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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

PAMELA COLEMAN,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,
et al.,

Defendants.

1:10-cv-01968-OWW-SKO

MEMORANDUM DECISION REGARDING
MOTION TO DISMISS FIRST
AMENDED COMPLAINT (Doc.34)

I. INTRODUCTION.

Pamela Coleman ("Plaintiff") proceeds with an action for damages against Boston Scientific Corporation ("Defendant") and various Doe Defendants. Plaintiff filed a First Amended Complaint ("FAC") on June 17, 2011. (Doc. 31).

Defendant filed a motion to dismiss the FAC on July 7, 2011. (Doc. 34). Plaintiff filed opposition to the motion to dismiss on August 1, 2011. (Doc. 39). Defendant filed a reply on August 8, 2011. (Doc. 44).

II. FACTUAL BACKGROUND.

On December 5, 2006, a physician implanted a surgical mesh device manufactured by Defendant into Plaintiff in connection with treatment of Plaintiff's stress urinary incontinence. The surgical mesh device is described as an Obtryx Transobturator Mid-Urethral

1 Sling System ("Mesh Device") and is designed to restore normal
2 vaginal structure secondary to pelvic organ prolapse. Plaintiff
3 began to experience "recurrent pelvic pain, erosions, and recurrent
4 infection of the tissue around the mesh" subsequent to implantation
5 of the Mesh Device. From July 2007 through January 2009, Plaintiff
6 underwent surgery, vaginal reconstruction, and mesh removal "to
7 correct the injuries caused by the mesh." (FAC at 8).

8 The FAC alleges that Defendant marketed the Mesh Device in a
9 deceptive manner to the medical community and patients at medical
10 conferences, hospitals, private offices, and through documents,
11 brochures, and websites. Contrary to Defendant's representations,
12 the Mesh Device has high failure, injury, and complication rates,
13 fails to perform as intended, and requires frequent re-operations.
14 Defendant withheld and underreported information about the safety
15 of its Mesh Device. Defendants also failed to adequately research
16 and test its Mesh Product.

17 **III. LEGAL STANDARD.**

18 Dismissal under Rule 12(b)(6) is appropriate where the
19 complaint lacks sufficient facts to support a cognizable legal
20 theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th
21 Cir.1990). To sufficiently state a claim to relief and survive a
22 12(b)(6) motion, the pleading "does not need detailed factual
23 allegations" but the "[f]actual allegations must be enough to raise
24 a right to relief above the speculative level." *Bell Atl. Corp. v.*
25 *Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).
26 Mere "labels and conclusions" or a "formulaic recitation of the
27 elements of a cause of action will not do." *Id.* Rather, there must
28 be "enough facts to state a claim to relief that is plausible on

1 its face." Id. at 570. In other words, the "complaint must contain
2 sufficient factual matter, accepted as true, to state a claim to
3 relief that is plausible on its face." *Ashcroft v. Iqbal*, --- U.S.
4 ----, ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (internal
5 quotation marks omitted).

6 The Ninth Circuit has summarized the governing standard, in
7 light of *Twombly* and *Iqbal*, as follows: "In sum, for a complaint to
8 survive a motion to dismiss, the nonconclusory factual content, and
9 reasonable inferences from that content, must be plausibly
10 suggestive of a claim entitling the plaintiff to relief." *Moss v.*
11 *U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir.2009) (internal
12 quotation marks omitted). Apart from factual insufficiency, a
13 complaint is also subject to dismissal under Rule 12(b)(6) where it
14 lacks a cognizable legal theory, *Balistreri*, 901 F.2d at 699, or
15 where the allegations on their face "show that relief is barred"
16 for some legal reason, *Jones v. Bock*, 549 U.S. 199, 215, 127 S.Ct.
17 910, 166 L.Ed.2d 798 (2007).

18 In deciding whether to grant a motion to dismiss, the court
19 must accept as true all "well-pleaded factual allegations" in the
20 pleading under attack. *Iqbal*, 129 S.Ct. at 1950. A court is not,
21 however, "required to accept as true allegations that are merely
22 conclusory, unwarranted deductions of fact, or unreasonable
23 inferences." *Spewell v. Golden State Warriors*, 266 F.3d 979, 988
24 (9th Cir.2001). "When ruling on a Rule 12(b)(6) motion to dismiss,
25 if a district court considers evidence outside the pleadings, it
26 must normally convert the 12(b)(6) motion into a Rule 56 motion for
27 summary judgment, and it must give the nonmoving party an
28 opportunity to respond." *United States v. Ritchie*, 342 F.3d 903,

1 907 (9th Cir.2003). "A court may, however, consider certain
2 materials-documents attached to the complaint, documents
3 incorporated by reference in the complaint, or matters of judicial
4 notice-without converting the motion to dismiss into a motion for
5 summary judgment." *Id.* at 908.

6 **IV. DISCUSSION.**

7 **A. Statute of Limitations**

8 California law establishes a two-year statute of limitations
9 for personal injury actions. Cal. Code Civ. Proc. 335.1; e.g.,
10 *Mito v. Temple Recycling Center Corp.*, 187 Cal. App. 4th 276, 278-
11 79 (Cal. Ct. App. 2011). As a general rule, a cause of action
12 accrues "when, under the substantive law, the wrongful act is done,
13 or the wrongful result occurs." E.g., *Unruh-Haxton v. Regents of*
14 *University of California*, 162 Cal. App. 4th 343, 359 (Cal. Ct. App.
15 2008). "An important exception to the general rule of accrual is
16 the 'discovery rule,' which postpones accrual of a cause of action
17 until the plaintiff discovers, or has reason to discover, the cause
18 of action." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797,
19 807) (citing *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (Cal.
20 1999)).

21 A plaintiff has reason to discover a cause of action when he
22 or she "has reason at least to suspect a factual basis for its
23 elements." *Id.* at 808. Plaintiffs are charged with presumptive
24 knowledge of an injury if they have "information of circumstances
25 to put them on inquiry," or if they have "the opportunity to obtain
26 knowledge from sources open to their investigation." *Id.*
27 (citations and quotations omitted). However, "the rule in
28 California is that it is not enough to commence the running of the

1 limitations period when the plaintiff knows of her injury and its
2 factual cause (or physical cause).” *Clark v. Baxter Healthcare*
3 *Corp.*, 83 Cal. App. 4th 1048, 1056 (Cal. Ct. App. 2000). “Rather,
4 the plaintiff must be aware of her injury, its factual cause, and
5 sufficient facts to put her on inquiry notice of a [wrongful] cause
6 [of injury].” *Id.* (citing *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d
7 1103, 1109-1114 (Cal. 1988)). The discovery rule is based on an
8 objective standard that looks not to what the particular plaintiff
9 actually knew but to what a reasonable inquiry would have revealed.
10 *Mills v. Forestex Co.*, 108 Cal. App. 4th 625, 648 (Cal. Ct. App.
11 2003) (citation omitted); accord *Landale-Cameron Court, Inc. v.*
12 *Ahonen*, 155 Cal. App. 4th 1401, 1407 (Cal. Ct. App. 2007) (citing
13 *Mills*).

14 The FAC alleges that Plaintiff underwent surgery in July 2007
15 in order to effect vaginal reconstruction, mesh removal, and
16 correction of “injuries caused by the mesh.” (FAC at 8). Although
17 the FAC’s allegations are vague, the plain meaning of the FAC’s
18 allegation that Plaintiff “was forced to undergo revisionary
19 surgery vaginal reconstruction, and mesh removal to correct the
20 injuries caused by the mesh” suggests that Plaintiff was aware of
21 sufficient facts to put her on inquiry notice in July 2007 that
22 reconstructive surgery was necessary because the device did not
23 perform. A reasonable person who is implanted with a medical
24 device, which requires a second corrective surgery to remove the
25 device and correct injuries resulting there from within a year of
26 implantation should suspect the defectiveness of the device and
27 conduct a reasonable inquiry and examination into the suitability
28 of the device. See *Henderson v. Pfizer, Inc.*, 285 Fed. Appx. 370,

1 372 (9th Cir. 2008) (unpublished) (holding that two-year
2 limitations period under California Code of Civil Procedure 335.1
3 for claim arising out of injury caused by medical device accrued at
4 the time plaintiff required surgery to remove the device). The
5 FAC's own allegations suggest that Plaintiff's claim is time-
6 barred, as it was not filed within two years of Plaintiff's July
7 2007 surgery.¹

8 Plaintiff contends she was not put on inquiry notice of her
9 claim until publication of an FDA warning in 2008. The FDA
10 publication discussed a range of potential risks associated with
11 implantation of medical devices such as the Mesh Device that
12 injured Plaintiff. Plaintiff's attempt to rely on the FDA
13 publication is unavailing, as it did not put Plaintiff on notice of
14 any new facts relevant to her claim. By the time of the FDA
15 publication in 2008, at least one of the types of risks discussed
16 in the FDA publication had already materialized for Plaintiff and
17 required surgery in July 2007. To the extent Plaintiff understood
18 the reason for her July 2007 surgery, she was on inquiry notice at
19 that time. Plaintiff's conclusory averments of fraud and
20 concealment are also unavailing. The FAC does not allege ultimate
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23 ¹ Due to the lack of detail concerning the nature of Plaintiff's 2007 surgery,
24 it cannot be said as a matter of law that Plaintiff was on inquiry notice of her
25 claims in 2007. For this reason, Plaintiff is given leave to amend. Because
26 Plaintiff's FAC suggests on its face that her claims are time-barred, any amended
27 complaint must plead facts sufficient to suggest application of the discovery
28 rule. See, e.g., *McKelvey v. Boeing North American, Inc.*, 74 Cal. App. 4th 151,
160, 86 Cal. Rptr. 2d 645 (Cal. Ct. App. 1999) *partially superceded on other*
grounds as stated in Grisham v. Philip Morris U.S.A., Inc., 40 Cal. 4th 623, 637
n.8, 54 Cal. Rptr. 3d 735, 151 P.3d 1151 (Cal. Ct. App. 2007). In the context
of Plaintiff's July 2007 surgery, Plaintiff must allege facts to suggest that,
due to the nature of the surgery and the information Plaintiff possessed
regarding the procedure, a reasonable person in Plaintiff's position would not
have suspected that the Mesh Device was defective.

1 facts sufficient to suggest that Defendant engaged in any conduct
2 that prevented Plaintiff from investigating the circumstances that
3 required her to undergo surgery in July 2007.

4 Plaintiff will be given one last opportunity to amend her
5 complaint to allege facts sufficient to suggest that Plaintiff's
6 claims are not time-barred, subject to the requirements of Federal
7 Rule of Civil Procedure 11. Plaintiff has not heeded the prior
8 instructions of the court. Her continued disregard of the court's
9 orders will be handled accordingly.

10 **B. Defendant's Learned Intermediary Argument**

11 Defendant invokes California's "learned intermediary
12 doctrine," which imposes the duty to warn of dangers associated
13 with a medical product on the physician, not the patient, under
14 appropriate circumstances. *See, e.g., Conte v. Wyeth, Inc.*, 168
15 Cal. App. 4th 89, 98 n.5 (Cal. Ct. App. 2008) ("under the
16 learned-intermediary doctrine Wyeth's duty to warn of risks
17 associated with its usage runs to the physician, not the patient").
18 The complaint sufficiently alleges that Defendant failed to
19 disclose material information concerning use of the Mesh Device to
20 "Plaintiff and/or Plaintiff's healthcare providers." (FAC at 6-7).
21 The FAC also alleges that Defendant's product literature falsely
22 assured "Plaintiff's healthcare providers and physicians" that the
23 Mesh Device was safe for treating Plaintiff's conditions. (Id.).
24 The learned intermediary argument articulated in Defendant's Motion
25 to Dismiss does not provide a basis for dismissing the FAC. The
26 motion to dismiss on this ground is DENIED.

27 **C. Express Warranty Claim**

28 "As a general rule, privity of contract is a required element

1 of an express breach of warranty cause of action." *E.g.*,
2 *Fieldstone Co. v. Briggs Plumbing Products, Inc.*, 54 Cal. App. 4th
3 357, n.10 (Cal. Ct. App. 1997). However, privity is not an
4 absolute requirement for express warranty claims under California
5 law, because reliance on a seller's representations may provide the
6 basis for an express warranty claim even absent privity. *Id.* The
7 memorandum decision dismissing Plaintiff's original complaint
8 provides, in pertinent part:

9 Defendants' contention that privity is an element of an
10 express warranty claim is incorrect. *E.g.*, *Evracts*, 29
11 Cal. App. 4th at 857 n.4 ("privity is not a requirement
12 for actions based upon an express warranty"); *Fieldstone*
13 *Co. v. Briggs Plumbing Products, Inc.*, 54 Cal. App. 4th
14 357, n.10 (Cal. Ct. App. 1997) ("As a general rule,
15 privity of contract is a required element of an express
16 breach of warranty cause of action. However, there is an
17 exception where plaintiff's decision to purchase the
18 product was made in reliance on the manufacturers'
19 written representations in labels or advertising
20 materials.") (citations omitted). However, Plaintiffs
21 express warranty claims must be dismissed, as the
22 complaint does not allege facts sufficient to give rise
23 to a plausible basis to believe that Plaintiffs relied on
24 any representations made by Defendants. *See, e.g., id.*

25 Plaintiffs' conclusory allegations that Defendants
26 advertised their products as safe and effective lack even
27 general information describing such alleged conduct. As
28 one district court has aptly noted, conclusory
allegations such as those advanced by Plaintiffs are
insufficient to support a plausible basis for an express
warranty claim:

29 Evraets stands as clear authority that at
30 least at the pleading stage, California law
31 permits a claim for breach of an express
32 warranty to go forward under circumstances
33 [where reliance is alleged]. That said, the
34 complaint as presently constituted fails to
35 allege any express warranties actually made by
36 Stryker, except in the most general and
37 conclusory terms. Accordingly, the claim for
38 breach of express warranty will be denied,
with leave to amend.

39 *Quatela v. Stryker Corp.*, 2010 U.S. Dist. LEXIS 133706 *
40 4-6 (N.D. Cal. 2010).

1 The FAC alleges neither privity nor reliance as the basis for
2 Plaintiff's express warranty claim. Plaintiff's argument that she
3 need not plead reliance in order to state a cognizable breach of
4 express warranty claim is contrary to California law and ignores
5 the analysis provided in the memorandum decision.² None of the
6 authorities Plaintiff cites in her opposition support the erroneous
7 proposition that reliance is not required in an express warranty
8 action not founded on privity.

9 Plaintiff cites *Weinstat v. Dentsply Intern., Inc.*, 180 Cal.
10 App. 4th 1213, 1225 (Cal. Ct. App. 2010) and *Keith v. Buchanan*, 173
11 Cal. App. 3d 13, 21 (Cal. Ct. App. 1985) for the proposition that
12 reliance is not a requirement of her express warranty claim. In
13 *Winestat* the purchasers of dental equipment sued the seller, and
14 the express warranty claim was based on privity. *See id.*
15 Similarly, in *Keith*, the purchaser of a boat sued the company that
16 sold him the boat and allegedly made express warranties antecedent
17 to the transaction. Neither *Weinstat* nor *Keith* supports
18 Plaintiff's erroneous contention that reliance is not required
19 where privity is absent.

20 Plaintiff's invocation of California Commercial Code section
21 2313 is unavailing, as it does not alter the requirement that
22 reliance (or some other substitute for privity) is required for an
23 express warranty claim against a non-selling manufacturer of a
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26 ² In light of the memorandum decision, Plaintiff's counsel's argument that
27 neither reliance nor privity is required, without so much as attempting to
28 address the court's prior analysis, violates Federal Rule of Civil Procedure 11
and applicable standards of professional conduct. Plaintiff's disingenuous
attempt to characterize the correct arguments advanced in Defendant's brief as
misleading compounds counsel's breach of duty.

1 product. See, e.g., *Wiley v. Yihua Int'l Group*, 2009 Cal. App.
2 Unpub. LEXIS 8880 * 13-16 (Cal. Ct. App. 2009) (unpublished).

3 In *Burr v. Sherwin Williams Co.* 42 Cal.2d 682, (1954) the
4 California Supreme Court held "[t]he general rule is that
5 privity of contract is required in an action for breach
6 of either express or implied warranty and that there is
7 no privity between the original seller and a subsequent
8 purchaser who is in no way a party to the original sale."
9 *Id.* at p. 695; see also *Windham at Carmel Mountain Ranch*
10 *Assn. v. Superior Court* 109 Cal. App. 4th 1162, 1169
11 (Cal. 2003) [same, quoting *Burr*]; *Arnold v. Dow Chemical*
12 *Co.* 91 Cal. App. 4th 698, 720 (Cal. Ct. App. 2001) [same,
13 quoting *Burr*]; *All West Electronics, Inc. v. M-B-W, Inc.*
14 64 Cal.App.4th 717, 725 (1998) [same, quoting *Burr*].)
15 *Burr* observed that courts created exceptions to the
16 privity rule for items such as foodstuffs (*Burr*, at p.
17 695), and after *Burr*, the exception was extended to
18 drugs and pesticides. See *Windham at Carmel Mountain*
19 *Ranch*, at p. 1169 & fn. 7 [observing these exceptions
20 were created by courts before the establishment of the
21 doctrine of strict liability in tort]; *Arnold v. Dow*
22 *Chemical Co.*, at pp. 720-721; *Fundin v. Chicago Pneumatic*
23 *Tool Co.* (1984) 152 Cal.App.3d 951, 956, fn. 1.) *Burr*
24 also recognized that "[a]nother possible exception to the
25 general rule is found in a few cases where the purchaser
26 of a product relied on representations made by the
27 manufacturer in labels or advertising material, and
28 recovery from the manufacturer was allowed on the theory
of express warranty without a showing of privity." (*Burr*,
42 Cal.2d at p. 696; see also *Smith v. Gates Rubber Co.*
Sales Division (1965) 237 Cal.App.2d 766, 768.)

18 Since *Burr*, the California Supreme Court has made
19 statements in cases broadly suggesting that courts no
20 longer require privity in express warranty cases. (See
21 *Seely v. White Motor Co.* (1965) 63 Cal.2d 9, 14 ["Since
22 there was an express warranty to plaintiff in the
23 purchase order, no privity of contract was required"];
24 *Hauter*, supra, 14 Cal.3d at p. 115, fn. 8 ["The fact that
25 [plaintiff] is not in privity with defendants [*20] does
26 not bar recovery. Privity is not required for an action
27 based upon an express warranty".]) However, *Seely* and
28 *Hauter* did not overrule *Burr*, and, unlike the case at
hand, both cases involve written warranties similar to
advertisements and labels where the plaintiffs saw and
relied upon the written statements in purchasing the
product at issue. (*Seely*, at p. 13 [plaintiff relied on
statements in purchase order when buying a truck];
Hauter, at pp. 109, 117 [plaintiff read and relied on
defendant's representation on the label of a shipping
carton].) The broad language in *Seely* and *Hauter* narrows
significantly when read in the context of those facts.
Further, as indicated above, several cases decided after

1 Seely reflect the continuing validity of Burr's privity
2 requirement. (Windham at Carmel Mountain Ranch Assn. v.
3 Superior Court, supra, 109 Cal.App.4th at p. 1169; Arnold
4 v. Dow Chemical Co., supra, 91 Cal.App.4th at p. 720; All
5 West Electronics, Inc. v. M-B-W, Inc., supra, 64
6 Cal.App.4th at p. 725.) We conclude plaintiffs' asserted
7 "independent liability" theory under section 2313 is
8 defeated by the fact they did not bargain with or
9 directly purchase the products from Yihua, and were not
10 in privity of contract with it.

11 *Id.*

12 Finally, Plaintiff's attempt to rely on California Civil Code
13 section 1791.2 fails. Section 1791 defines the term "consumer
14 goods" as

15 any new product or part thereof that is used, bought, or
16 leased for use primarily for personal, family, or
17 household purposes, except for clothing and consumables.
18 "Consumer goods" shall include new and used assistive
19 devices sold at retail.

20 Cal Civ. Code. 1791(a). Assistive device is defined as:

21 any instrument, apparatus, or contrivance, including any
22 component or part thereof or accessory thereto, that is
23 used or intended to be used, to assist an individual with
24 a disability in the mitigation or treatment of an injury
25 or disease or to assist or affect or replace the
26 structure or any function of the body of an individual
27 with a disability, except that this term does not include
28 prescriptive lenses and other ophthalmic goods unless
they are sold or dispensed to a blind person, as defined
in Section 19153 of the Welfare and Institutions Code and
unless they are intended to assist the limited vision of
the person so disabled.

Cal. Civ. Code 1791 (p). Although the Mesh Device appears to fall
within the scope of the term "assistive device," the FAC does not
allege the "sale at retail" of any assistive device.

In light of Plaintiff's inability to amend her complaint to
allege reliance or privity after being provided with express
instructions in the Memorandum Decision, Plaintiff's express

1 warranty claim is DISMISSED WITH PREJUDICE.

2 **ORDER**

3 For the reasons stated, IT IS ORDERED:

4 1) Plaintiff's express warranty claim is DISMISSED WITH
5 PREJUDICE;

6 2) Plaintiff's remaining claims are dismissed, without
7 prejudice;

8 3) Plaintiff shall file an amended complaint within thirty
9 days of electronic service of this decision; no further leave
10 to amend will be given. Defendant shall respond to any
11 amended complaint within thirty days; and

12 4) Defendant shall file a form of order consistent with this
13 memorandum decision within five days of electronic service of
14 this decision.

15 IT IS SO ORDERED.

16 **Dated: August 29, 2011**

/s/ Oliver W. Wanger
UNITED STATES DISTRICT JUDGE