing specifically to the same alleged misrepresentations plaintiff identified in a separate allegation regarding defendants' marketing materials. (*Id.* at 37–38, ¶¶ 131(D) & 131(F)); *compare* (*Id.* at 11, ¶ 47), *with* (*Id.* at 37 ¶ 131). However, plaintiff also alleges that the FDA fully evaluated the SynchroMed device through the PMA process. (*Id.* at 8, ¶¶ 32–34.) Such PMA review would necessarily have included an evaluation of promotional materials for the device. *See Buckman*, 531 U.S. at 349. To the extent plaintiff challenges statements approved by the FDA during the PMA process, his fraud claim is expressly preempted, because it seeks to impose duties beyond those required under federal law. *Id.* Moreover, to the extent plaintiff challenges misrepresentations made to the FDA, the claim is subject to implied preemption, since it would be based entirely on claimed violations of federal law. *See McClellan*, 776 F.3d at 1039 ("emphasizing that claims challenging "fraudulent representations *during* the [PMA] process, *to the FDA*," were impliedly preempted, but that parallel claims challenging misrepresentations made "outside the context of the regulatory process" were not subject to preemption); *Frere*, 2016 WL 1533524, at *9 (finding that any of plaintiff's fraud claims based on misrepresentations were impliedly preempted); *see also Hawkins*, 62 F. Supp. 3d 1144, 1151 ("[T]he vast majority of the courts in this Circuit have [concluded], that . . . the MDA prohibits false or misleading off-label promotion of a Class III FDA approved medical device").

The court will next address plaintiff's fraudulent concealment claim. In making that claim, plaintiff contends that defendants fraudulently concealed and suppressed material facts relating to the danger posed by the device from the medical community, doctors, and plaintiff. (Doc. No. 18 at 38, ¶ 132.) However, by alleging that defendants are liable for this conduct, plaintiff seeks to impose duties beyond the mandates imposed on defendants by the MDA, and plaintiff's fraudulent concealment claim is therefore subject to express preemption. *See Perez*, 711 F.3d at 1119 (holding that the FDCA expressly preempted plaintiff's fraud by omission claim); *Frere*, 2016 WL 1533524, at *10.

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f. De Facto Physician Assistants Claim

Plaintiff's sixth cause of action alleges that defendants failed to properly train medical providers on how to properly carry out plaintiff's implantation surgery and ensure the device was operating properly. (Doc. No. 18 at 39.)

The MDA establishes that "[e]ach manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities." 21 C.F.R. § 820.25(b). Under California law, meanwhile, "if a manufacturer undertakes to train physicians and fails to exercise reasonable care in that undertaking, it may be held liable for harm caused to third parties as a result of its negligent undertaking." *Scott v. C.R. Bard, Inc.*, 231 Cal. App. 4th 763, 774 (2014). A state law failure to train claim can survive express preemption "only to the extent the manufacturer failed to provide the training required by the premarket approval process." *De La Paz*, 2016 WL 392972, at *9 (citing *Chao v. Smith & Nephew, Inc.*, No. 13–CV–0114–H (BLM), 2013 WL 6157587, at *4 (S.D. Cal. Oct. 22, 2013)).

In the FAC, plaintiff does not allege that defendants' training procedure deviated from the training procedure approved by the FDA in the PMA process. (Doc. No. 18.) The FAC also does not allege that any potential deviations are causally related to plaintiff's injuries. (*Id.*) Instead, plaintiff asserts generally that defendants' alleged negligence in training caused his injury, and that defendants are liable for "failing to properly instruct the medical providers on one or more . . . aspects of plaintiff's implementation surgery." (*Id.* at 39, ¶ 138). Accordingly, the court concludes that plaintiff's sixth cause of action is also expressly preempted because that negligent training claim would impose requirements that are "different from, or in addition to" federal requirements. *Riegel*, 552 U.S. at 323; *see also Ebner v. Fresh, Inc.*, 838 F.3d 958, 964 (9th Cir. 2016); *Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1022–23 (C.D. Cal. 2015) ("Courts must then determine whether the plaintiff's claims are based on state requirements regarding the device that are "different from, or in addition to" the federal requirements, and that relate to safety and effectiveness. . . . If so, the MDA expressly preempts the plaintiff's claims.") (internal citation omitted).

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g. California UCL Claim

Plaintiff's seventh cause of action is premised on defendants' alleged violation of California's UCL. (Doc. No. 18 at 40.)

As part of the PMA process, the MDA imposes duties of disclosure on medical device manufacturers, and imposes restrictions on marketing as a condition to awarding PMA. 21 U.S.C. § 301, et seq.; *see also* 21 C.F.R. § 803.10(c). California's UCL also prohibits any "unlawful, unfair, or fraudulent business act or practice. Cal. Bus. & Prof. Code § 17200. In order to plead a violation of the UCL, the plaintiff must allege that the defendants engaged in "unfair competition" or "acts or practices [that] are unlawful, or unfair, or fraudulent." *Shvarts v. Budget Grp., Inc.*, 81 Cal. App. 4th 1153, 1157 (2000) (quoting *Podolsky v. First Healthcare Corp.*, 50 Cal. App. 4th 632, 647 (1996)).

In the FAC, plaintiff alleges that defendants committed "acts of unfair competition," which include the following: "falsely advertising the efficacy and safety" of the device, "intentionally concealing dangerous conditions of their product," and "creating the fiction of a need for people to use the [device]." (Doc. No. 18 at 40, ¶ 141.) Plaintiff also claims that defendants "engaged in fraudulent business practices to stimulate the promotion and use of their products and gain an unfair advantage over alternative treatment for pain management." (*Id.* at 40, ¶ 142.) Though not specified in the FAC, in opposing the pending motion to dismiss, plaintiff clarifies that his UCL claim is entirely "based on violation of federal law." (Doc. No. 36 at 39.) Because plaintiff's UCL claim does not seek to impose requirements that are additional or different from federal marketing requirements under the MDA, the court concludes finds that it is not expressly preempted.[4] However, as plaintiff concedes, his UCL claim rests entirely on alleged violations of federal law. Thus, in light of the fact that private actions to enforce the FDA are barred, the court finds that plaintiff's UCL claim is impliedly preempted. *See, e.g.*, *Michajlun v. Bausch & Lomb, Inc.*, No. 14-cv-1365 JM (JMA), 2015 WL 1119733, at *11 (S.D. Cal. Mar. 11, 2015) ("Because common-law claims cannot be the basis of a UCL 'unlawful' claim, and

[4] To the extent that plaintiff's UCL claim is premised on actions sanctioned by the FDA through the PMA process, the claim is expressly preempted. *See Riegel*, 552 U.S. at 323.

private actions to enforce the FDCA are barred, combining them cannot result in a viable claim under the 'unlawful' prong of the UCL."); *see generally Buckman*, 531 U.S. at 348.

h. MN Consumer Protection Claim

Finally, plaintiff alleges in his eighth cause of action that defendants engaged in fraudulent business practices in violation of Minnesota law. (Doc. No. 18 at 41.)

Plaintiff's Minnesota law claims are based upon the same facts he has alleged in support of the breach of implied warranty and fraud causes of action. Because the court has already found that plaintiff's claims for implied warranty and fraud are impliedly preempted, the court concludes that plaintiff's Minnesota Consumer Protection claims fail for the same reasons. *See Frere*, 2016 WL 1533524, at *11 (finding that plaintiff's Minnesota law claims, which were based on breach of implied warranty and fraud causes of action previously held to be impliedly preempted, were also subject to implied preemption).

II. Pleading Adequacy

In their motion to dismiss plaintiff's FAC, defendants argue that to the extent plaintiff's claims are not preempted, the allegations of the FAC with respect to several of those claims do not satisfy federal pleading standards. (Doc. No. 25-1 at 22–24.) In particular, defendants argue that plaintiff has not alleged facts showing causality for claims concerning manufacturing defects and the failure to warn; that plaintiff has not pled facts concerning the content of any claimed warranty sufficient to support an express warranty claim; that plaintiff has not pled vertical privity sufficient to support an implied warranty claim; and that plaintiff has failed to plead claims sounding in fraud with the particularity required under Federal Civil Procedure Rule 9(b). (*Id.*) The court analyzes each argument in turn.

a. Fraud Claims

Federal Civil Procedure Rule 9 provides that, "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To plead circumstances with particularity, plaintiff must include "the who, what, when, where, and how of the misconduct charged." *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (internal quotation marks omitted) (citing *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir.

1997)). The allegations with respect to fraud must be sufficiently specific "to give defendants notice of the particular misconduct [that] is alleged to constitute the fraud . . . so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985); *see also Hawkins v. Medtronic, Inc.*, 62 F. Supp. 3d 1144, 1149, 1155 (E.D. Cal. 2014). Where a plaintiff's UCL claim "sounds in fraud," that claim is also subject to the heightened pleading requirement of Federal Rule of Civil Procedure 9(b). *Frere*, 2016 WL 1533524, at *11; *see also Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009).

Both plaintiff's fraud and UCL claims are held to the heightened pleading standards of Federal Civil Procedure Rule 9(b). In particular, because plaintiff's UCL claim tracks his fraud cause of action, and is based on the same alleged facts, the entirety of plaintiff's UCL cause of action sounds in fraud and is subject to the requirements of Rule 9(b). *Compare* (Doc. No. 18 at 37–38, ¶¶ 130–134) (misrepresentation and concealment allegations), *with* (*Id.* at 40–41, ¶¶ 140–146) (allegation in connection with plaintiff's UCL claim)). The court concludes that plaintiff has failed to plead his fraud and UCL claims with the particularity required by Federal Rule of Civil Procedure 9(b). In the FAC, plaintiff pleads the fraudulent misrepresentation claim by alleging that defendants "negligently or intentionally made misrepresentations of material facts" that "were in fact false," and that defendants acted "with the intent to defraud." (Doc. No. 18 at 37–38, ¶ 131.) The misrepresentations alleged by plaintiff include that the SynchroMed devices would relieve pain, reduce adverse effects from oral opioids, and significantly improve quality of life. (*Id.*) Plaintiff bases his fraudulent concealment claim on allegations that defendants "concealed or suppressed material facts" of the danger posed by the SynchroMed device from the medical community, doctors, and plaintiff. (*Id.* at 38, ¶ 132.) Finally, plaintiff pleads the UCL claim by alleging that defendants engaged in unfair competition by "falsely advertising the efficacy and safety" of the device, "intentionally concealing dangerous conditions of their product," and "creating the fiction of a need" for people to use the [device]." (*Id.* at 40, ¶ 141.) Plaintiff's FAC, however, "does not allege when and where Defendants allegedly made these false or misleading statements, to whom they were made, which parts of Defendants'

misrepresentations were misleading, and how they are false." *Frere*, 2016 WL 1533524, at *10; *see also Beavers-Gabriel*, 15 F. Supp. 3d at 1022 (finding plaintiff's fraud claim inadequately pled because "the Complaint fails to identify what particular misrepresentations and/or concealments were made to Plaintiff and Plaintiff's physicians (as opposed to the medical field generally), who made those particular representations and/or omissions, and when those events occurred."). Because plaintiff has not alleged facts describing the "who, what, when, where, and how of the misconduct charged," plaintiff's fraud and UCL claims fail to meet minimum federal pleading standards. *Vess*, 317 F.3d at 1106.

b. Manufacturing Defect and Failure to Warn Claims

To state a cause of action for strict products liability, a plaintiff must allege "a defect in the manufacture or design of the product or a failure to warn, causation, and injury." *County of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 318 (2006) (citing *Soule v. Gen. Motor Corp.*, 8 Cal. 4th 548, 560 (1994)). An element of both a manufacturing defect claim and a failure to warn claim is that the defect or the failure to warn causes the plaintiff's injury. *See Soule*, 8 Cal. 4th at 568 n.5 (explaining that manufacturers "are liable in tort only when 'defects' in their products cause injury"); *see also Frere*, 2016 WL 1533524, at *6.

In their pending motion to dismiss, defendants argue that the manufacturing defect claims asserted in the FAC should be dismissed because plaintiff has not alleged facts plausibly showing causation. (Doc. No. 25-1 at 2–23.) In particular, defendants argue that the plaintiff does not allege facts linking the allegedly deficient manufacturing and reporting processes to the SynchroMed device's purported breakage, or showing how defendants' actions impacted the decision by plaintiff's physician to use the SynchroMed infusion system. (*Id.*) In opposing the pending motion plaintiff does not address defendants' arguments in this regard. (Doc. No. 36.)

The court concludes that, even if the FAC's claims were to survive preemption, plaintiff has not plausibly alleged facts showing a causal connection between the alleged medical device defect and his injuries. With respect to plaintiff's manufacturing defect claim, the FAC merely alleges: (i) that "the catheters at issue were occluded, fractured, obstructed, and/or malfunctioning, which caused Plaintiff to suffer severe injuries," (Doc. No. 18 at 30, ¶ 98); and

that (ii) "as a direct result of the defects, Plaintiff suffered crippling injuries [that] left Plaintiff with permanent and significant disabilities compensable under the law," (*Id.* at 31, ¶ 101). Similarly, with respect to the failure to warn claim, plaintiff alleges only that "[a]s a foreseeable, direct and proximate result of [Defendants'] failure to warn Plaintiff, Plaintiff's medical providers, and the FDA . . . about the defective condition of the [Device], Plaintiff suffered crippling injuries that left Plaintiff with permanent and significant disabilities." (*Id.* at 34, ¶ 116.)

However, plaintiff's FAC does not identify the particular manufacturing defect, or specify any adverse events that defendants failed to report to the FDA. *See De La Paz v. Bayer Healthcare, LLC*, 159 F. Supp. 3d 1085, 1095 (N.D. Cal. 2016) ("[Plaintiff's] failure to allege a causal link between any adulteration of [defendants'] device and her injuries is fatal to her manufacturing-defect claims."); *Hawkins*, 2014 WL 346622, at *8 ("Plaintiff generally alleges that Defendants failed to report adverse events to the FDA. He also generally alleges that these failures caused or contributed to his injuries. What is not alleged is any factual content that would support the causal nexus."). The FAC also fails to allege any non-conclusory facts explaining how defendants' alleged manufacturing defect and failure to warn resulted in plaintiff's injuries. *See Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678) (noting that, for a complaint to survive a motion to dismiss, "the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief"); *see also Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (finding "impermissibly conclusory and vague" allegations stating that "the [device] contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues, and bacteria remained on the [device] in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA"); *cf. Knoppel v. St. Jude Medical, Inc.*, 2013 WL 12116393, at *3 ("[T]he alleged insulation deficiencies and risks of externalization of the [medical device] can be linked to [plaintiff's] specific injury of electrical

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shocks and subsequent invasive removal surgery; thus, a 'causal nexus' is established.").[5]

Accordingly, the court concludes that plaintiff has not alleged facts stating a facially plausible claim for manufacturing defect or failure to warn.

c. Breach of Warranty Claims

To state a claim for relief for a breach of express warranty, plaintiff must allege: (i) that defendants made an "affirmation or promise" or provided a "description" of the device; (ii) the statement was "part of the basis of the bargain"; and, (iii) defendants breached the warranty. *Weinstat v. Dentsply Int'l, Inc.*, 180 Cal. App. 4th 1213, 1227 (2010); *see also* Cal. Com. Code § 2313(1). However, an "affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Weinstat*, 180 Cal. App. 4th at 1227.

California law also generally requires that a plaintiff asserting a breach of implied warranty claim be in vertical privity with the defendant. *Cardinal Health 301, Inc. v. Tyco Electronics Corp.*, 169 Cal. App. 4th 116, 138 (2009) (citing *Burr v. Sherwin Williams Co*., 42 Cal. 2d 682, 695 (1954)); *see also Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008); *Tietsworth v. Sears*, 720 F. Supp. 2d 1123, 1142 (N.D. Cal. 2010) ("Vertical privity is a necessary element of an implied warranty claim"). "A buyer and seller stand in privity if they are in adjoining links of the distribution chain." *Osborne v. Subaru of Am. Inc.*, 198 Cal. App. 3d

[5] The insufficiency of plaintiff's allegations with respect to causation has been highlighted by defendants who, in moving to dismiss, have included a table listing each of the FDA's regulatory actions and explaining why each fails to have a causal connection to plaintiff's injuries. (Doc. No. 25-1 at 19–20.); *see also Stengel v. Medtronic Inc.*, 676 F.3d 1159, 1160 (9th Cir. 2012), *rev'd en banc on other grounds*, 704 F.3d 1224 (9th Cir. 2013) (finding FDA documents appropriate for judicial notice, since the "accuracy of FDA records cannot reasonably be questioned."). Defendants contend that the FDA documents referred to by plaintiff in his complaint to show FDA violations either involved a different medical device than the one implanted in plaintiff, or occurred prior to plaintiff's 2009 surgery. (*Id.*) The court notes that, while plaintiff's allegations are construed as true for the purpose of analyzing defendants' motion to dismiss, the court can consider "inescapable" contradictions between pleadings and attached exhibits subject to judicial notice. *Estate of Prasad ex rel. Prasad v. Cty. of Sutter*, 958 F. Supp. 2d 1101, 1110–11 (E.D. Cal. 2013); *see also Gonzalez v. Planned Parenthood of Los Angeles*, 759 F.3d 1112, 1116 (9th Cir. 2014) (noting a court may ignore factual allegations in the complaint where "one cannot plausibly conclude" a claim exists in light of a contradiction between the pleadings and an exhibit).

646, 656 n.6 (1988); *see also Clemens*, 534 F.3d at 1023. Thus, an end consumer who purchases a product from a retailer is not in vertical privity with a manufacturer. *Id.*; *see also T&M Solar and Air Conditioning, Inc. v. Lennox International, Inc.*, 83 F. Supp. 3d 855, 874 (N.D. Cal. 2015). There are "particularized exceptions" to this privity requirement. *Clemens*, 534 F.3d at 1023. These exceptions include: "when the plaintiff relies on written labels or advertisements of a manufacturer," as well as "special cases involving foodstuffs, pesticides, and pharmaceuticals." *Id.* (citations omitted).

In their motion to dismiss, defendants argue that plaintiff's allegations in support of his claims based on breach of express and implied warranty do not satisfy federal pleading standards. Defendants contend that plaintiff's breach of express warranty claim fails because plaintiff's FAC does not adequately plead the content of any warranty made by defendants upon which plaintiff relied, or allege when or how any such warranty was made. (Doc. No. 25-1 at 23.) "Such allegations are insufficient to state a plausible claim for breach of warranty," defendants conclude. (*Id.*) Defendants also argue that plaintiff's implied warranty claim fails because plaintiff "did not (and cannot) allege that they are in privity of contract with [defendant] with respect to the sale of the [SynchroMed device]"). (Doc. No. 25-1 at 23 n.10.) In his opposition, plaintiff does not respond to defendants' arguments concerning the sufficiency of his breach of warranty claims. (Doc. No. 36.)

The court concludes that, even if the breach of warranty claims were not preempted, plaintiff has not sufficiently pled facts showing a plausible claim for breach of express or implied warranty. The court first analyzes plaintiff's breach of express warranty claim. In the FAC, plaintiff identifies a number of "warranties" allegedly made by defendants—product labeling, patient package inserts, articles in medical journals, advertising and/or other documents and/or promotional materials. (Doc. No. 18 at 34, ¶ 119.) The FAC also states that "Plaintiff and his physicians relied upon the Defendants' express warranties that [the SynchroMed device] conformed to FDA regulations and specifications [and] was safe and fit for such uses." (Id. at 35, ¶ 120.) However, plaintiff does not allege the contents of any alleged warranties made by defendants. Based on the allegations in the FAC, it is unclear whether the alleged warranties

contained affirmations of fact sufficient to form the basis of an express warranty claim, or whether they simply contained opinions or commendations regarding the Synchromed device. *See Weinstat*, 180 Cal. App. 4th at 1227; *cf. Houston*, 2014 WL 1364455, at *10 ("Regarding the first element [of a breach of express warranty claim]—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."); *Keith v. Buchanan*, 173 Cal. App. 3d 13, 21 (1985) ("Courts have liberally construed affirmations of quality made by sellers in favor of injured consumers"). Plaintiff also fails to plead any non-conclusory allegations as to how any warranties were made to him or his physician, and whether any alleged warranties were relied upon by either. *See Hammarlund v. C.R. Bard, Inc.*, 2015 WL 5826780, at *5 (C.D. Cal. Oct. 2, 2015) (finding plaintiff's express warranty claim insufficiently pled when the complaint alleged only that "Plaintiff, individually and/or by and through is physician, reasonably relied upon Defendants' express warranties and guarantees that the [medical device] was safe, merchantable, and reasonably fit for its intended purpose."). Thus, the allegations supporting plaintiff's express warranty cause of action fail to satisfy federal pleading standards. *See Frere*, 2016 WL 1533524, at *8.

The court next addresses plaintiff's breach of implied warranty claim. The FAC alleges defendants "impliedly warranted to Plaintiff . . . that the [SynchroMed device] was safe and fit for purposes for which they were provided," "of merchantable quality," and manufactured, packaged, and labeled "in accordance with FDA regulations." (*Id.* at 36, ¶ 125.) The FAC does not, however, allege any facts indicating plaintiff and defendants were in adjoining links of the distribution chain for SynchroMed devices. Plaintiff has thus failed to allege facts stating a plausible claim for breach of implied warranty. *See Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1059 (2008) (finding plaintiff's breach of implied warranty claim failed because plaintiff could not allege privity with a heart valve manufacturer); *see also Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1159–60 (S.D. Cal. 2015) (recognizing that there is an exception to the privity requirement for implied warranty claims involving foodstuffs and prescription drugs, but observing the exception does not apply to claims involving implanted medical devices); *Quatela v. Stryker Corp.*, 820 F. Supp. 2d 1045, 1047–48 (N.D. Cal. 2010) (same).

III. State Law Grounds for Dismissal

a. Statute of Limitations

California law provides for a two year statute of limitations governing causes of action premised on personal injury. *See* Cal. Civ. Proc. Code § 335.1. A cause of action typically accrues on the date of the injury. *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1110 (1988); *Pouncil v. Tilton*, 704 F.3d 568, 574 (9th Cir. 2012). However, under the delayed-discovery rule, California law postpones accrual of a claim "until the plaintiff discovers, or has reason to discover" the essential elements of that claim. *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 807 (2005); *see also Tucker v. Baxter Healthcare Corp.*, 158 F.3d 1046, 1049 (9th Cir. 1998). A plaintiff seeking to benefit from the delayed discovery rule has the burden of showing its applicability, and must allege facts demonstrating: (i) the time and manner of discovery and (ii) the inability to have made earlier discovery despite reasonable diligence. *Fox*, 35 Cal. 4th at 808. The question of when accrual occurred under the delayed-discovery rule is generally "a question of fact unless the evidence can support only one reasonable conclusion." *Ovando v. County of Los Angeles*, 159 Cal. App. 4th 42, 61 (2008) (citations omitted); *see also Darringer v. Intuitive Surgical, Inc.*, Case No. 5:15-cv-00300, 2015 WL 6735333, at *2 (N.D. Cal. Nov. 4, 2015).

Defendants argue that even if plaintiff's claims are not preempted they are barred by California's two-year statute of limitations applicable to personal injury actions. (Doc. No. 25-1 at 24–25.) Defendants argue that the FAC alleges plaintiff's symptoms began manifesting themselves in November 2008, but that plaintiff did not file his original complaint in this action until June of 2015, "approximately six and one-half years after his complications allegedly began." (*Id.* at 24.) Defendants also argue that plaintiff cannot invoke the delayed discovery rule because he has not alleged specific facts showing his inability to discover the cause of his injury prior to June 2015. (*Id.*)

Plaintiff denies that the statute of limitations bars his claims. In particular, plaintiff contends that he "did not become aware [of the alleged] wrongdoing [that] caused his injuries until 2013, when the [SynchroMed device] was explanted from his body and his physician

discovered a defective catheter." (Doc. No. 36 at 40–41.) Plaintiff argues that he reasonably relied on information provided by his treating physician in this regard. (*Id.* at 41) (citing *Kitzig v. Nordquist*, 81 Cal. App. 4th 1384, 1393 (2000) (quoting *Sanchez v. South Hoover Hosp.*, 18 Cal. 3d 93, 102 (1976)).

The court concludes that plaintiff has adequately alleged that he was reasonably diligent in discovering the cause of his injury. In the FAC, plaintiff alleges that he received medical attention, and depended on his treating physician to inform him of the cause of his injury. (Doc. No. 18 at 3–8, ¶¶ 15, 17–30.) Plaintiff has thus met his burden of alleging facts that, if proven, would demonstrate the applicability of the delayed discovery rule. *See Regter v. Stryker Corp.*, 607 Fed. Appx. 732, 733 (9th Cir. 2015)[6] (stating that plaintiff's personal injury cause of action was not barred by the statute of limitations because the plaintiff "adequately alleged that he was reasonably diligent in discovering the cause of his injury when he alleged that he sought medical attention and relied on his treating physician to inform him of the injury's cause").

b. California's Unfair Competition Law

"In California, unfair competition claims are subject to the safe harbor doctrine, which precludes plaintiffs from bringing claims based on 'actions the Legislature permits.'" *Ebner v. Fresh, Inc.*, 838 F.3d 958, 963 (9th Cir. 2016) (citing *Cel–Tech Commc'ns, Inc. v. Los Angeles Cellular Tele. Co.*, 20 Cal.4th 163, 182 (1999)). This rule applies both to actions by the California legislature and actions by the U.S. Congress. *See, e.g.*, *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1164 (9th Cir. 2012). For the safe harbor doctrine to apply, the challenged conduct must be "affirmatively permitted by statute—the doctrine does not immunize from liability conduct that is merely not unlawful." *Id.*; *see also Hauk v. JP Morgan Chase Bank USA*, 552 F.3d 1114, 1122 (9th Cir. 2009) ("To forestall an action under the unfair competition law, another provision must actually 'bar' the action or clearly permit the conduct").

In moving to dismiss, defendants argue that even if plaintiff's UCL claims are not subject to federal preemption, they are barred by California's safe harbor doctrine. (Doc. No. 25-1 at 25–

[6] Citation to this unpublished Ninth Circuit opinion is appropriate pursuant to Ninth Circuit Rule 36–3(b).

26.) In opposition, plaintiff argues that the UCL claims are not barred, but does not specifically address defendants' arguments concerning the safe harbor doctrine. (Doc. No. 36 at 38–39.)

As noted above, the FAC does not clearly state whether plaintiff's UCL claim challenges conduct that was previously approved by the FDA during the PMA process, or whether the claim seeks to challenge conduct going beyond that which the FDA approved. *See supra* Section I(g). To the extent that plaintiff's UCL claim challenges conduct previously authorized by the FDA during the PMA process, FDA approval of SynchroMed labeling brings plaintiff's claims within the California safe harbor provision.[7] *See, e.g.*, *Nowrouzi v. Maker's Mark Distillery, Inc.*, No. 14CV2885 JAH (NHS), 2015 WL 4512551, at *2–3 (S.D. Cal. July 27, 2015) (listing cases outside of California that have applied the California safe harbor doctrine to bar suits after a federal agency has reviewed and pre-approved labels for regulatory compliance); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 13-11343-NMG, 2014 WL 866571 *3 (D. Mass. Mar. 5, 2014) (barring claims that a prescription drug label was "misleading and inadequate" based on California's safe harbor provision, given that the labeling received approval from the FDA). As such, the safe harbor doctrine provides an additional ground for dismissal of any UCL claim brought by plaintiff based on such conduct.[8]

IV. Leave to Amend

The court has carefully considered whether plaintiff is capable of further amending the FAC to state cognizable claims for relief. A district court should provide leave to amend upon

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[7] To the extent that plaintiff's UCL claims are premised on conduct that violates federal law, such claims are not barred by the UCL safe harbor rule. *See Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1127 n.5 (N.D. Cal. Sept. 16, 2013) ("[T]o the extent [defendants' conduct] is not [permitted under federal law], there is no basis for shielding that conduct under a safe harbor."); *Samet v. Procter & Gamble Co.*, No. 5:12–CV–01891 PSG, 2013 WL 3124647, at *10 (N.D. Cal. June 18, 2013) ("[A]rguments regarding safe harbor cover the same ground as those regarding federal express preemption."). However, as noted above, *see supra* Section (g), plaintiff's claims premised solely on violations of federal law are nonetheless subject to implied preemption.

[8] Defendants also argue that plaintiff's UCL claims should be dismissed because plaintiff seeks relief in connection with his UCL claims that is unavailable as a matter of law. (*Id.* at 26.) Having found plaintiff's UCL claims barred by the safe harbor provision, the court declines to address defendants' additional arguments concerning proper remedies under the UCL.

granting a motion to dismiss unless it is clear that the complaint could not be saved by any amendment. *See Mueller v. Auker*, 700 F.3d 1180, 1191 (9th Cir. 2012) (citing *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008)). "Valid reasons for denying leave to amend include undue delay, bad faith, prejudice, and futility." *California Architectural Bldg. Prod. v. Franciscan Ceramics*, 818 F.2d 1466, 1472 (9th Cir. 1987); *see also Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1144 (9th Cir. 2015) (leave to amend is properly denied if the proposed amendment lacks merit or would be futile in saving plaintiff's suit); *Klamath–Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1293 (9th Cir. 1983) (holding that while leave to amend shall be freely given, the court does not have to allow futile amendments).

Applying these standards, the court concludes that here it may be possible for plaintiff to re-allege certain claims to avoid preemption and address the pleading deficiencies noted above. Accordingly, the court will grant plaintiff leave to file a second amended complaint to address, where possible, the deficiencies noted in this order. *See Frere*, 2016 WL 1533524, at *7; *Houston*, 957 F. Supp. 2d at 1181 n.12 (granting motion to dismiss with leave to amend after finding that certain claims were preempted by federal law).

CONCLUSION

For the reasons set forth above, the court grants defendants' motion to dismiss (Doc. No. 25), and dismisses plaintiff's claims with leave to amend, specified as follows:

1. Plaintiff's strict products liability claim based on an alleged manufacturing defects is impliedly preempted by the MDA, and is dismissed with leave to amend;
2. Plaintiff's failure to warn claim is expressly preempted by the MDA, and is dismissed with leave to amend;
3. Plaintiff's breach of express warranty claim is expressly preempted by the MDA, and is dismissed with leave to amend;
4. Plaintiff's breach of implied warranty of merchantability claim is impliedly preempted by the MDA, and is dismissed with leave to amend;

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5. Plaintiff's fraud claims based on negligent misrepresentation and concealment are expressly preempted by the MDA, and are dismissed with leave to amend;
6. Plaintiff's failure to train/de facto physician assistants claim is expressly preempted by the MDA, and is dismissed with leave to amend;
7. Plaintiff's UCL claim is impliedly preempted by the MDA and is also barred by the California safe harbor provision, and is dismissed with leave to amend;
8. Plaintiff's Minnesota consumer protection claim is impliedly preempted by the MDA, and is dismissed with leave to amend.
9. Should he wish to pursue this action, plaintiff is granted leave to file a second amended complaint within twenty one days of the date of this order. Failure to file a second amended complaint within the time provided will result in the dismissal of this action.

IT IS SO ORDERED.

Dated: **February 24, 2017**

Dale A. Drozd
UNITED STATES DISTRICT JUDGE