UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JESUS TAPIA, an individual,

Plaintiff,

vs.

DAVOL, INC., a corporation; BARD DEVICES INC., a corporation; C.R. BARD, INC., a corporation, and DOES 1-50,

Defendants.

CASE NO. 15cv179-GPC(JLB)

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT DAVOL, INC'S MOTION TO DISMISS

[Dkt. No. 6.]

Before the Court is Defendant Davol, Inc.'s[1] motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 6.) An opposition was filed on July 9, 2015. (Dkt. No. 10.) A reply was filed on July 17, 2015. (Dkt. No. 12.) Based on a review of the complaint, the briefs and the applicable law, the Court GRANTS in part and DENIES in part Defendant's motion to dismiss.

Factual Background

On January 27, 2015, Plaintiff Jesus Tapia ("Plaintiff") filed a complaint against Defendants Davol, Inc., Bard Devices, Inc., and C.R. Bard, Inc. ("Defendants") for personal injuries suffered as a proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging,

[1]Defendants Bard Devices, Inc. and C.R. Bard, Inc. have not yet been served with the complaint.

promoting, marketing, distribution, labeling, sale, and/or post-market surveillance and corrective action of the Bard Composix Kugel Hernia Repair Patch ("Kugel Patch" or "Patch"). (Dkt. No. 1.) Defendants manufactured and sold the Kugel Patch for use in repairing hernias. (Id. ¶ 2.)

The Kugel Patch at issue was manufactured and sold by Defendants between 2001 and March 2006. (Id. ¶ 22.) The Kugel Patch is a prosthetic device used primarily to repair ventral and inguinal hernias. (Id. ¶ 23.) The Patch is composed of two sides where one side is constructed of a double layer of monofilament polypropylene (mesh), and the other side is a barrier of expanded polytetrafluoroethylene (ePTFE). (Id.) This double layer creates a positioning pocket, in which a polymer "memory recoil ring" is placed. (Id.) During the hernia repair surgery, the Kugel Patch is inserted behind the hernia defect through a small incision. (Id.) The memory recoil ring then allows the Kugel Patch to swing open and maintain its shape during placement. (Id.)

In October 2000, Defendants submitted a section 510(d) notification of intent to market the Kugel Patch with the Federal Drug Administration ("FDA"). (Id. ¶ 24.) The FDA approved the Kugel Patch for marketing as a Class II medical device in January 2001. (Id.) Immediately after the Kugel Patch was placed on the market, Defendants became aware and obtained knowledge it was defective and causing serious injury to those persons in whom it had been implanted. (Id. ¶ 25.)

Defendants were required to conduct post market surveys as part of the device validation process. (Id. ¶ 26.) On or about January 2006, the FDA inspected a Kugel Patch manufacturing facility which resulted in the FDA issuing an Establishment Inspection Report ("2006 EIR"). (Id.) The 2006 EIR found that the post market survey validation process of the device was incomplete and failed to include all data from physicians surveyed during this time, including those which demonstrated unfavorable or "dissatisfied" results. (Id.) According to Plaintiff, these complaints and concerns of physician surveyors were actively concealed by Defendants from Plaintiff, the

healthcare community, and other consumers. (Id.)

No later than September 2004, Defendants became aware of serious problems with the weld process involving the memory recoil ring. (Id. ¶ 27.) Despite attempts to correct the problem, the corrective measures were ineffective and the process was still not in control. (Id.) Defendants were aware that these weld issues had existed from the time the Kugel Patch was placed on the market and all current sizes and lots suffered from this defect. (Id.) Plaintiff alleges this information was intentionally withheld from Plaintiff, the healthcare community, the FDA, and other consumers. (Id.)

According to the 2006 EIR, Davol corporate executives informed the FDA that the spring and summer period of 2005 showed a marked increase in the number of adverse event complaints regarding the Kugel Patch and the memory recoil ring. (Id. ¶ 28.) As of August 2005, Defendants received at least the following adverse event reports: seventeen (17) instances of ring breaks, at least one of which resulted in death; two (2) unexplained bowel perforations; four (4) ring breaks during implant procedures; five (5) cases of device deformity; and eight (8) instances of bowel adhesions to the Patch. (Id.)

Despite the increasing number of complaints and complications arising from the Kugel Patch, Defendants failed to cease distribution or notify Plaintiffs, physicians, hospitals, the FDA, or other consumers of the severity of complications associated with the unreasonably dangerous and defective Kugel Patch until late December 2005. (Id. ¶ 29.)

In December 2005, there was a limited recall of "Extra Large" sized Kugel Patches even though Defendant knew that there were similar serious adverse events as to the nonrecalled Kugel Patch sizes. (Id. ¶ 30.) Defendants also violated federal law by not timely notifying the FDA of the December 2005 recall. (Id.)

The FDA classified the December 2005 recall as a Class 1 recall which is the most serious type of recalls and involve situations where the FDA believes there is a

reasonable probability that use of the product will cause serious injury or death. (Id. ¶ 31.)

The recall was due to the breakage of the memory recoil ring that opens the Kugel Patch, under stress or pressure, including the stress of implantation. (Id. ¶ 32.) The Kugel Patch is also known to become deformed and migrate within the body. (Id.) These defects are known to cause severe injuries including, *inter alia*, perforation of the bowel, ring migration through the abdominal wall, abnormal chronic enteric fistulae, infection, abscesses, bowel obstruction, intense abdominal pain, peritonitis, sepsis, and adhesions between the bowel and the Patch. (Id.) The following conditions are symptoms of these injuries: fever, unexplained or persistent abdominal tenderness, vomiting, abnormal bowel movements, tenderness at implant site, abdominal distention, or other unusual symptoms. (Id.)

On March 24, 2006, Defendants expanded the recall to include the following Kugel Patch sizes: 1) "Oval" Patches, 2) "Large Circle" Patches, and 3) "Large Oval" Patches. (Id. ¶ 34.) In January 2007, Defendants expanded the recall for the second time, to include further production lots of the "Large Oval" and "Large Circle" Kugel Patches. (Id. ¶ 35.)

The FDA inspected the Cranston, Rhode Island Kugel Patch manufacturing facility for the second time from January 23, through March 13, 2007. (Id. ¶ 36.) On April 24, 2007, the FDA issued a "Warning Letter" to Defendants that the inspection again uncovered "serious violations of the law" with regards to the quality assurance programs used in manufacturing the Kugel Patch. (Id.)

These violations were of such a degree and nature that the FDA determined the Kugel Patch to be "adulterated" under section 501(h) of the Federal Food, Drug and Cosmetic Act. (Id.) The warning letter specifically mentions, *inter alia*, the following violations:

a. Failure to establish and maintain adequate corrective and preventative action procedures which ensure identification of actions needed to correct and prevent

the recurrence of nonconforming product and other quality problems;

b. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained;

c. Failure to document the implementation of corrective and preventative actions;

d. Failure to validate your device's design to ensure that the device conforms to defined user needs and intended uses;

e. Failure of your firm to establish procedures to completely address the identification, documentation, evaluation, segregation, disposition and investigation of non-conforming product.

(Id.)

Around December 15, 2005, Plaintiff Jesus Tapia underwent a hernia repair procedure during which a Bard Composix Kugel Hernia Patch (Ref. # 0010202, Lot # 43IPD472) was implanted. (Id. ¶ 37.) On or about January 27, 2013, Plaintiff Jesus Tapia was admitted to the emergency department at Menifee Valley Medical Center. (Id. ¶ 39.) He presented with redness and pain above his Kugel Patch surgical site. (Id.) He was diagnosed with abdominal wall mesh infection and abscess. (Id.) Around February 3, 2013, Plaintiff underwent emergency surgery to remove the Kugel Patch. (Id. ¶ 40.) During the removal procedure, it was noted that the plastic ring that supported the Kugel Patch broke and caused an enterotomy which led to Kugel Patch infection. (Id.)

As a result, Plaintiff will require continuous monitoring of his Kugel Patch related injuries for the remainder of his life. (Id. ¶ 42.) His physical injuries, proximately caused by his implantation with a Kugel Patch, are severe, life threatening, and permanent, and have adversely impacted the quality of his life. (Id.)

Plaintiff alleges that Defendants knew, or in the exercise of reasonable care should have known, prior to the recalls of the Kugel Patch and prior to its implantation into Plaintiff, that the Patch was not properly developed, tested, designed,

manufactured, inspected, marketed, labeled, promoted, distributed and sold, were not suitable for the purpose they were intended, and were unreasonably likely to injure users of the products. (Id. ¶ 45.) Plaintiff also alleges that Defendants did not timely apprise Plaintiffs, the healthcare industry, the FDA, or other consumers of the defective and unreasonably dangerous condition of the Kugel Patch, despite Defendants' knowledge of said condition. (Id. ¶ 46.) Plaintiff further maintains that Defendants misrepresented the known risks inherent in the use of the Kugel Hernia patch. (Id. ¶ 47.)

Discussion

A. Legal Standard on Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure ("Rule") 12(b)(6) permits dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. See Balistreri v. Pacifica Police Dep't., 901 F.2d 696, 699 (9th Cir. 1990). Under Rule 8(a)(2), the plaintiff is required only to set forth a "short and plain statement of the claim showing that the pleader is entitled to relief," and "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint may survive a motion to dismiss only if, taking all well-pleaded factual allegations as true, it contains enough facts to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (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." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "In sum, 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." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009) (quotations omitted). In reviewing a Rule 12(b)(6) motion, the Court accepts as true all facts alleged in the complaint, and draws all reasonable inferences in favor of the plaintiff. al-Kidd v. Ashcroft, 580 F.3d 949, 956 (9th Cir. 2009).

Where a motion to dismiss is granted, "leave to amend should be granted 'unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.'" DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992) (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986)). In other words, where leave to amend would be futile, the Court may deny leave to amend. See Desoto, 957 F.2d at 658; Schreiber, 806 F.2d at 1401.

With the exception of the first count of negligence/products liability, Defendant moves to the dismiss all causes of action which include the following:

1. Count II: Strict Products Liability - Design Defect
2. Count III: Strict Products Liability - Manufacturing Defect
3. Count IV: Strict Products Liability - Failure to Warn
4. Count V: Products Liability - Breach of Implied Warranty of Fitness for a Particular Purpose and Breach of Implied Warranty of Merchantability
5. Count VI: Products Liability - Breach of Express Warranty
6. Count VII: Negligent Misrepresentation
7. Count VIII: Fraud and Deceit

In opposition, Plaintiff withdraws his causes of action for strict products liability - design defect (Count II); and breach of implied warranty of fitness for a particular purpose (subpart of Count V). Accordingly, the Court GRANTS Defendants' motion to dismiss these two causes of action as unopposed.

B. Strict Products Liability - Counts III and IV

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." Anderson v. Owens-Corning Fiberglas Corp., 53 Cal. 3d 987, 994 (1991) (quoting Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 62 (1963)). The goal underlying strict liability is to put the burden on the manufacturers for the costs of any injuries resulting from a defective product instead of the injured persons who lack to power to protect themselves. Id. However, strict liability, was not intended to make a manufacturer of a product its insurer and is not an absolute liability. Id. In California, "strict liability has been imposed for three types of product defects: manufacturing defects, design defects, and 'warning defects.'" O'Neil v. Crane Co., 53 Cal. 4th 335, 347 (2012).

1. Count III - Strict Products Liability - Manufacturing Defect

Defendant argues that Plaintiff does not allege how his Patch deviated from the intended design specifications or how such deviation caused Plaintiff's injuries. Plaintiff asserts that he has sufficiently alleged a manufacturing defect.

A manufacturing defect is "one that differs from the manufacturer's intended result or from other ostensibly identical units of the same line of products." Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 429 (1978). A "manufacturing defect" theory posits that a "suitable design is in place, but that the manufacturing process has in some way deviated from that design." In re Coordinated Latex, 99 Cal. App. 4th 594, 613 (2002). "A manufacturing defect [is] a legal cause of injury only if the defect [is] a substantial factor in producing the injury." Garrett v. Howmedica Osteonics Corp., 214 Cal. App. 4th 173, 190 (2013) (citation omitted).

Contrary to Defendant's argument that Plaintiff only alleges a boilerplate allegation that could be inserted into any products liability complaint, the complaint alleges that Defendants became aware of serious problems with the weld process involving the memory recoil ring causing the ring to break during or after implantation. (Dkt. No. 1, Compl. ¶¶ 27, 32.) Despite corrective measures, the problem persisted. (Id. ¶¶ 27, 28.) Plaintiff asserts that numerous failures were reported to Defendants and

the device was ultimately subject to a Class I recall due to the breakage of the memory recoil ring under stress or pressure. (Id. ¶¶ 28, 30-32.) All Kugel Patches were intended for use in a similar fashion to repair hernias. (Id. ¶¶ 23, 30.) Plaintiff's Patch differed from Defendants' intended result and/or from other identical units of the same product line. (Id. ¶ 81.) Plaintiff also alleges that his Kugel Patch was used in a reasonably foreseeable manner but that Plaintiff's "plastic ring that supported the Kugel Patch broke and caused an enterotomy which led to Kugel Patch infection." (Id. ¶¶ 40, 82.) As a result, Plaintiff suffered severe and permanent physical injuries. (Id. ¶ 83.)

The allegations that the memory coil ring differs from the manufacturer's intended result and that Plaintiff's injuries were due to breakage of the plastic ring inside his Kugel Patch causing him an infection sufficiently state a claim for strict products liability for a manufacturing defect. Accordingly, the Court DENIES Defendant's motion to dismiss the strict products liability for a manufacturing defect.

2. Count IV - Strict Products Liability - Failure to Warn

Defendant maintains that the strict liability failure to warn cause of action is deficient because the complaint does not adequately allege what Defendant failed to warn about or how any such failure caused Plaintiff's alleged injuries. Plaintiff asserts that he has identified the specific nature of defect of Defendant's product, that Defendants were aware of the problem and they failed to provide any labeling or instructions for use that warned of this known defect.

The California Supreme Court has applied strict liability to manufacturers of all products "for failure to warn of known or reasonably scientifically knowable risks . . . ." Carlin v. Superior Court, 13 Cal. 4th 1104, 1109 (1996). "The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Id. at 1112.

California applies the "learned intermediary" doctrine which provides that the duty to warn in the case of medical devices runs to the physician, not the patient. Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 (1992) (prescription implanted medical device case); see also Carlin, 13 Cal. 4th at 1116 (prescription drugs). A manufacturer fulfills its duty to warn if it provides adequate warnings to the physician. Plenger, 11 Cal. App. 4th at 362 n. 6 (citing cases); see also Brown v. Superior Court, 44 Cal.3d 1049, 1062 n. 9 (1998). In order to prove causation, Plaintiff must allege that the inadequate warning or lack of warning about the medical device risk would have altered the prescribing physician's decision to use the product. Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) ("[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician."). The parties do not dispute that the learned intermediary doctrine applies in this case.

Plaintiff alleges Defendants failed to warn about the faulty weld process on the memory recoil ring, which caused it to break, (Dkt. No. 1, Compl. ¶¶ 27, 28, 32), and failed to warn that it failed to comply with FDA minimum safety design requirements and that there were safer alternative treatment methods available. (Id. ¶¶33(g), 36(d).) Specifically, the complaint asserts that the device was subject to a Class 1 recall, because the memory recoil rings inside the device were not strong enough to resist pressure or stress from implantation and/or other forces once permanently implanted, and that once broken, the plastic ring could cause perforations of the bowel and other serious injuries. (Id. ¶¶ 28, 31, 32). Plaintiff further alleges that by September 2004, Defendants were aware of "serious problems with the weld process involving the memory recoil ring" and that despite efforts to correct the problem, Defendants knew "the process was still not in control." (Id. ¶ 27). Plaintiff further asserts that Defendant violated FDA minimum safety regulations by failing to perform strength testing on the memory recoil rings and by failing to establish that the device met user needs. (Id.

¶¶33(g), 36(d).) In the 2006 EIR, the FDA determined that Defendants failed to report adverse events associated with the memory recoil ring breaks and had understated the severity of injuries in other device failure reports, including one possibly related to a patient death. (Id. ¶¶ 33(a), (f).) Based on these allegations, the Court concludes that Plaintiff has sufficiently alleged what Defendant failed to warn about.

As to Defendant's second argument regarding causation, while Plaintiff alleges the specific defect in Defendants' product and specific warnings they failed to provide, he does not allege that Defendants failed to warn *his own* prescribing physician and that *his own* physician would not have used the Patch if warnings had been given. Instead, Plaintiff makes allegations as to "physicians" in general, and the "healthcare community" and does not allege any facts as to his own prescribing physician. (See Dkt. No. 1, Compl. ¶¶ 27, 29, 87, 89.)

Based on the fact that Plaintiff has failed to allege that Defendants failed to warn his prescribing physician[2] and failed to allege that if his prescribing physician had been warned, then he would not have prescribed the Patch to Plaintiff, the Court concludes that Plaintiff has not sufficiently alleged a cause of action for failure to warn under strict products liability. Accordingly, the Court GRANTS Defendant's motion to dismiss the strict products liability - failure to warn cause of action with leave to amend.

C. Breach of Warranty (Count V & VI)

In general, privity of contract is required in an action for breach of express warranty and breach of implied warranty. Burr v. Sherwin Williams Co., 42 Cal. 2d 682, 695 (1954); see also Blanco v. Baxter Healthcare Corp., 158 Cal. App. 4th 1039, 1058-59 (2008). There "is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." Burr, 42 Cal. 2d at 695.

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[2]Plaintiff's argument that the Court can infer, based on all the facts alleged, that Plaintiff's prescribing physician was never made aware of these risks and that his physician would not have used the device if the risks had been disclosed, is without legal support and not persuasive.

As to the implied warranty, California courts have recognized an exception to the privity requirement in cases involving foodstuff "where it is held that an implied warranty of fitness for human consumption runs from the manufacturer to the ultimate consumer regardless of privity of contract." Burr, 42 Cal. 2d at 695. The exception has been extended to drugs and pesticides. Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602, 607 (1960) (vaccine); Arnold v. Dow Chemical Co., 91 Cal. App. 4th 698, 720-21 (2001) (pesticide spray). As to an express warranty claim, the Burr court noted an exception where the "purchaser of a product relied on representations made by the manufacturer in labels or advertising material . . . ." Id. at 696.

In the motion, the parties dispute whether privity of contract is required for the causes of action for breach of the implied warranty of merchantability and breach of express warranty.

1. Breach of the Implied Warranty of Merchantability

Defendant argues privity is a requirement for breach of the implied warranty of merchantability. In opposition, Plaintiff argues that the rationale behind the cases that address the exception to the privity requirement in foodstuff and prescription drug cases should apply to implanted medical devices. Second, he argues there is a distinction between breach of the implied warranty of fitness for a particular purpose, which he concedes requires privity, and breach of implied warranty of merchantability which he argues does not require privity. In reply, Defendant argues that Plaintiff fails to cite and it has not found any authority that distinguishes between the implied warranty of fitness and implied warranty of merchantability in applying the privity requirement.

Plaintiff does not provide any legal support for his argument that the exception to the privity requirement in food stuff and prescription drug cases should apply to the Patch, a medical implant device. Recent cases concerning medical implant devices have held that the implied warranty of merchantability requires privity. Quatela v. Stryker Corp., 820 F. Supp. 2d 1045, 1047-48 (N.D. Cal. 2010) (plaintiff was

implanted with a prescription infusion pump following surgery on her shoulder); Blanco, 158 Cal. App. 4th at 1058-59 (mitral heart valve implant) (citing Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 788 (1994)).[3] The court of appeals explained that, in the context of an implantable medical device, a patient lacks the privity because the patient relies on his/her physician's skill or judgment to provide a suitable product, and cannot seek relief against the manufacturer. Blanco, 158 Cal. App. 4th at 1058-59.

Moreover, Plaintiff has not provided, and the Court has not found cases that distinguish the privity requirement for the implied warranty of fitness and implied warranty of merchantability. The Court agrees with Defendant that courts have applied the privity requirement to both breach of the implied warranty of fitness, and breach of the implied warranty of merchantability. See Blanco, 158 Cal. App. 4th at 1058 (court required privity as to claims for both breach of the implied warranty of merchantability and breach of the implied warranty of fitness for a particular purpose); Fieldstone Co. v. Briggs Plumbing Prods., Inc., 54 Cal. App. 4th 357, 371 (1997) (stating that "[v]ertical privity is a prerequisite in California for recovery on a theory of breach of the implied warranties of fitness and merchantability."); In re ConAgra Foods, Inc., – F. Supp. 3d – (C.D. Cal. Feb. 23, 2015) (in a claim for implied warranty of merchantability, court stated that "California law requires that a plaintiff asserting a breach of implied warranty claim be in vertical privity with the defendant.") (citing Clemens v. Daimler Chrylser Corps., 534 F.3d 1017, 1023 (2008)); McCarty v. Johnson & Johnson, No. 10cv350 OWW-DLB, 2010 WL 2629913, at *6 (E.D. Cal. June 29, 2010) (in a orthopaedic implant case, court stated that "[u]nder California law, privity between parties is required for either claim of implied warranty.").

Accordingly, the Court GRANTS Defendant's motion to dismiss the breach of the implied warranty of merchantability claim with prejudice for lack of privity.

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[3]While Evraets concerned only a breach of the implied warranty of fitness for a particular purpose, no subsequent case has distinguished between the two implied warranties to assert different standards on the issue of privity.

2. Breach of Express Warranty

Defendant argues that the breach of express warranty claim fails because there is no privity alleged. Second, it maintains that Plaintiff fails to allege the elements of a breach of express warranty claim with sufficient facts to assert the exact terms of the warranties, and fails to allege facts to plausibly infer justifiable reliance. Plaintiff argues that the court of appeal in Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 789 n. 4 (1994) ("privity is not a requirement for actions based upon an express warranty") abolished the requirement of privity for express warranty claims.

An express warranty "is a contractual promise from the seller that the goods conform to the promise." Daugherty v. American Honda Motor Co., Inc., 144 Cal. App. 4th 824, 830 (2006). Breach of express warranty requires the exact terms of the warranty, plaintiff's reasonable reliance and a breach which proximately cause plaintiff injury. Williams v. Beechnut Nutrition Corp., 185 Cal. App. 3d 135, 142 (1986).

In general, privity is a required element of a breach of express warranty cause of action. Burr, 42 Cal. 2d at 695. However, privity is not an absolute requirement in express warranty claims. In Burr, the California Supreme Court noted an exception based on a plaintiff's reliance on a seller's representations in labels or advertising materials to provide the basis for an express warranty. Id. at 696; see Dagher v. Ford Motor Co., – Cal. Rptr. 3d –, 2015 WL 4380378, at *12 (Cal. App. July 17, 2015) (California courts have not adhered to a strict application of privity for express warranty claims in products liability cases.).

Since Burr, the California Supreme Court has made statements stating that privity is no longer required in an express warranty claim. Seely v. White Motor Co., 63 Cal. 2d 9, 14 (1965) ("Since there was an express warranty to plaintiff in the purchase order, no privity of contract was required."); Hauter v. Zogarts, 14 Cal. 3d 104, 115 n. 8 (1975) ("The fact that [plaintiff] is not in privity with defendants does not bar recovery. Privity is not required for an action based upon an express warranty."). However, in both cases, the plaintiff, in Seely, relied on a written purchase order, and,

in Hauter, the plaintiff relied on words on a product container. Therefore, the broad statements that privity is no longer a requirement for an express warranty claim are narrowed by the facts of their cases.

Since these cases, California courts of appeal have asserted the continuing viability of privity in a express warranty claim but also assert all the exceptions to the general rule. See Jones v. ConocoPhillips, 198 Cal. App. 4th 1187, 1201 (2011) (quoting Burr for general rule of privity for breach of implied and express warranty but also stating there are "multiple court-created exceptions to the general rule of privity"); Cardinal Health 301, Inc. v. Tyco Elecs. Corp., 169 Cal. App. 4th 116, 143-44 (2008) ("Privity is generally not required for liability on an express warranty because it is deemed fair to impose responsibility on one who makes affirmative claims as to the merits of the product, upon which the remote consumer presumably relies.");Fieldstone Co. v. Briggs Plumbing Prods., Inc., 54 Cal. App. 4th 357, n. 10 (1997) ("As a general rule, privity of contract is a required element of an express breach of warranty cause of action. However, there is an exception where plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials."); Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 789 n. 4 (1994) (citing Seely for the proposition that "privity is not a requirement for actions based upon an express warranty"); Fundin v. Chicago Pneumatic Tool Co., 152 Cal. App. 3d 951, 957 (1984) ("when a consumer relies on representations made by a manufacturer in labels or advertising material, recovery is allowable on the theory of express warranty without a showing of privity).

Defendant argues that the footnote in the Evraets case where the court stated "privity is not a requirement for actions based upon an express warranty" is not binding and cites to post-Evraets cases that still require privity in a claim for breach of express

warranty claim.[4] Plaintiff argues that the broad statement in the Evraets case essentially abolishes the privity requirement.

After a review of the caselaw, the Court concludes that Plaintiff's argument that Evraets abolishes the privity requirement is too simplistic and does not consider the development of the exceptions to the privity requirements for express warranty cases due to the development of the doctrine of strict liability. See Jones, 198 Cal. App. 4th at 1201 ("Whether these cases [concerning exceptions to the general rule] are viewed as expanding the doctrine of privity or relieving a plaintiff of the obligation to demonstrate privity in favor of the emerging tort doctrine of strict liability . . . the result is the same.")

Whether privity has been abolished for express warranty claims is not dispositive in this case because the complaint alleges an exception to the general rule that privity is required. Here, Plaintiff alleges an express warranty based on the manufacturer's written representations in labels and written advertising materials. (Dkt. No. 1, Compl. ¶ 109.) Therefore, Plaintiff's express warranty claim, as alleged, does not require privity of contract. See Fundin, 152 Cal. App. at 957.

The Court further concludes that the "learned intermediary" rule applies to a breach of express warranty claim predicated on a failure to warn claim. See Carlin, 13 Cal. 4th at 1118 (holding that breach of warranty claim predicated on an allegation of failure to warn could not be dismissed for failure to state a claim, but that the claims were subject to the learned intermediary doctrine). Under the "learned intermediary"

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[4] However, the cases cited by Defendant are consistent with the California caselaw on express warranties and do not support Defendant's argument. For example, in Cellars v. Pacific Coats Packaging, Inc., 189 F.R.D. 575, 579-80 (N.D. Cal. 1999), the district court noted that based on California law, privity of contract remains a requirement in express warranty claims unless one of the exceptions to the general rule applies. Id. In Cellars, the plaintiff was a producer of blended wine alcohol cocktails and purchased plastic bottles from the defendant. The plaintiff filed a complaint alleging the bottles were defective because they bulged when filled. Id. at 577. In Cellars, there was no contract and the exception to the rule where a manufacturer warrants its products in "labels or advertising material" did not apply. Id. at 580. Therefore, the district court held that privity of contract was required on the breach of express warranty cause of action and dismissed the cause of action. Id.

doctrine, the express warranties run to the physician, and not to Plaintiff. Plenger, 11 Cal. App. 4th at 362. The complaint fails to allege that Plaintiff's prescribing physician read and relied on the express warranties contained in the packaging and written advertisements. Plaintiff only alleges that the "healthcare community" relied on the express warranties in the packaging and written advertisements. (See Dkt. No. 1, Compl. ¶ 112.) Therefore, Plaintiff fails to allege reliance on the express warranties, and therefore, the claim shall be dismissed.

As to whether the complaint alleges the terms of the express warranty, the complaint alleges that "Defendants expressly warranted that the Kugel Patch was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use." (Dkt. No. 1, Compl. ¶ 109.) It also alleges that Defendants expressly warranted that the side effects it did produce were accurately reflected in the warnings and did not pose dangerous health risks greater than those risk associated with other similar hernia repair devices. (Id. ¶ 114.) The Court concludes that these allegations sufficiently allege the terms of the express warranty.

Thus, the Court GRANTS Defendant's motion to dismiss breach of express warranty claim with leave to amend.

D. Fraud Based Claims - Negligent Misrepresentation and Fraud/Deceit

Plaintiff alleges causes of action for negligent misrepresentation (Count VII) and fraud and deceit which Plaintiff construes as "fraudulent concealment" and "fraudulent misrepresentation" (Count VIII).

Defendant asserts that Plaintiff has failed to satisfy the heightened pleading requirement under Federal Rule of Civil Procedure 9(b). Plaintiff contends that it has sufficiently alleged facts for the fraudulent concealment; however, seeks leave to supplement his pleadings as to his affirmative misrepresentation claims once he has the opportunity to depose the prescribing physician.

Where a plaintiff alleges fraud in the complaint, Rule 9(b) requires a plaintiff to

"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). A party must set forth "the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." Odom v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007) (internal quotation marks omitted). Rule 9(b) also applies to claims that are "grounded in fraud" or "sound in fraud." Vess v. Ciba-Geigy Corp., U.S.A., 317 F.3d 1097, 1103-04 (9th Cir. 2003).

As to multiple fraud defendants, a plaintiff "must provide each and every defendant with enough information to enable them 'to know what misrepresentations are attributable to them and what fraudulent conduct they are charged with.'" Vegas v. JPMorgan Chase Bank, N.A., 654 F. Supp. 2d 1104, 1115 (E.D. Cal. 2009) (quoting Pegasus Holdings v. Veterinary Centers of America, Inc., 38 F. Supp. 2d 1158, 1163 (C.D. Cal. 1998)). A plaintiff cannot lump multiple defendants but must state the allegations as to each defendant separately concerning that defendant's alleged participation in the fraud. Swartz v. KPMG LLP, 476 F.3d 756, 764-65 (9th Cir. 2007) (quotation omitted). In a fraud action against a corporation, a plaintiff must "allege the names of the persons who made the allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written." Tarmann v. State Farm Mut. Auto. Ins. Co., 2 Cal. App. 4th 153, 157 (1991).

First, Plaintiff improperly lump the three corporate defendants together as "Defendants" without specifying which Defendant did what. Moreover, as to each Defendant corporation, a plaintiff must allege the names of people who made the fraudulent misrepresentations and the content of the misrepresentation. See id. Plaintiff's failure to allege facts as to each of the three corporate Defendants requires dismissal of these causes of action.

"The required elements for fraudulent concealment are (1) concealment or suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing

or suppressing the fact; (4) the plaintiff was unaware of the fact and would not have acted as he or she did if he or she had known of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of the concealment or suppression of the fact." Graham v. Bank of America, N.A., 226 Cal. App. 4th 594, 606 (2014) (citation omitted).

The Ninth Circuit has held that claims of nondisclosure and omissions are subject to the pleading standard of Rule 9(b). Kearns v. Ford Motor Co., 567 F.3d 1120, 1126-27 (9th Cir. 2009). "To plead the existence of an omission sufficient to support a fraudulent concealment claim, a plaintiff 'must describe the content of the omission and where the omitted information should or could have been revealed.'" Erickson v. Boston Scientific Corp., 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (quoting Marolda v. Symantec Corp., 672 F. Supp. 2d 992, 1005 (N.D. Cal. 2009) (holding that a plaintiff must also provide "representative samples of advertisements, offers, or other representations that plaintiff relied on to make her purchase and that failed to include the allegedly omitted information.")).

As to the claim for fraudulent concealment, the Court concludes that Plaintiff has sufficiently alleged "what" was concealed, "when" it was concealed and "why" it was concealed. Specifically, Plaintiff alleges that Defendants concealed that there was a problem with the welds on the memory recoil rings that were causing them to break, (id. ¶¶ 25, 27, 32), that these failures caused bowel perforations and other serious injuries, (id. ¶ 32), that in violation of federal law, Defendants failed to test the strength of the welds on the memory recoil rings before marketing the product and failed to ensure the device would be safe, (id. ¶¶ 33(g), 59(c)), and that there were safer alternative devices, (id. ¶ 59(e). This information was not disclosed on their labeling materials and instructions for use distributed with the device. (Id. ¶¶ 94, 130, 131.) The complaint alleges that Defendants knew about the defect and concealed it prior to the device being implanted in Plaintiff on December 15, 2005, (id. ¶¶ 5, 27, 28, 29), and concealed the information in order to induce health care providers to continue to

purchase and use the device. (Id. ¶ 135.)

While Plaintiff has alleged what, when and why as to the concealment, Plaintiff fails to assert facts as to causation alleging that *his own* prescribing physician would not have used the device had Defendants not concealed these facts. See Jones v. Medtronic,– F. Supp. 3d –, 2015 WL 1004667, at *9 (D. Az. Mar. 6, 2015) (granting motion to dismiss fraud claim since there was no allegation the defendant fraudulent induced *her doctor* to use defendants products in *her* surgeries). Therefore, the fraudulent concealment cause of action should also be dismissed for this reason.

On the fraudulent concealment count, Plaintiff argues he should be subject to a relaxed Rule 9(b) standard where facts constituting fraud are particularly within the defendant's knowledge and are otherwise inaccessible to the plaintiff. See United States v. Smithkline Beecham Clinical Labs., 245 F.3d 1048, 1052 (9th Cir. 2001) (declining to apply lenient standard where the plaintiff was employed at defendant's company for 20 years) (citing Wool v. Tandem Computers, Inc., 818 F.2d 1433, 1439 (9th Cir. 1987) and Deutsch v. Flannery, 823 F.2d 1361, 1366 (9th Cir. 1987)).

The lenient standard applies to securities fraud cases. Deutsch, 823 F.2d at 1366. The cases cited by the court in Smithkline Beecham, demonstrate that even under a lenient standard, the complaint still requires some form of specific facts to support fraud allegations. In Wool, although the facts were based on information and belief, each alleged misstatements and acts of fraud were very precise and were identified "by content, date, and the document or announcement in which it appeared." Wool, 818 F.2d at 1439-40. In Deutsch, under a lenient Rule 9(b) standard in a securities fraud case, the court determined that defendants received precise statements of what they allegedly failed to disclose. Deutsch, 823 F.2d at 1366.

It is not clear whether a relaxed Rule 9(b) standard would apply in this products liability case and Plaintiff has not provided legal authority to support his position. However, the Court need not determine whether a lenient Rule 9(b) standard should apply since the Court has concluded that Plaintiff has sufficiently alleged facts to

support the specific facts of what information was concealed. Plaintiff has only failed to assert causation and the role of each Defendant in the concealment. Accordingly, the Court GRANTS Defendant's motion to dismiss the fraudulent concealment count with leave to amend.

Fraudulent misrepresentation requires "(1) the defendant represented to the plaintiff that an important fact was true; (2) that representation was false; (3) the defendant knew that the representation was false when the defendant made it, or the defendant made the representation recklessly and without regard for its truth; (4) the defendant intended that the plaintiff rely on the representation; (5) the plaintiff reasonably relied on the representation; (6) the plaintiff was harmed; and (7) the plaintiff's reliance on the defendant's representation was a substantial factor in causing that harm to the plaintiff." Graham, 226 Cal. App. 4th at 606 (citation omitted). Negligent misrepresentation requires "(1) the misrepresentation of a past or existing material fact, (2) without reasonable ground for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) justifiable reliance on the misrepresentation, and (5) resulting damage." Apollo Capital Fund, LLC v. Roth Capital Partners, LLC, 158 Cal. App. 4th 226, 243 (2007) (citation omitted).

As to the affirmative misrepresentation claims, Defendant argues that the complaint fails to allege the specific contents of the misrepresentations, when and where Defendants allegedly made them, and to whom they were made and why they are false, and do not specify which Defendant made which misrepresentation. Plaintiff appears to concede that his affirmative misrepresentation claim does not meet the heightened Rule 9(b) pleading requirement because he seeks leave to supplement this claim once he has the opportunity to depose the prescribing physician. The Court agrees with Defendant that Plaintiff has failed to allege facts with sufficient particularity under Rule 9(b) where the complaint does not allege the specific content of the misrepresentations, where they are located, and when and where the misrepresentations were made and who made them.

Accordingly, the Court GRANTS Defendant's motion to dismiss the fraudulent concealment, fraudulent misrepresentation and negligent misrepresentation counts with leave to amend.

E. Leave to Amend

In his opposition, Plaintiff seeks leave to amend if the Court dismisses any of his claims. Leave to amend, whether or not requested by the plaintiff, should be granted unless amendment would be futile. Schreiber Distrib. Co., 806 F.2d at 1401. Here, the Court grants Plaintiff leave to amend his claims of strict products liability - failure to warn, breach of express warranty, and fraud causes of action. As to the claim for breach of the implied warranty of merchantability, the Court denies Plaintiff leave to amend since a proposed amendment would be futile. See id.

Conclusion

Based on the above, the Court GRANTS in part and DENIES in part Defendant Davol, Inc.'s motion to dismiss. Specifically:

1. The Court GRANTS Defendant's motion to dismiss the claims for strict products liability - design defect (Count II); and breach of the implied warranty of fitness for a particular purpose (Count V) as unopposed.

2. The Court GRANTS Defendant's motion to dismiss the breach of the implied warranty of merchantability (Count V) without leave to amend.

3. The Court GRANTS Defendant's motion to dismiss strict products liability - failure to warn (Count IV); breach of express warranty (Count VI); and fraud causes of action (Counts VII & VIII) with leave to amend.

4. The Court DENIES Defendant's motion to dismiss the cause of action for strict products liability - manufacturing defect (Count III).

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Plaintiff shall file an amended complaint no later than **August 14, 2015.** The hearing set for July 31, 2015 shall be **vacated.**

IT IS SO ORDERED.

DATED: July 28, 2015

HON. GONZALO P. CURIEL
United States District Judge