

1 UNITED STATES DISTRICT COURT  
2 NORTHERN DISTRICT OF CALIFORNIA

3  
4 NICOLE BAKER,

5 Plaintiff,

NO. C13-0490 TEH

6 v.

7 BAYER HEALTHCARE  
8 PHARMACEUTICALS, INC.,

**ORDER GRANTING IN PART AND  
DENYING IN PART DEFENDANT'S  
MOTION TO DISMISS**

9 Defendant.  
10

11  
12 This matter came before the Court on December 9, 2013, on Defendant Bayer  
13 Healthcare Pharmaceuticals, Inc.'s ("Defendant") motion to dismiss Plaintiff Nicole  
14 Baker's ("Plaintiff") Second Amended Complaint ("SAC"). After carefully considering  
15 the parties' written and oral arguments, and relevant law, the Court now GRANTS in part  
16 and DENIES in part Defendant's motion.

17  
18 **BACKGROUND**

19 This suit is a product liability case stemming from Plaintiff's use of the intrauterine  
20 contraceptive device known as "Mirena." Mirena is made by Defendant, a Delaware  
21 corporation, which is in the business of designing, manufacturing, marketing, testing, and  
22 distributing prescription drugs and women's healthcare products, including Mirena. SAC  
23 ¶¶ 4, 10, Docket No. 21. Mirena is a T-shaped polyethylene frame with a steroid reservoir  
24 that releases 20 µg/day of levonorgestrel, a prescription medication used as a  
25 contraceptive; it is inserted into the uterus by a healthcare provider during an office visit.  
26 The federal Food and Drug Administration approved Defendant's New Drug Application  
27 for Mirena in December 2000. *Id.* ¶ 14-15.

28 Plaintiff, a California resident, alleges that Mirena's label does not accurately warn

1 and understates the risks of certain medical conditions or injuries associated with use of  
2 Mirena, including spontaneous migration of Mirena, perforation of the uterus, embedment,  
3 infections, cysts, ectopic and intrauterine pregnancy, adhesions, fetal injury and fetal death  
4 caused by Mirena. *Id.* ¶¶ 18-19. Plaintiff alleges that Defendant did not effectively test or  
5 analyze results of pre-market tests before putting Mirena on the market, but nonetheless  
6 promoted Mirena through social media and online marketing campaigns while understating  
7 the associated risks. *Id.* ¶¶ 20-21. Plaintiff further alleges that in March 2009, the  
8 Department of Health and Human Services’ Division of Drug Marketing, Advertising, and  
9 Communications (“DDMAC”) issued a warning regarding Defendant’s advertising  
10 materials for Mirena, stating that they did not communicate any risk information and  
11 inadequately communicated Mirena’s indications. *Id.* ¶¶ 22-23. Plaintiff also alleges that  
12 in December 2009, DDMAC contacted Defendant regarding its “Mirena Simple Styles  
13 Statements Program,” which Plaintiff alleges were consumer-directed live presentations  
14 directed toward “busy moms” that utilized scripts that omitted information regarding the  
15 serious risks associated with using Mirena. *Id.* ¶¶ 24-27. Plaintiff alleges that Defendant  
16 concealed its knowledge of the defects in their products from the Plaintiff, her physicians,  
17 hospitals, pharmacists, the FDA and the public in general. *Id.* ¶ 28.

18 Plaintiff had her Mirena inserted on January 6, 2010 at Community Physicians  
19 Network for Women in Indianapolis, Indiana by her healthcare provider. Plaintiff alleges  
20 that she chose Mirena because it was promoted as a safe and effective method of birth  
21 control. *Id.* ¶ 29. On June 21, 2011, after suffering from extreme pelvic pain, Plaintiff was  
22 rushed to the emergency room (“ER”) at Parkview Community Hospital in Riverside,  
23 California. She received treatment for abdominal pain. *Id.* ¶ 30. Over the next four  
24 months, Plaintiff repeatedly went to the ER. On June 28, 2011, Plaintiff went to the ER at  
25 Riverside Community Hospital in Riverside, California for sharp pains on her left side. An  
26 ultrasound showed a left ovarian cyst. Plaintiff was treated for her pain. *Id.* ¶ 31. On  
27 September 3, 2011, Plaintiff went to the ER at Parkview Community Hospital for severe  
28 abdominal pain, nausea and pain associated with an ovarian cyst. *Id.* ¶ 32. On October 10,

1 2011, Plaintiff was again rushed to the ER at Riverside Community Hospital for extreme  
2 pelvic pain, and noted that her pain level was a 7 out of 10. Plaintiff had a urinary tract  
3 infection, a fever and leukocytosis. *Id.* ¶ 33. Plaintiff’s Mirena “was expelled” on October  
4 20, 2011. After removal, Plaintiff continued to suffer from vaginal bleeding, pelvic pain,  
5 and pain when urinating. *Id.* ¶ 34. Prior to having Mirena, Plaintiff alleges that she did  
6 not suffer from these injuries. *Id.* In sum, Plaintiff maintains she has suffered severe  
7 injuries, including, but not limited to, abdominal pain, an ovarian cyst, infections,  
8 substantial mental and physical pain and suffering, and has incurred medical expenses for  
9 treatment and care, and will continue to incur expenses in the future. *Id.* ¶ 35.

10 Plaintiff filed suit on February 4, 2012, invoking this Court’s diversity jurisdiction  
11 pursuant to 28 U.S.C. § 1332. She asserts claims against Defendant for negligence, for  
12 strict liability for design defects, failure to warn, and manufacturing defects, as well as for  
13 breach of implied and express warranties. On March 12, 2013, the Court stayed the case  
14 pending a motion to transfer the case as potentially related to the Judicial Panel on  
15 Multidistrict Litigation (“JPML”) Docket No. 2434, *In re: Mirena IUD Products Liability*  
16 *Litigation*. Docket No. 13. On August 7, 2013, the JPML vacated the conditional transfer  
17 of the case because the Panel found that Plaintiff alleged injuries broader than injury  
18 related to the risk of perforation and migration associated with Mirena, which was the  
19 scope of the MDL. Docket Nos. 14, 16. After the Court lifted the stay, Plaintiff filed the  
20 SAC and this motion to dismiss followed.

21

22 **LEGAL STANDARD**

23 Dismissal is appropriate under Rule 12(b)(6) of the Federal Rules of Civil  
24 Procedure<sup>1</sup> when a plaintiff’s allegations fail “to state a claim upon which relief can be  
25 granted.” Fed. R. Civ. P. 12(b)(6). A dismissal under Rule 12(b)(6) “can be based on the  
26 lack of a cognizable legal theory or the absence of sufficient facts alleged under a  
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28 <sup>1</sup> All references to “Rules” hereinafter refer to the Federal Rules of Civil Procedure.

1 cognizable legal theory.” *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir.  
2 1990).

3 Under Federal Rule of Civil Procedure 8(a), a plaintiff must plead “enough facts to  
4 state a claim to relief that is plausible on its face” with sufficient specificity to “give the  
5 defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell*  
6 *Atlantic Corp. v. Twombly*, 550 U.S. 544, 545, 570 (2007) (citation and quotation marks  
7 omitted). “Rule 8 . . . does not require ‘detailed factual allegations,’ but it demands more  
8 than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*,  
9 556 U.S. 662, 678 (2009) (citation omitted). Plausibility does not equate to probability,  
10 but it requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.*  
11 “A claim has facial plausibility when the plaintiff pleads factual content that allows the  
12 court to draw the reasonable inference that the defendant is liable for the misconduct  
13 alleged.” *Id.* In ruling on a motion to dismiss, a court must “accept all material allegations  
14 of fact as true and construe the complaint in a light most favorable to the non-moving  
15 party.” *Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007). The Court,  
16 however, is not “bound to accept as true a legal conclusion couched as a factual  
17 allegation.” *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted). Dismissal of  
18 claims that fail to meet this standard should be with leave to amend unless it is clear that  
19 amendment could not possibly cure the deficiencies in the complaint. *Steckman v. Hart*  
20 *Brewing, Inc.*, 143 F.3d 1293, 1296 (9th Cir. 1998).

21

22 **DISCUSSION**

23 Defendant moves for dismissal on all claims under Rule 12(b)(6). For the reasons  
24 discussed below, Defendant’s motion is GRANTED in part and DENIED in part.

25

26 **I. Negligence Claim**

27 Under California law, to maintain a negligence action, Plaintiff must allege that  
28 Defendant owed a legal duty, breached that duty, and that the breach proximately caused

1 injury to the Plaintiff. *Garcia v. W & W Cmty. Dev., Inc.*, 186 Cal. App. 4th 1038, 1044  
2 (2010). Defendant argues Plaintiff’s negligence claim is insufficiently pleaded under Rule  
3 8 because Plaintiff does not allege sufficient facts and relies on bare legal conclusions to  
4 assert her negligence claim.

5 The Court holds that Plaintiff has sufficiently alleged facts supporting a negligence  
6 claim. The Court notes at the outset that the SAC is far from a model of clarity in  
7 pleading. Nonetheless, the Court must construe the SAC in a light most favorable to the  
8 non-moving party and assume the truth of non-conclusory, material allegations of fact  
9 contained therein. Plaintiff alleges that Defendant had a duty to exercise reasonable care  
10 in the designing, researching, manufacturing, marketing, supplying, promoting, packaging,  
11 selling or distributing Mirena, which included a duty to assure that Mirena would not cause  
12 users to suffer unreasonable, dangerous side effects. SAC ¶ 37. Plaintiff alleges that  
13 Defendant breached that duty when it, among other things: failed to adequately warn the  
14 Plaintiff, other Mirena users, physicians and the FDA of serious side effects of Mirena,  
15 including but not limited to, migration, perforation, embedment, ectopic pregnancies,  
16 intrauterine pregnancies, infections, adhesions, cysts, fetal injury and death. *Id.* ¶ 37(g).  
17 Plaintiff alleges that Defendant concealed its knowledge of the defects of Mirena from  
18 Plaintiff and her physician, *id.* ¶ 28, and that Plaintiff chose Mirena because it was  
19 promoted as a safe and effective method of birth control. *Id.* ¶ 29. Plaintiff alleges that  
20 Defendant’s breach caused her injuries because after Mirena was inserted by her healthcare  
21 provider, she subsequently suffered from a series of injuries including extreme pelvic and  
22 abdominal pain, an ovarian cyst, nausea, urinary tract infection, fever, leukocytosis, all of  
23 which culminated when “Plaintiff’s Mirena was expelled,” after which she suffered from  
24 vaginal bleeding, pelvic pain, and pain when urinating. *Id.* ¶ 34. Plaintiff alleges that prior  
25 to having Mirena, Plaintiff did not suffer from these injuries. *Id.* Thus, read in a favorable  
26 light, Plaintiff has alleged sufficient factual matter to state a claim for negligence that is  
27 plausible on its face.

28 Defendant states that the “only allegation that provides any specificity at all

1 includes a number of injuries that Plaintiff does not contend to have suffered from.” Reply  
2 at 3-4, Docket No. 26 (citing SAC ¶ 38(g) and listing alleged injuries, but omitting  
3 “infections” and “cysts,” which are the injuries for which Defendant allegedly failed to  
4 provide adequate warnings and from which Plaintiff allegedly suffered). During oral  
5 argument, the Court questioned Plaintiff’s counsel regarding how a negligence action may  
6 be maintained based on a failure to warn about injuries Plaintiff did not allege she  
7 sustained. Plaintiff’s counsel argued that had Plaintiff been aware of the other alleged  
8 risks of Mirena, including migration of Mirena, that warning, had it been given, would  
9 have been relevant to her decision-making process. As the parties did not specifically brief  
10 this narrow issue, and because “adequacy of a warning is a question of fact for the jury” in  
11 most cases, the Court cannot say at the motion to dismiss stage that Plaintiff’s theory is  
12 implausible as a matter of law. *Jackson v. Deft, Inc.*, 223 Cal. App. 3d 1305, 1320 (1990).

13 Defendant also argues that it cannot be held liable for a failure to test Mirena  
14 because California law does not recognize an independent cause of action for failure to  
15 test. Defendant is correct. “Imposing liability for breach of a purported ‘independent duty  
16 to conduct long-term testing’ would be beyond the pale of any known California tort  
17 doctrine, because, *inter alia*, the causal link between Plaintiff’s known harm, and the  
18 unknown outcome of the hypothetical testing is entirely speculative.” *Phillippi v. Stryker*  
19 *Corp.*, No. 2:08-CV-02445-JAM, 2010 WL 2650596, at \*2 (E.D. Cal. July 1, 2010) *aff’d*,  
20 471 F. App’x 663 (9th Cir. 2012) (citing *Valentine v. Baxter Healthcare Corporation*, 68  
21 Cal. App. 4th 1467, 1485-86 (1999)). However, Plaintiff argues that she is not asserting  
22 that Defendant had an independent duty to conduct long-term testing, but that the duty to  
23 test was one of the duties owed to Plaintiff as part of the obligation to protect the end-user  
24 from long term risks. This concession brings Plaintiff’s duty to test allegation within the  
25 ambit of *Valentine*, which recognizes that testing and inspection duties may be tied to  
26 liability for manufacture, design, and failure to warn, even if they are not maintainable as  
27 an independent duty. 68 Cal. App. 4th at 1485.

28 Accordingly, because Plaintiff has sufficiently pleaded a negligence claim,

1 Defendant’s motion to dismiss the First Cause of Action for Negligence is DENIED.

2

3 **II. Strict Liability – Product Liability**

4 California recognizes strict liability for three types of product defects –  
5 manufacturing defects, warning defects (inadequate warnings or failure to warn), and  
6 design defects. *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1154 (E.D. Cal. 2010)  
7 (citing *Anderson v. Owens-Corning Fiberglas Co.*, 53 Cal. 3d 987, 995 (1991)). Plaintiff  
8 alleges that Defendant is strictly liable under all three product defect theories.

9 **A. Strict Liability – Defective Manufacturing Claim**

10 Under the “manufacturing defect” theory, generally a “manufacturing or production  
11 defect is readily identifiable because a defective product is one that differs from the  
12 manufacturer’s intended result or from other ostensibly identical units of the same product  
13 line.” *Lucas*, 726 F. Supp. 2d at 1155 (citing *Barker v. Lull Engineering Co.*, 20 Cal. 3d  
14 413, 429 (1978)). The “manufacturing defect” theory posits that “a suitable design is in  
15 place, but that the manufacturing process has in some way deviated from that design.” *Id.*  
16 (citation omitted). To survive a challenge to a manufacturing defect claim under Rule  
17 12(b)(6), a plaintiff must “*identify/explain how* the [product] either deviated from  
18 [defendant’s] intended result/design or *how* the [product] deviated from other seemingly  
19 identical [product] models.” *Id.* (emphasis in original) (citing *Barker*, 20 Cal. 3d at 429);  
20 *see also Trabakoolas v. Watts Water Technologies, Inc.*, No. 12-CV-01172-YGR, 2012  
21 WL 2792441, at \*4 (N.D. Cal. July 9, 2012) (dismissing manufacturing defect claim on  
22 motion to dismiss).

23 Plaintiff’s claim for a strict product liability manufacturing defect fails because  
24 Plaintiff does not allege facts that identify or explain how Mirena either deviated from  
25 Defendant’s intended result or design or how Mirena deviated from other seemingly  
26 identical Mirena models. *Lucas*, 726 F. Supp. 2d at 1155. Plaintiff argues that because  
27 she suffered from certain injuries which she alleges were caused by Mirena, in hindsight,  
28 Mirena then clearly deviated from the Defendant’s intended result. However, the SAC

1 contains no allegations of *how* the deviation occurred or whether her Mirena was  
2 manufactured defectively. Plaintiff has thus provided only insufficient legal conclusions  
3 that Mirena had a manufacturing defect, which are insufficient to state a legally cognizable  
4 manufacturing defect claim. Defendant’s motion to dismiss Plaintiff’s Second Cause of  
5 Action with respect to the strict liability manufacturing defect claim is GRANTED WITH  
6 LEAVE TO AMEND.

7 **B. Strict Liability – Failure to Warn Claim**

8 The California Supreme Court has held that manufacturers of prescription drugs can  
9 be held strictly liable for failure to warn of knowable risks. *Brown v. Superior Court*, 44  
10 Cal. 3d 1049, 1069 (1988). In California, a defendant manufacturer can be held strictly  
11 liable for failure to warn if the plaintiff proves the following: “(1) the defendant  
12 manufactured, distributed, or sold the product; (2) the product had potential risks that were  
13 known or knowable at the time of manufacture or distribution, or sale; (3) that the potential  
14 risks presented a substantial danger to users of the product; (4) that ordinary consumers  
15 would not have recognized the potential risks; (5) that the defendant failed to adequately  
16 warn of the potential risks; (6) that the plaintiff was harmed while using the product in a  
17 reasonably foreseeable way; (7) and that the lack of sufficient warnings was a substantial  
18 factor in causing the plaintiff’s harm.” *Tucker v. Wright Med. Tech., Inc.*, No. 11-CV-  
19 03086-YGR, 2013 WL 1149717, at \*12 (N.D. Cal. Mar. 19, 2013) (citing *Rosa v. City of*  
20 *Seaside*, 675 F. Supp. 2d 1006, 1011 (N.D. Cal. 2009)), *aff’d sub nom.*, *Rosa v. Taser Int’l,*  
21 *Inc.*, 684 F.3d 941 (9th Cir. 2012) & (citing Jud. Council of Cal. Civ. Jury Instructions No.  
22 1205 [entitled “Strict Liability – Failure to Warn – Essential Factual Elements”] ). With  
23 respect to a known or knowable risk, the plaintiff must prove that “the defendant did not  
24 adequately warn of a particular risk that was known or knowable in light of the generally  
25 recognized and prevailing best scientific and medical knowledge available at the time of  
26 manufacture and distribution.” *Rosa*, 675 F. Supp. 2d at 1012 (citing *Anderson*, 53 Cal. 3d  
27 at 1002).

28 A manufacturer of a prescription drug is obligated to warn physicians, not patients,



1 of potential side effects associated with its pharmaceutical products. *Motus v. Pfizer Inc.*,  
2 358 F.3d 659, 661 (9th Cir. 2004) (“*Motus II*”); *Carlin v. Superior Court*, 13 Cal. 4th  
3 1104, 1116 (1996). Known as the “learned intermediary” doctrine, the duty to warn the  
4 physician – rather than the patient – is discharged if a manufacturer provides an adequate  
5 warning to the physician, regardless of whether the warning reaches the patient. *Motus v.*  
6 *Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) *aff’d sub nom. Motus v. Pfizer Inc.*  
7 (*Roerig Div.*), 358 F.3d 659 (9th Cir. 2004). “A plaintiff asserting causes of action for  
8 failure to warn must prove not only that no warning was provided or that the warning was  
9 inadequate, but also that the inadequacy or absence of a warning caused the plaintiff’s  
10 injury.” *See Wendell v. Johnson & Johnson*, No. C 09–04124 CW, 2012 WL 3042302, at  
11 \*7 (N.D. Cal. July 25, 2012) (emphasis added) (internal citations omitted)); *Brown*, 44 Cal.  
12 3d at 1062.

13 Defendant contends that it “is left to guess about what aspects of the FDA-approved  
14 Mirena warnings are allegedly inadequate and how Plaintiff believes the warnings should  
15 be different.” Reply at 5. The Court disagrees.

16 Plaintiff has alleged that (1) Defendant manufactured, distributed, and sold Mirena;  
17 (2) Mirena poses potential risks to users such as developing infection, cysts, and physical  
18 pain and these risks were known or knowable at the time of manufacture or distribution,  
19 *see* SAC ¶¶22, 70-74 (alleging that the Department of Health and Human Services issued a  
20 warning in March 2009 regarding Defendant’s advertising material noting that Defendant  
21 did not communicate any risk information); (3) the potential risks presented a substantial  
22 danger to users of Mirena; (4) ordinary consumers such as Plaintiff would not have  
23 recognized the potential risks; (5) the Defendant failed to adequately warn of the potential  
24 risks of developing infections and cysts, among other injuries; (6) Plaintiff was harmed  
25 while using the product in a reasonably foreseeable way; (7) and the lack of sufficient  
26 warnings was a substantial factor in causing Plaintiff’s harm because Plaintiff alleges she  
27 would not have used Mirena had she received adequate warnings disclosing these risks, *see*  
28 *id.* ¶ 79. Plaintiff has thus alleged in the SAC sufficient facts to state a plausible claim for

1 strict liability failure to warn.

2 Neither party raised the learned intermediary defense in their papers with respect to  
3 strict liability failure to warn. Had Defendant invoked the learned intermediary defense at  
4 this procedural stage, the result would be no different. Defendant can discharge its duty to  
5 warn about Mirena if it provides an adequate warning to the physician. *Motus I*, 196 F.  
6 Supp. 2d at 991. Here, Plaintiff has also alleged that Defendant’s warning to her physician  
7 was non-existent or inadequate and that the inadequacy of the warning or its absence  
8 caused Plaintiff’s injury. *See* SAC ¶ 79 (“Plaintiff did not have the same knowledge as  
9 Defendant and no adequate warning was communicated to her or her physician(s). Had  
10 the Plaintiff received adequate warnings regarding Mirena, she would not have had the  
11 device implanted.”). At the motion to dismiss stage, even had Defendant raised the  
12 learned intermediary defense, Plaintiff has alleged sufficient facts to withstand the motion  
13 to dismiss. *See Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 271423, at  
14 \*3 (N.D. Cal. Jan. 20, 2010) (Wilkin, J.) (denying drug manufacturer’s motion to dismiss  
15 because at pleading stage manufacturer could not prove that the learned intermediary  
16 doctrine barred all plaintiff’s claims where plaintiff alleged manufacturer did not  
17 adequately convey to physicians the known or knowable risks of the drug).

18 For the foregoing reasons, Defendant’s motion to dismiss Plaintiff’s Second Cause  
19 of Action with respect to the strict liability – failure to warn claim is DENIED.

20 **C. Strict Liability – Design Defect Claim**

21 A design defects exist where a product is built in accordance with its intended  
22 specifications, but the design itself is inherently defective. *Barker*, 20 Cal. 3d at 429.  
23 Controlling California authority unequivocally prohibits strict liability claims for design  
24 defect against manufacturers of prescription drugs. *See Brown*, 44 Cal. 3d at 1069  
25 (holding that no manufacturer strict liability exists for design defect injuries caused by a  
26 prescription drug); *Tucker*, 2013 WL 1149717, at \* 6 (collecting cases in accord and  
27 dismissing strict liability claim based on design defect as precluded by California law).  
28 Moreover, the California Court of Appeal has squarely held that a manufacturer of

1 intrauterine devices cannot be held strictly liable for design defect. *Plenger v. Alza Corp.*,  
2 11 Cal. App. 4th 349, 360-61 (1992).

3 Here, Plaintiff alleges that her Mirena administers a prescribed drug, levonorgestrel,  
4 and was installed by a healthcare provider at Community Physicians Network for Women  
5 in Indianapolis, Indiana. SAC ¶¶ 14-16, 29. Accordingly, the Court holds that Plaintiff’s  
6 strict liability claim based on purported design defect in Mirena is precluded as a matter of  
7 California law. The Court therefore GRANTS WITHOUT LEAVE TO AMEND  
8 Defendant’s motion to dismiss Plaintiff’s strict liability – design defect claim.

9  
10 **III. Implied and Express Warranty Claims**

11 **A. Breach of Implied Warranty**

12 Plaintiff alleges in her Third Cause of Action for breach of implied warranty that  
13 Defendant warranted Mirena to be of merchantable quality, safe and “fit for the ordinary  
14 purpose” of its use to Plaintiff, other Mirena users, physicians and healthcare providers.  
15 SAC ¶¶ 87-88. To maintain her claim, a plaintiff must allege (1) that she intended to use  
16 the product for a particular purpose; (2) that the defendant had reason to know of this  
17 purpose; (3) that the plaintiff relied on defendant’s skill or judgment to provide a product  
18 suitable for this purpose; (4) that the defendant had reason to know that buyers relied on its  
19 skill or judgment; and (5) that the product was unfit for the purpose for which it was  
20 purchased and that it subsequently damaged the plaintiff. *Frisby-Cadillo v. Mylan, Inc.*,  
21 No. C 09-05816 SI, 2010 WL 1838729, at \*3 (N.D. Cal. May 5, 2010) (citing *Keith v.*  
22 *Buchanan*, 173 Cal. App. 3d 13, 25 (1985)).

23 The Court finds that Plaintiff has adequately stated a claim for breach of an implied  
24 warranty. Plaintiff has alleged that she chose Mirena because it was promoted as a safe  
25 and effective method of birth control, SAC ¶ 91; Defendant had reason to know of this  
26 purpose because it promoted Mirena as a contraceptive, *id.* ¶¶ 87-88; Plaintiff relied on  
27 Defendant’s skill and judgment as Defendant is in the business of designing,  
28 manufacturing, advertising and distributing prescription drugs and women’s healthcare

1 products, *id.* ¶ 90; that Defendant knew or had reason to know that consumers so relied, *id.*  
2 ¶ 87; that Mirena was unfit for that purpose and Plaintiff subsequently suffered from  
3 infections, a cyst and abdominal pain as a result of Mirena, *id.* ¶¶ 93-95. These  
4 allegations, while brief, are sufficient to state a claim.

5 In addition to challenging the sufficiency of the pleadings, Defendant also argues  
6 that her breach of implied warranty claim fails because she was not in contractual privity  
7 with Defendant. *See Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058-59  
8 (2008). However, California recognizes an exception to the privity requirement in breach  
9 of warranty claims pertaining to food or drug products. *Wendell*, 2010 WL 271423, at \*5  
10 (citing *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602 (1960)); *see also Arnold v. Dow*  
11 *Chem. Co.*, 91 Cal. App. 4th 698, 720 (2001) (citing *Gottsdanker* with approval). This  
12 exception allows an implied warranty to run from the manufacturer to the ultimate  
13 consumer. *Aaronson v. Vital Pharm., Inc.*, No. 09-CV-1333 W (CAB), 2010 WL 625337,  
14 at \*5 (S.D. Cal. Feb. 17, 2010) (citing *Windham at Carmel Mtn. Ranch Assn. v. Superior*  
15 *Court*, 109 Cal. App. 4th 1162, 1168-70 (2003)).

16 Accordingly, that Plaintiff was not in privity with Defendant does not bar her  
17 implied breach of warranty claim as a matter of law given that claim is sufficiently  
18 pleaded. Defendant’s motion to dismiss Plaintiff’s Third Cause of Action is DENIED.

19 **2. Breach of Express Warranty**

20 Under California law, “[i]n order to plead a cause of action for breach of express  
21 warranty, one must allege the exact terms of the warranty, plaintiff’s reasonable reliance  
22 thereon, and a breach of that warranty which proximately causes plaintiff injury.” *Frisby-*  
23 *Cadillo*, 2010 WL 1838729, at \*4 (citing *Williams v. Beechnut Nutrition Corp.*, 185 Cal.  
24 App. 3d 135, 142 (1986)). In *Frisby-Cadillo*, the court recognized that a plaintiff need not  
25 quote the exact terms of the warranty when the plaintiff alleged that defendant “utilized the  
26 advertising media to urge the use and application of [the subject product] and expressly  
27 warranted to the general public including plaintiff herein, that said product was effective,  
28 proper and safe for its intended use.” *Id.* (quotation marks omitted). Indeed, “[p]roduct

1 advertisements, brochures, or packaging can serve to create part of an express warranty.”  
2 *Rosales v. FitFlop USA, LLC*, 882 F. Supp. 2d 1168, 1178 (S.D. Cal. 2012)) (citing Cal.  
3 Com. Code § 2313(1)(b) (2002)). While a plaintiff need not have relied on the individual  
4 advertisements, plaintiff must have actually been exposed to the advertising. *See In re*  
5 *Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Products Liab.*  
6 *Litig.*, 754 F. Supp. 2d 1145, 1183 (C.D. Cal. 2010).

7 Contrary to Defendant’s argument, Plaintiff has pleaded a breach of express  
8 warranty claim. First, Plaintiff has sufficiently pleaded that Mirena’s advertising failed to  
9 adequately warn about the potential health risks of Mirena and that Defendant promoted  
10 Mirena as safe for use. SAC ¶¶ 18-19, 21, 97. Plaintiff’s allegations in the SAC allow for  
11 an inference to be drawn that Plaintiff knew about Defendant’s claims that Mirena was  
12 safe and effective for use by the public at large. *Id.* ¶ 97. Second, Plaintiff alleges that she  
13 reasonably relied on these warranties in choosing Mirena, thus obviating the requirement  
14 to show privity in a breach of express warranty claim. *Id.* ¶¶ 98-99. *See Fieldstone Co. v.*  
15 *Briggs Plumbing Products, Inc.*, 54 Cal. App. 4th 357, 369 n. 10 (1997), *superseded by*  
16 *statute on other grounds as stated in Greystone Homes, Inc. v. Midtec, Inc.*, 168 Cal. App.  
17 4th 1194, 1213 (2008) (an exception to the general rule that privity of contract is a required  
18 element of an express breach of warranty cause of action exists where a plaintiff’s decision  
19 to purchase the product was made in reliance on the manufacturers’ written representations  
20 in labels or advertising materials). Third, Plaintiff alleged that a breach of the express  
21 warranty proximately caused her injuries when she suffered from infections, an ovarian  
22 cyst, and abdominal pain caused by Mirena. SAC ¶¶ 101. Plaintiff has thus stated a claim  
23 for breach of express warranty. Identification of the specific statements used by Plaintiff  
24 in her purchasing decision are certainly an appropriate avenue for discovery, but at this  
25 procedural stage Plaintiff has adequately pleaded facts to establish an express warranty that  
26 was reasonably relied upon. Thus, Defendant’s motion to dismiss Plaintiff’s Fourth Cause  
27 of Action for breach of express warranty is DENIED.

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**CONCLUSION**


For the foregoing reasons, the Court:

- 1) DENIES Defendant’s motion to dismiss Plaintiff’s First Cause of Action for negligence;
- 2) GRANTS WITH LEAVE TO AMEND Defendant’s motion to dismiss Plaintiff’s Second Cause of Action with respect to the strict liability – manufacturing defect claim;
- 3) DENIES Defendant’s motion to dismiss Plaintiff’s Second Cause of Action with respect to the strict liability – failure to warn claim;
- 4) GRANTS WITHOUT LEAVE TO AMEND Defendant’s motion to dismiss Plaintiff’s Second Cause of Action with respect to strict liability – design defect claim;
- 5) DENIES Defendant’s motion to dismiss Plaintiff’s Third Cause of Action for breach of implied warranty; and
- 3) DENIES Defendant’s motion to dismiss Plaintiff’s Fourth Cause of Action for breach of express warranty.

Should Plaintiff amend the complaint, any amended pleading shall be filed no later than **January 9, 2014**.

**IT IS SO ORDERED.**

Dated: 12/19/13

  
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THELTON E. HENDERSON, JUDGE  
UNITED STATES DISTRICT COURT