UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

CARMA WOODS,

Plaintiff,

v.

DAVOL, INC.; BARD DEVICES, INC.; C.R. BARD; and DOES[1] 1–10, inclusive,

Defendants.

No. 16-cv-02616-KJM-CKD

ORDER

Plaintiff Carma Woods sues the manufacturers of a hernia surgical mesh she says injured her due to a manufacturing defect. The manufacturers, defendants Davol, Inc., Bard Devices Inc., and C.R. Bard, Inc. (collectively, "defendants"), move to dismiss all claims in the operative complaint. Mot., ECF No. 12. Woods opposes the motion. Opp'n, ECF No. 15. For the reasons explained below, the court DENIES the motion.

[1] The Ninth Circuit provides "plaintiff[s] should be given an opportunity through discovery to identify . . . unknown defendants" "in circumstances . . . 'where the identity of the alleged defendant[] [is] not [] known prior to the filing of a complaint.'" *Wakefield v. Thompson*, 177 F.3d 1160, 1163 (9th Cir. 1999) (fourth, fifth, and sixth alterations in original) (quoting *Gillespie v. Civiletti*, 629 F.2d 637, 642 (9th Cir. 1980)). Plaintiff is cautioned that such defendants will be dismissed where "it is clear that discovery would not uncover the identities, or that the complaint would be dismissed on other grounds." *Id*. (quoting *Gillespie*, 629 F.2d at 642). Federal Rule of Civil Procedure 4(m) provides for dismissal of defendants not served within 90 days of filing of the complaint unless plaintiff shows good cause. *See Glass v. Fields*, No. 1:09-cv-00098-OWW-SMS PC, 2011 U.S. Dist. LEXIS 97604, at *2–3 (E.D. Cal. Aug. 31, 2011); *Hard Drive Prods. v. Does*, No. C 11-01567 LB, 2011 U.S. Dist. LEXIS 109837, at *2–4 (N.D. Cal. Sep. 27, 2011).

I. BACKGROUND

A. Procedural Background

Woods filed the original complaint on November 2, 2016, and the operative First Amended Complaint on November 23, 2016. Compl., ECF No. 1; First Am. Compl. ("FAC"), ECF No. 8. On January 12, 2017, defendants filed the motion to dismiss and a request for judicial notice. Mot.; Req. for Judicial Notice ("RJN"), ECF No. 13. Woods opposed the motion and objected to the request. Opp'n; Obj. to RJN, ECF No. 15-2. Defendants replied to each. Reply, ECF No. 16; Reply to RJN, ECF No. 17. On March 24, 2017, the court held a hearing on the motion, at which Kristy Arevalo appeared for Woods and Michelle Cheng appeared for defendants. ECF No. 23.

B. Request for Judicial Notice

Defendants ask the court to take judicial notice of their surgical product's instructions for use ("IFU"). RJN. Because plaintiffs do not challenge the authenticity of the IFU, *see* Obj. to RJN, which defendants assert they prepared and submitted to the FDA as part of the approval process for the product, *see* RJN, the court GRANTS the request. *See Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010) (recognizing the doctrine of incorporation extends to documents where the contents of the document are alleged in a complaint, the document's authenticity is not in question, and there are no disputed issues as to the document's relevance).

C. Factual Allegations

1. The Kugel Patch and Design

Defendants designed the Bard® Composix® Kugel® Hernia Patch ("Kugel Patch") to repair patients' hernias. FAC ¶ 12. A hernia occurs when an organ, intestine or fatty tissue squeezes through a hole or a weak spot surrounding muscles or connective tissue. *Id.* ¶ 10. Hernias often occur at the abdominal wall and are sometimes visible as an external bulge. *Id.* The Kugel Patch is placed inside the abdominal wall, which in turn puts pressure on the body to assist in holding the patch in place over the patient's hernia defect. *Id.* ¶ 12. The Kugel Patch is a two-sided "dual mesh," with an adhesive side designed to face the abdominal wall and a non-

adhesive side designed to face the bowels. *Id.* ¶ 16. The Patch includes a memory recoil ring that allows the Patch to re-deploy after it is folded and inserted through a small abdominal incision during placement. *Id.* ¶ 15.

In January 2001, the FDA approved the Kugel Patch for marketing as a Class II medical device.[2] *Id.* ¶ 14.

2. Defects and Recalls

As a result of a manufacturing defect present in the Kugel Patch, the adhesive side of the Patch sometimes comes into contact with other organs when it is folded over, wrinkled during placement, or pulled away from the patient's abdominal wall, which can cause the bowels to contort and cause the mesh to adhere to vital organs. *Id.* ¶ 18. When this happens, it can be impossible for surgeons to remove the Kugel Patch without also removing large portions of the patient's bowel, which can lead to complications including death. *Id.* ¶ 19. As a result of another manufacturing defect, the memory recoil ring occasionally fails in one of a number of ways, including pulling apart at the weld, breaking away from the weld, bending and folding across from the weld, and separating or tearing away from the Patch's other material. *Id.* ¶¶ 20–21. When this happens, parts of the Patch can pierce or perforate parts of the body or adhere to organs and lead to complications. *Id.* ¶¶ 22–23.

Defendants first learned about a ring break in the Kugel Patch in 2003. *Id.* ¶ 25. After finding additional reported ring breaks, defendants stopped production of the Extra Large Kugel Patch in August 2005 and issued a voluntary recall of three product varieties of the Patch in December 2005. *Id.* ¶¶ 26–31. By March 24, 2006, defendants' recall included several sizes of the X-Large Oval, Large Oval and Large Circle varieties. *Id.* ¶¶ 34–35. On January 10, 2007, defendants expanded the recall to include all sizes of the Large Oval and Circle varieties, including the variety implanted in Woods. *Id.* ¶ 35 & n.6.

[2] The FDA assigns medical devices to one of three classes based on the level of regulatory control necessary to assure the safety and effectiveness of the device. *Classify Your Medical Device*, U.S. Food & Drug Admin., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ (last visited June 2, 2017). Class II is the intermediate level. *See id.*

3. Regulatory Action

After defendants' initial recalls in late 2005, the FDA issued an Establishment Inspection Report ("EIR") that reviewed defendants' post market survey validation process. *Id.* ¶ 36. The EIR found defendants' validation process was incomplete as it lacked data from some physicians' surveys. *Id.*

After defendants' full recall in January 2007, the FDA conducted an investigation of defendants' manufacturing facility and observed "serious regulatory problems" involving the Kugel Patch. *Id.* ¶ 46. As a result, the FDA found the Kugel Patch to be an "adulterated device" under the Federal Food, Drug and Cosmetic Act ("FDCA"). *Id.* ¶ 47. On April 24, 2007, the FDA issued a letter warning defendants they had violated federal regulations and established inadequate processes to prevent, identify and control non-conforming products. *Id.* ¶ 48.

4. Woods' Experience and Claims

On December 13, 2006, plaintiff Woods underwent a hernia repair procedure that used defendants' large[3] Kugel Patch. *Id.* ¶ 54.

Approximately eight years later, Woods began to experience abdominal pain, distention, nausea and vomiting, among other symptoms. *Id.* ¶ 57. A November 8, 2014 CT scan revealed Woods' small bowel was obstructed, and Woods underwent exploratory laparotomy[4] surgery the next day. *Id.* ¶¶ 57–58. During the procedure, doctors found the Patch in the anterior abdominal fascia and discovered it had extensively adhered to the small bowel, "particularly at the edge of the Kugel mesh where there was a [] ring that was quite stiff and [was] invading into several loops of [Woods'] small bowel." *Id.* ¶ 58 (first and second alteration in original). After separating the Patch from Woods' small bowel, doctors observed the small bowel change colors from dark purple to pink and Woods' blood pressure dramatically improve. *Id.* ¶¶ 58–59. The next day, Woods experienced further bowel obstruction and underwent another

[3] The complaint does not clarify whether doctors implanted a Large Oval or Large Circle, or some other variety of Kugel Patch. *See* FAC ¶¶ 35 n.6, 54.

[4] A laparotomy is an "incision into the loin." *Laparotomy*, Stedman's Medical Dictionary (28th ed. 2014).

procedure. *Id.* ¶ 60. During the November 10, 2014 procedure, doctors continued to separate and remove portions of the small bowel that had adhered to the Kugel Patch. *Id.* ¶ 61.

Woods filed this case on November 2, 2016, bringing four claims against all defendants in the operative complaint: (1) Negligence; (2) Strict Products Liability (Manufacturing Defect); (3) Strict Products Liability (Inadequate Warning); and (4) Negligent Misrepresentation. *Id.* ¶¶ 71–128.

II. MOTION TO DISMISS

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a party may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." A court may dismiss "based on the lack of 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).

Although a complaint need contain only "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), in order to survive a motion to dismiss this short and plain statement "must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint must include something more than "an unadorned, the-defendant-unlawfully-harmed-me accusation" or "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action.'" *Id.* (quoting *Twombly*, 550 U.S. at 555). Determining whether a complaint will survive a motion to dismiss for failure to state a claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Ultimately, the inquiry focuses on the interplay between the factual allegations of the complaint and the dispositive issues of law in the action. *See Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984).

In making this context-specific evaluation, this court must construe the complaint in the light most favorable to the plaintiff and accept as true the factual allegations of the complaint. *Erickson v. Pardus*, 551 U.S. 89, 93–94 (2007). This rule does not apply to "a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), nor to

"allegations that contradict matters properly subject to judicial notice" or to material attached to or incorporated by reference into the complaint, *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988–89 (9th Cir. 2001). A court's consideration of documents attached to a complaint or incorporated by reference or matter of judicial notice will not convert a motion to dismiss into a motion for summary judgment. *United States v. Ritchie*, 342 F.3d 903, 907–08 (9th Cir. 2003); *Parks Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). *But cf. Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002) (noting that even though court may look beyond pleadings on motion to dismiss, generally court is limited to face of the complaint on 12(b)(6) motion).

III. DISCUSSION

Defendants move to dismiss all four claims of the first amended complaint and to dismiss Woods' request for punitive damages. *See* Mot. The court addresses each claim separately and then turns to punitive damages.

A. Negligence (Claim 1)

To prevail on a negligence claim, a plaintiff must allege (1) a legal duty, (2) a breach of that duty, (3) causation and (4) damages. *Hammarlund v. C.R. Bard, Inc.*, No. 2:15-cv05506-SVW-JEM, 2015 WL 5826780, at *3 (C.D. Cal. Oct. 2, 2015) (citing *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465 (2001)). Because defendants broadly challenge each of these elements, Mot. at 10–14, the court addresses them in turn.

Under California law, a manufacturer owes a duty of care to foreseeable users of its product. *Bettencourt v. Hennessy Indus., Inc.*, 205 Cal. App. 4th 1103, 1118 (2012). Here, Woods alleges defendants' product is intended for use in hernia repair surgeries and the product was used in her own hernia repair. FAC ¶¶ 12, 54. Woods has sufficiently pled she was a foreseeable user of the product and that defendants owed a duty to her.

A manufacturer breaches its duty where it "did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." *Carlin v. Super. Court*, 13 Cal. 4th 1104, 1112 (1996). Here, the complaint alleges defendants were aware of a growing number of

complaints regarding the effectiveness and safety of the Kugel Patch and yet did not warn of defects or issue a recall in a timely manner. FAC ¶¶ 18–48. Specifically, defendants first learned of a ring break in 2003, *id.* ¶ 24, and discovered an increasing number of complaints regarding the Kugel Patch long before Woods' surgery on December 13, 2006, *id.* ¶¶ 26–29, but recalled and warned doctors of the risks associated with the type of Kugel Patch implanted in Woods only on January 10, 2007, *id.* ¶ 35. Woods has sufficiently pled defendants breached their duty. *See Jager v. Davol Inc.* (*Jager II*), EDCV 16-1424 JGB (KKx), 2017 WL 696081, at *3 (C.D. Cal. Feb. 9, 2017) (finding similar allegations sufficient to establish breach).

The above timeline also supports the element of causation. Woods alleges her surgeon would not have implanted the Kugel Patch had the surgeon known about the risks associated with the product. FAC ¶ 70. As a result, had defendants recalled the product just one month earlier, Woods would not have been harmed. Woods' case is distinguishable in this respect from *Jager II*, which found causation lacking. 2017 WL 696081, at *3. In *Jager II*, the court found Ms. Jager's October 2004 surgery implanting the Extra Large Kugel Patch occurred prior to defendants' first awareness of large-scale problems with the Kugel Patch in 2005. *Id.* at *4. In contrast, Woods' December 2006 surgery occurred well after 2005, and defendants could have recalled the product in time to prevent her use of the product. Woods has sufficiently pled causation.

Finally, Woods has sufficiently pled damages based on health complications and the multiple surgeries she had in 2014 due to her experience with the defective product. *Id.* ¶ 82.

Woods has sufficiently pled all elements of her negligence claim. The court DENIES the motion to dismiss this claim.

B. Manufacturing Defect (Claim 2)

A manufacturer is strictly liable for injuries caused by a product that is (1) defectively manufactured, (2) defectively designed or (3) distributed without adequate instructions and warnings of its potential for harm. *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 428 (1978).

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To adequately plead a manufacturing defect claim, a plaintiff must demonstrate that the product caused a plaintiff's injury because it deviated from the manufacturer's intended result or from other ostensibly identical units of the same product line. *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1335 (C.D. Cal. 1987) (citing *Barker*, 20 Cal. 3d at 429). The "manufacturing defect" theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *Schwartz v. Wright Med. Tech., Inc.* (*Schwartz II*), No. EDCV 14-01615 JGB (SPx), 2014 WL 11320637, at *4 (C.D. Cal. Sept. 11, 2014) (quoting *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 605 (2002)). The allegations should "elucidate[] the manner in which [p]laintiff's . . . implant differed from [d]efendants' intended design." *Schwartz v. Wright Med. Tech., Inc.* (*Schwartz I*), EDCV 14-01615 JGB (SPx), 2015 WL 12781704, at *3 (C.D. Cal. Jan. 27, 2015).

Defendants move to dismiss the manufacturing defect claim because, they say, Woods has not identified the manufacturing defect that her Kugel Patch exhibited. Mot. at 14-15. But Woods first describes a defect by which the adhesive side of the Kugel Patch "comes into contact with other organs when it [is] folded over, wrinkled during placement or pulled away from the patient's abdominal wall, which can cause the bowels to contort and/or cause the mesh to adhere to vital organs." FAC ¶ 18. She next describes several ways the memory recoil ring can fail, including "pulling apart at the weld, breaking away from the weld, bending and folding across from the weld, and separating or tearing away from patch's other material." *Id.* ¶¶ 20–21.

In Woods' case, her pleadings put both defects at issue. First, the operating surgeon found the Kugel Patch had pulled away, was in the anterior abdominal fascia and formed "extensive adhesions" to the small bowel. *Id.* ¶ 58. Second, the surgeon found the memory recoil ring to be "quite stiff" and "invading into several loops of [Woods's] small bowel." *Id.* The Patch's relocation and the memory ring's failure sufficiently allege Woods' Patch deviated from defendants' intended result of "reconstruct[ing] soft tissue deficiencies, such as for repair of hernias and chest wall defects," *id.* ¶ 86, and differed from other units in these respects, *id.* ¶ 91. The allegations based on the surgeon's report are thus sufficient at this stage to "elucidate[] the

manner in which [p]laintiff's . . . implant differed from [d]efendants' intended design." *Schwartz I*, 2015 WL 12781704, at *3.

Woods has sufficiently pled the existence of a manufacturing defect. The court DENIES the motion to dismiss this claim.

C. Inadequate Warning (Claim 3)

Woods' third claim alleges defendants failed to adequately warn Woods' surgeon of the true risks of the Kugel Patch, including that the "implant was more likely to fracture, migrate, perforate, adhere to and obstruct vital organs and/or become infected after its implantation." FAC ¶¶ 102–05. This claim is different from Woods' negligence failure-to-warn claim: Whereas negligence law "requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care," 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." *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112 (1996). 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); *see also Carlin*, 13 Cal. 4th at 1116. 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 (1988).

Defendants move to dismiss Woods' claim because they claim their warnings were adequate. Mot. at 15–17. Whether a warning is adequate is generally a question of fact, *Schwoerer v. Union Oil Co.*, 14 Cal. App. 4th 103, 111 (1993), which is usually left to the jury, *Jackson v. Deft, Inc.*, 223 Cal. App. 3d 1305, 1320 (1990). Defendants do not cite any case that decides this issue at the pleadings stage. *See* Mot. at 15–16 (citing *Dash v. Roche Laboratories*, 74 F.3d 1245 (9th Cir. 1996) (affirming summary judgment); *Temple v. Velcro USA, Inc.*, 148 Cal. App. 3d 1090 (1983) (same)). And whether defendants adequately warned of the risks involved in using the Kugel Patch is not susceptible to resolution at this stage. Defendants'

Instructions for Use lists numerous "possible complications," including "adhesions." *See* IFU. Although the Kugel Patch adhered to Woods' small bowel, FAC ¶ 58, the IFU does not warn of the defects that would cause such adhesions, such as the Patch's relocation or the memory recoil ring's failure. *Compare* IFU *with* FAC ¶ 58. Whether defendants should have warned of these specific risks, whether those risks were known or knowable when defendants manufactured Woods' Kugel Patch, and whether defendants' general "adhesions" warning was adequate are all issues of fact. *See Carlin*, 13 Cal. 4th at 1116. The court cannot resolve them here.

In sum, Woods has sufficiently pled defendants' failure to adequately warn, and defendants have not shown their warning was sufficient so as to preclude Woods' claim from moving forward. The court DENIES the motion to dismiss this claim.

D. Negligent Misrepresentation (Claim 4)

In order to state a claim for negligent misrepresentation, a plaintiff must show defendants: (1) made a 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. *Anschutz Corp. v. Merrill Lynch and Co. Inc.*, 785 F. Supp. 2d 799, 822 (N.D. Cal. 2011) (quoting *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 243 (2007)).

The Ninth Circuit has not decided whether Federal Rule of Civil Procedure 9(b), which imposes heightened pleading requirements on claims of "fraud or mistake," applies to negligent misrepresentation claims. *Jager v. Davol Inc. (Jager I*), EDCV 16-1424 JGB (KKx), 2016 WL 6157942, at *6 (C.D. Cal. Oct. 20, 2016); *compare Miller v. Int'l Bus. Mach. Corp.*, 138 Fed. App'x 12, 17 (9th Cir. 2005) (unpublished decision) (applying Rule 8 to negligent misrepresentation claim), *with In re iPhone 4s Consumer Litig.*, 637 Fed. App'x 414, 415 (9th Cir. 2016) (unpublished opinion) (applying Rule 9(b)). District courts have split on the question.[5]

[5] When the undersigned has had occasion to decide the issue, she has applied Rule 9(b). *Compare Lac v. Nationstar Mortg. LLC*, 2:15-cv-00523-KJM-AC (TEMP), 2016 WL 1212582, at *3 (E.D. Cal. Mar. 28, 2016) (recognizing split of authority), *and Wilson v. Household Fin. Corp.*, CIV S-12-1413 KJM AC, 2013 WL 1310589, at *5 (E.D. Cal. Mar. 28, 2013) (same), *with*

Compare Villegas v. Wells Fargo Bank, N.A., No. C 12-02004 LB, 2012 WL 4097747, at *7 (N.D. Cal. Sept. 17, 2012) (applying Rule 9(b) to negligent misrepresentation claim), *with Petersen v. Allstate Indem. Co.*, 281 F.R.D. 413, 416 (C.D. Cal. 2012) (criticizing line of cases applying 9(b) to negligent misrepresentation claims).

A growing trend of authority applies Rule 8, and not Rule 9(b), to a California law negligent misrepresentation claim. Negligent misrepresentation requires that the defendant "lacked any reasonable ground for believing [its] statement to be true," whereas fraud requires that the defendant "made an intentionally false statement." *Charnay v. Cobert*, 145 Cal. App. 4th 170, 184 (2006). As the court reasoned in *Petersen v. Allstate Indem. Co.*, analyzing negligent misrepresentation under Rule 9(b) is thus contrary to the express language and policy of the Federal Rule, which was designed to protect individuals from "*intentional* malfeasance." 281 F.R.D. 413, 418 (C.D. Cal. 2012) (citing *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985)) (emphasis in original). The *Petersen* court also noted "the tide of precedent is turning" to favor Rule 8's application in these circumstances. *Id.* at 418 (citing *Tricontinental Indus. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 833 (7th Cir. 2007); *GE Capital Corp. v. Posey*, 415 F.3d 391, 394 & n.2 (5th Cir. 2005); *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)).

Many courts have adopted *Petersen*'s reasoning and applied Rule 8 to a negligent misrepresentation claim. *See, e.g.*, *Jager I* at *6; *Unichappell Music, Inc. v. Modrock Prod., LLC*, CV 14–02382 DDP (PLAx), 2015 WL 546059, at *4 (C.D. Cal. Feb. 10, 2015); *Ctr. for Neuro Skills v. Blue Cross of California*, 1:13–CV–00743–LJO–JLT, 2013 WL 5670889, at *7 n.4 (E.D. Cal. Oct. 15, 2013); *Roberts v. Orange Glo*, 2:14–000421 WBS DAD, 2014 WL 5780961 (E.D. Cal. Nov. 5, 2014); *Eghtesadi v. Wells Fargo Bank, N.A.*, 3:12–cv–1978–GPC–JMA, 2013 WL 1498999, at *10 (S.D. Cal. Apr. 11, 2013); *Bernstein v. Vocus, Inc.*, 14–cv–01561–TEH, 2014

Newhouse v. Aurora Bank FSB, 915 F. Supp. 2d 1159, 1168 (E.D. Cal. 2013) (applying rule 9(b)), *and Michaluk v. Vohra Health Servs., P.A.*, CIV S-12-1162 KJM CKD, 2012 WL 3993940, at *4 (E.D. Cal. Sept. 11, 2012) (same). The two decisions applying Rule 9(b), however, did not consider the recent line of cases following *Petersen* discussed below, which the court believes represent a clear and wise trend; in addition, the court's orders applying Rule 9(b) fit two exceptions courts following *Petersen* have recognized, as also discussed below.

WL 3673307, at *5 (N.D. Cal. July 23, 2014); *Cutler v. Rancher Energy Corp.*, SACV 13–00906–DOC (JPRx), 2014 WL 1153054, at *6 (C.D. Cal. Mar. 11, 2014) (applying Rule 8 because "claims of negligent misrepresentation sound primarily in negligence" and do not automatically implicate Rule 9(b)'s heightened pleading standard"); *Howard v. First Horizon Home Loan Corp.*, 12-cv-05735-JST, 2013 WL 6174920, at *5 (N.D. Cal. Nov. 25, 2013); *Liberty Ins. Corp. v. S.W. Traders Incorp.*, ED CV-12-02151-JLQ, 2013 WL 12132048, at *4 (C.D. Cal. July 10, 2013); *but see Gilmore v. Wells Fargo Bank N.A.*, 75 F. Supp. 3d 1255, 1270 (N.D. Cal. 2014) (agreeing with line of cases that hold that negligent misrepresentation is a species of fraud and must comply with Rule 9(b)). Many of the decisions that departed from *Petersen* did so because the negligent misrepresentation claims arose out of the same factual allegations as other claims for fraud.[6] *Sater v. Chrysler Group LLC*, EDCV 14–00700–VAP (DTBx), 2015 WL 736273, at *11 (C.D. Cal. Feb. 20, 2015) (adopting *Petersen*, noting this trend among departing authority); *see also McNeil v. Wells Fargo Bank, N.A.*, 13–5519 SC, 2014 WL 6681604, at *3 (N.D. Cal. Nov. 25, 2014) (applying Rule 9(b) where "plaintiffs' pleadings indicates that the negligent misrepresentation claim is really just an attempt to repackage the intentional misrepresentation claim"). Others that departed from *Petersen* did so in the limited mortgage fraud context. *See Ventimiglia v. Wells Fargo Bank, N.A.*, CIV. 2:13–00953 WBS CMK, 2013 WL 3367330, at *4 (E.D. Cal. July 5, 2013) ("In the mortgage fraud context, California district courts have generally required that negligent misrepresentation be pled with particularity under Rule 9(b)."") (citations omitted).[7]

Based on the court's persuasive reasoning in *Petersen*, and falling in with the more recent trend of authority, the court now considers whether plaintiff has satisfied the elements of a negligent misrepresentation claim under Rule 8.

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[6] The undersigned's first decision applying Rule 9(b) matches this description. *See Michaluk*, 2012 WL 3993940, at *4 (applying Rule 9(b) where plaintiff asserted claims of negligent and intentional misrepresentation).

[7] The most recent decision in which the undersigned applied Rule 9(b) was in this mortgage fraud context. *See Newhouse*, 915 F. Supp. 2d at 1168 (applying Rule 9(b) in mortgage fraud action).

Defendants move to dismiss Woods' fourth claim because they contend Woods has not identified any affirmative representation defendants made. Mot. at 17–21. The requirement that a plaintiff must plead an affirmative misrepresentation is crucial to a negligent misrepresentation claim: unlike fraud, negligent misrepresentation does not require scienter, and this lesser mental state "is balanced by its requirement of a false 'positive assertion' or 'assertion of fact,' and not a mere 'implied assertion.'" *Hynix Semiconductor Inc. v. Rambus Inc.*, No. CV-00-20905 RMW, 2007 WL 4209399, at *11 (N.D. Cal. Nov. 26, 2007) (citation omitted). Thus, even under the more lenient Rule 8(a) standard, a plaintiff must identify the alleged misrepresentation. *See Carbajal v. Wells Fargo Bank, N.A.*, No. CV 14-7851 PSG (PLAx), 2015 WL 2454054, at *3 (C.D. Cal. Apr. 10, 2015) (explaining earlier dismissal of negligent misrepresentation claim because complaint did not plead any specific misrepresentations made by one of the defendants).

Here, Woods repeatedly alleges defendants made affirmative representations about the quality and safety of the Kugel Patch. She alleges defendants misrepresented to physicians that the Kugel Patch was "appropriate, safe, cost effective, and suitable" for hernia repairs, FAC ¶¶ 55–56; "claim[ed] the device had not caused or contributed to serious adverse events and/or effects requiring the premature explant of the device," *id.* ¶ 80; and asserted the "memory recoil ring was safe and met all applicable manufacturing requirements," *id.* ¶ 114. These statements also are affirmative representations of a "past or existing material fact" and are therefore actionable. The court DENIES the motion to dismiss this claim.

E. Punitive Damages

California Civil Code section 3294 provides for punitive damages for a violation of state law:

> (a) In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.

Cal. Civ. Code § 3294.

While Woods ultimately must meet the substantive standard requiring "oppression, fraud, or malice," in order to obtain punitive damages, alleging facts to support a claim of punitive damages is governed by the Federal Rules of Civil Procedure, which impose no requirement of particularity. *See Kelly Moore Paint Co., Inc. v. Nat'l Union Fire Ins. Co. of Pittsburgh, PA*, Case No. 14-cv-1797–MEJ, 2014 WL 2119996, at *3 (N.D. Cal. May 21, 2014). In addition, Woods "need not ultimately prove a subjective intent to harm, as 'malice in fact, sufficient to support an award of punitive damages . . . may be established by a showing that the defendant's wrongful conduct was willful, intentional, and done in reckless disregard of its possible results.'" *Alberts v. Liberty Life Assurance Co. of Boston*, 65 F. Supp. 3d 790, 796 (N.D. Cal. 2014) (quoting *Schroeder v. Auto Driveaway Co.*, 11 Cal. 3d 908, 922 (1974)).

Woods' failure to warn claims, both of which survive here, provide sufficient support for her request for punitive damages. *See, e.g.*, *Pfeifer v. John Crane, Inc.*, 220 Cal. App. 4th 1270, 1300 (2013) (upholding punitive damages award where there was circumstantial evidence that manufacturer knew products posed danger to consumers, yet failed to warn them). Woods alleges defendants first learned about a Kugel Patch ring break in 2003, FAC ¶ 25, but defendants waited nearly two years to report any issues to the FDA, *id.* ¶ 28, and nearly four years before issuing a full recall despite mounting evidence of product failure, *id.* ¶ 35. These allegations support the inference that defendants were aware of the probable dangerous consequences of failing to issue warnings, yet willfully failed to avoid such consequences by concealing surveys indicating unfavorable outcomes and withholding information about the numerous complaints they received. *See Jager I* at *7 (denying motion to dismiss where plaintiff alleged same defendants as here failed to provide accurate information and warning to healthcare community so as to dissuade physicians from surgically implanting Kugel Patch); *Tapia v. Davol, Inc.*, No. 15CV179-GPC (JLB), 2015 WL 6828660, at *8 (S.D. Cal. Nov. 6, 2015) (same).

The court finds plaintiff has alleged sufficient facts to support her claim for punitive damages.

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IV. CONCLUSION

The court DENIES the motion to dismiss the First Amended Complaint.

Defendants shall file an Answer within fourteen (14) days of this order.

This order resolves ECF No. 12.

IT IS SO ORDERED.

DATED: August 8, 2017.

UNITED STATES DISTRICT JUDGE