UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

KAREAMA PATTERSON, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS, INC., Defendant.	Case No. 1:14-CV-01087-LJO-JLT ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS. (Doc. 9)

Before the Court in the above-styled and numbered cause of action is Defendant Bayer Healthcare Pharmaceuticals, Inc.'s ("Defendant" or "Bayer") Motion to Dismiss, filed November 25, 2014 (Doc. 9). Plaintiff Kareama Patterson's ("Plaintiff" or "Patterson") filed her Opposition on January 12, 2015 (Doc. 12), and Bayer filed a reply on January 16, 2015 (Docs. 13 & 15). The matters are appropriate for resolution without oral argument. *See* Local Rule 230(g). Having considered the record in this case, the parties' briefing, and the relevant law, the Court will grant in part and deny in part Bayer's motion.

BACKGROUND

This suit is a product liability case stemming from Patterson's use of the intrauterine contraceptive device ("IUD") known as "Mirena." *See* Complaint ("Compl.") ¶ 13, Doc. 1. Mirena is made by Defendant, a Delaware corporation, which is in the business of designing, testing, manufacturing, marketing, and distributing prescription drugs and women's healthcare products, including Mirena. *Id.* ¶¶ 2, 6, 8. Inserted into the uterus by a healthcare provider during an office visit, the Mirena IUD is a T-shaped polyethylene frame with a steroid reservoir of 52mg of the

synthetic progestogen levonorgestrel, a prescription medication used as a contraceptive released directly into the uterus at the rate of 20 μg/day. *Id*. ¶ 13, 17. The federal Food and Drug Administration ("FDA") approved Defendant's New Drug Application for Mirena in December 2000. *Id*. ¶ 14, 15.

Patterson, a 34 year old woman and California resident, had a Mirena IUD inserted by her healthcare practitioner according to the manufacturer's instructions and without complication. *Id*. ¶¶ 1, 74, 75. Bayer provides a "Patient Information Booklet" ("Booklet") to physicians to be given to patients at the time of Mirena insertion. *Id.* ¶ 28. When her healthcare provided placed her Mirena IUD, Patterson received Bayer's Booklet, which she read and relied upon when deciding to use Mirena. *Id.* ¶¶ 76, 78. The Booklet does not mention pseudotumor cerebri ("PTC"), also known as idiopathic intracranial hypertension ("IIH," or together, "PTC/IIH"). *Id.* ¶ 29, 80. In deciding whether to use and prescribe Mirena, Patterson and her healthcare practitioners relied on Bayer's representations about Mirena in its package insert, the Patient Information Booklet, or information otherwise disseminated by Bayer. *Id.* ¶ 77.

Subsequent to her Mirena placement, Patterson began experiencing severe headaches and vision problems, including blurred vision. *Id*. ¶ 79. She was ultimately diagnosed with PTC/IIH. *Id*. ¶ 80. Patterson also suffered other injuries related to her Mirena IUD and PTC/IIH. *Id*. ¶ 81. Eventually, she had her Mirena IUD removed by a healthcare practitioner. *Id*. ¶ 82.

Neither Mirena's label nor Bayer's Patient Information Booklet mention PTC/IIH, despite the known link between levonorgestrel and PTC/IIH. *Id*. ¶¶ 27-29. Patterson includes in her Complaint a reference to the "Mirena Label," as of August 7, 2013. *Id*. ¶ 20. The Mirena package labeling: (1) recommends that Mirena be used in women who have had at least one child, *id*. ¶ 20; (2) recommends that Mirena be placed at least six weeks post-partum, *id*. ¶ 21; indicates that Mirena should be used with caution in patients who have "[m]igraine, focal migraine with

asymmetrical visual loss or other symptoms indicating transient cerebral ischemia," *id*. ¶ 22; indicates that removal of Mirena should be considered if patients develop for the first time "[m]igraine, focal migraines with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia," *id.* ¶ 23. Upon information and belief, Patterson alleges that the Mirena label indications are specifically designed to caution healthcare providers about a possible increased risk of transient cerebral ischemia or stroke with Mirena use. *id*. ¶ 25. Patterson alleges that Mirena's label does not accurately or sufficiently warn patients and understates the risks of certain medical conditions or injuries associated with use of Mirena, including non-stroke neurological conditions such as PTC/IIH. *Id*. ¶¶ 1, 26-29, 68.

PTC/IIH is a condition that develops in the skull when a person's cerebrospinal fluid becomes elevated, causing increased pressure. *Id*. ¶ 31. Fluid builds up in the skull and is not released and absorbed at the proper rate. *Id*. Pseudotumor cerebri, or PTC, derives its name from the fact that the condition acts like a tumor, but is not actually a tumor. *Id*. Patients with PTC/IIH typically develop symptoms of severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies. *Id*. ¶ 32. Visual problems and symptoms are a result of increased pressure on the optic nerve. *Id.* Patients with PTC/IIH often develop papilledema, or optic disc swelling due to increased intracranial pressure. *Id*. PTC/IIH patients may also develop a "whooshing" or ringing in the ear, clinically called tinnitus. *Id*. ¶ 33. PTC/IIH is frequently diagnosed after a lumbar puncture or spinal tap is performed, which allows a physician to evaluate the level of cerebrospinal fluid in the skull. *Id*. ¶ 34. When patients present with symptoms of PTC/IIH, they often first undergo an MRI, CT scan, and/or other diagnostic radiology tests to rule out an actual tumor or blood clot in the brain. *Id*. Normal intracranial pressure is considered between 5 and 15 millimeters of mercury (mmHg). *Id*. ¶ 37. Pressure above the 15mmHg range may lead to a diagnosis of PTC/IIC. *Id.* Failure to

correctly diagnose and treat PTC/IIH may lead to permanent vision loss and even blindness. *Id.* ¶ 38. There is currently no treatment to reverse permanent injury to the optic nerves caused by increased intracranial pressure. *Id.* ¶ 39. PTC/IIH treatment focuses on halting visual loss that has already occurred. *Id.* Though it may take years before normal pressure is maintained, PTC is considered reversible in some patients, and irreversible in others. *Id.* ¶ 40. PTC/IIH may also recur throughout a patient's lifetime. *Id.* ¶ 41. Treatment for PTC/IIH may include weight loss, frequent lumbar punctures (which may provide some immediate relief, but does not cure the condition), or medication. *Id.* ¶ 36, 42. PTC/IIH patients are frequently prescribed the medicine Acetazolamine (Diamox), which has its own set of adverse reactions. *Id.* ¶ 42. In severe cases, therapeutic shunting, which involves surgical insertion of a tube to help drain cerebrospinal fluid from the lower back or from the skull, is recommended. *Id.* ¶ 44.

Estimates are that approximately 1-2 people per 100,000 in the United States have PTC or IIH, although reports suggest that the prevalence of the disorder is increasing. *Id.* ¶ 50. In 1994, a study found that in females between the ages of 15-44, IIH occurred at a rate of approximately 3.3 per 100,000 per year. *Id.* Patterson alleges upon information and belief that women who use levonorgestrel-containing products, like Mirena, more commonly develop PTC/IIH, and that the synthetic hormone released by Mirena – levonorgestrel – causes or contributes to the development of PTC/IIH, increases the risk of developing PTC/IIH, and/or worsens or exacerbates PTC/IIH. *Id.* ¶¶ 51, 52. Also, because Mirena is known to cause rapid weight gain in women, the risk of developing PTC/IIH is even greater with Mirena use. *Id.* ¶ 53.

Patterson alleges that issues with other levonorgestrel-related products illustrate that Bayer knew or should have known of the link between such products and PTC/IIH. *Id.* ¶¶ 54-66. Norplant, another levonorgestrel-releasing implant, became available in the United States in 1991, after its manufacturer obtained FDA approval in December 1990. *Id.* ¶ 54. Norplant was developed

by the Population Council and distributed in the United States by Wyeth-Ayerst Laboratories ("Wyeth"), as the "Norplant System" (or "Norplant"). *Id.* Norplant consisted of a set of six small silicone capsules, each containing 36 mg of levonorgestrel, which together were implanted subdermally in the upper arm as contraception, and effective for five years. *Id.* ¶ 55. Norplant released levonorgestrel at an estimated 86 μg/day initially, falling after nine months to 50 μg/day, and by 18 months post-implantation to about 35 μg/day, ultimately dropping to about 30 μg/day. *Id.*

In February 1993, Wyeth submitted a supplemental new drug application to the FDA for the Norplant System, requesting the addition of "idiopathic intracranial hypertension" (also known as PTC/IIH) and other modifications to the "PRECAUTIONS" section of the Norplant physician labeling. *Id.* ¶ 56. The supplemental NDA also requested other modifications to the physician labeling and the patient package insert. *Id.* Wyeth requested expedited review of its supplemental NDA. *Id.* In March 1993, the FDA approved the supplemental NDA, including the proposed addition of warning regarding PTC/IIH to the Norplant System. *Id.* ¶ 57. The new labeling addition included under the "PRECAUTIONS" section stated:

> Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT SYSTEM should be removed from patients experiencing this disorder.

Id. ¶ 58. A warning for PTC/IIH was also added to the patient package insert and stated:

> Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) – An increase in intracranial pressure has been reported in NORPLANT SYSTEM users. Symptoms may include headache (associated with a change in the frequency, pattern, severity, or persistence, of particular importance are those headaches that do not stop) and visual disturbances. Contact your physician or health-care provider if you experience these symptoms. While a causal relationship is unclear, your health-care provider may recommend that the NORPLANT SYSTEM be removed.

Id. ¶ 59.

By 1995, the New England Journal of Medicine reported findings of women with PTC or IIH where levonorgestrel may have contributed to the onset of the condition. *Id.* ¶ 60. The authors concluded that until more information became available, patients should be screened for symptoms and the implants should be removed in patients who show increased intracranial pressure. *Id.* Additional studies concluded the same and noted that PTC/IIH had been reported in Norplant users. *Id.* ¶ 61.

By 2001, Norplant's label included an entry under the "Warnings" section for "Idiopathic Intracranial Hypertension" that stated:

> Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT (levonorgestrel implants (unavailable in us)) SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms, particularly obese patients or those with recent weight gain, should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT (levonorgestrel implants (unavailable in us)) SYSTEM should be removed from patients experiencing this disorder.

Id. The "Warning" section of the package label for Jadelle or "Norplant II" (a two-rod version of a levonorgestrel-releasing implant), also contained similar language. *Id.* ¶ 62. The labels for both Jadelle and Norplant II included warning of PTC/IIH specifically informing patients of the disorder. *Id.* ¶ 64. Jadelle was approved in the United States in 1996 for up to five years' use, although it has never been marketed in the United States. *Id.* ¶ 63. Jadelle is contraindicated in patients with a history of IIH. *Id.*

By the mid-1990s, tens of thousands of lawsuits were filed claiming injuries due to Norplant. *Id.* ¶ 65. In 1996, the FDA received a "Citizen's Petition before the Food and Drug Administration requesting withdrawal for sale of Norplant." *Id.* The petition claimed a number of

adverse events were related to Norplant use, including PTC/IIH. *Id.* In June 2002, Wyeth pulled Norplant off the market. *Id.*

Despite the existence of "a wide body of information available to Defendant regarding the connection between levonorgestrel and PTC/IIH, Mirena's label lacks any warning regarding PTC or IIH." *Id.* ¶ 66. Upon information and belief, Patterson alleges that because Mirena's label is devoid of any warnings about PTC or IIH, once a patient's healthcare provider rules out transient cerebral ischemia or stroke as a cause of symptoms of migraine and/or asymmetrical visual loss, the healthcare provider will not typically know or advise a patient with PTC to remove Mirena, which causes or contributes to the development and/or progression of PTC/IIH. *Id.* ¶ 67. Bayer has a history of overstating the efficacy of Mirena, while understating the potential safety concerns. *Id.* ¶ 68. Bayer knew or should have known that Mirena, and specifically, the synthetic progestin levonorgestrel, causes and/or contributes to the development of PTC/IIH, a severe and possibly irreversible brain condition. *Id.* ¶ 101. Despite over a decade of literature indicating that further testing of the causal relationship between levonorgestrel and PTC/IIH is needed, Patterson alleges that Bayer did not conduct any clinical testing of Mirena and its known link to the development of PTC/IIH. *Id.* ¶¶ 30.

According to Plaintiff's allegations, Bayer was aware of the inadequacies in its warnings because, for example, the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC") contacted Defendants about Bayer's advertising materials for Mirena, stating that they did not communicate any risk information and inadequately communicated Mirena's indications. *Id.* ¶¶ 69-71. Specifically, the DDMAC contacted Bayer in December 2009 regarding its "Mirena Simple Styles Statements Program," consumer-directed live presentations directed toward "busy moms" that utilized scripts which omitted information regarding the serious risks associated with using Mirena. *Id.* ¶¶ 24–27. The portion of the Simple

Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena. *Id.* ¶ 72. Bayer falsely claimed that its product did not require compliance with a monthly routine. *Id.* ¶ 73. Patterson alleges that Bayer concealed its knowledge of the defects in their products from her, her physicians, hospitals, pharmacists, the FDA, and the public in general. *Id*. ¶ 224, 257.

Patterson chose Mirena because it was promoted as a "safe and effective" method of birth control. *Id*. ¶ 100, 186. Had Bayer properly warned of the risks associated with Mirena – including the risk of developing PTC/IIH and that Mirena should be removed immediately once a patient is diagnosed with or suffers symptoms of PTC/IIH – Patterson's healthcare providers would not have prescribed Mirena to her, and she would not have chosen to use Mirena. *Id*. ¶ 186. Patterson alleges that as a direct and proximate result of one or more of Bayer's wrongful or acts or omissions, she has been permanently injured and has incurred or will incur medical expenses for treatment and care, will continue to incur expenses in the future, and has experienced or will experience lost wages and past and future pain and suffering, and is subject to an increased risk of future harm. *Id*. ¶ 161.

Patterson filed suit on July 11, 2014 (Doc. 1), invoking this Court's diversity jurisdiction pursuant to 28 U.S.C. § 1332, and supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367. By her Complaint, she alleges nine causes of action: (1) negligence, (2) strict liability – design defect, (3) strict liability – failure to warn, (4) strict liability – misrepresentation, (5) breach of implied warranty, (6) breach of express warranty, (7) negligent misrepresentation, (8) fraudulent misrepresentation, and (9) fraud by suppression and concealment.

On November 25, 2014, Bayer filed a motion to dismiss Patterson's Complaint (Doc. 9). Patterson filed her Opposition on January 12, 2015 (Doc. 12), and Bayer filed its Reply on January 16, 2015 (Doc. 13). The matter is now ripe for review.

LEGAL STANDARD

Rule 12(b)(6)

Dismissal is appropriate under Rule 12(b)(6) of the Federal Rules of Civil Procedure[1] when a plaintiff's allegations fail "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A dismissal under Rule 12(b)(6) "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't,* 901 F.2d 696, 699 (9th Cir. 1990).

Under Federal Rule of Civil Procedure 8(a), a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face" with sufficient specificity to "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, 545, 570 (2007) (citation and quotation marks omitted). "Rule 8 . . . does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (citation omitted). Plausibility does not equate to probability, but it requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "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.* In ruling on a motion to dismiss, a court must "accept all material allegations of fact as true and construe the complaint in a light most favorable to the non-moving party." *Vasquez v. Los Angeles Cnty.,* 487 F.3d 1246, 1249 (9th Cir. 2007). The Court, however, is not "bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal,* 556 U.S. at

[1] All references to "Rules" hereinafter refer to the Federal Rules of Civil Procedure.

678 (internal quotation marks omitted). Dismissal of claims that fail to meet this standard should be with leave to amend unless it is clear that amendment could not possibly cure the deficiencies in the complaint. *Steckman v. Hart Brewing, Inc.,* 143 F.3d 1293, 1296 (9th Cir. 1998).

Rule 9(b)

Claims for fraud must overcome the heightened pleading requirements of Rule 9(b). Fed. R. Civ. P. 9(b). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." *Id.* A complaint must "be 'specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.' " *Kearns v. Ford Motor Co.,* 567 F.3d 1120, 1124 (9th Cir. 2009) (citation omitted). The complaint must include an account of the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Edwards v. Marin Park, Inc.,* 356 F.3d 1058, 1066 (9th Cir. 2004) (citation omitted). In addition, "[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false." *In re GlenFed, Inc. Sec. Litig.,* 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc), *superceded by statute on other grounds.* A plaintiff must also plead "the statements made and by whom made, an explanation of why or how such statements were false or misleading when made, and the role of each defendant in the alleged fraud." *Erickson v. Boston Scientific Corp.,* 846 F.Supp.2d 1085, 1090 (C.D. Cal. 2011).

Leave to Amend

If the Court determines that a complaint should be dismissed, it must then decide whether to grant leave to amend. Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "should be freely granted when justice so requires," bearing in mind that "the underlying purpose of Rule 15 . . . [is] to facilitate decision on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith,* 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks omitted).

Nonetheless, a court "may exercise its discretion to deny leave to amend due to 'undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . , [and] futility of amendment.' " *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892-93 (9th Cir. 2010) (alterations in original) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

DISCUSSION

I. Bayer's Global Deficiency Argument

The gravamen of Bayer's motion to dismiss is that there is a global deficiency in Patterson's Complaint because it "fails to specify key facts to rise to the level of a plausible claim, such as the name of the physician who prescribed and placed the Mirena and location of the procedure; the name of the physician who removed the Mirena and location of that procedure; the dates of insertion and removal; the physician who diagnosed Plaintiff with IIH and when that diagnosis was made; and whether the physician who allegedly diagnosed plaintiff with IIH or any other physician has attributed that injury to Plaintiff's Mirena use." Reply at 6, Doc. 9. Bayer argues that because the Complaint is globally insufficiently pled under Rule 8(a), the Court should dismiss it in its entirety without leave to amend.

In support of this argument, Bayer relies entirely on cases from outside the Ninth Circuit, three brief orders out of Kentucky which the Court does not find persuasive. *See Hardwick v. Bayer Healthcare Pharm., Inc.*, No. 3:14- CV-00082-JGH (W.D. Ky.) (Heyburn, J.) (declining to provide an advisory opinion, foregoing analysis, and granting plaintiff leave to amend); *Smith v. Bayer Healthcare Pharm., Inc*., No. 3:14-CV- 00006-JGH (W.D. Ky.) (Heyburn, J.) (same); *Bosch v. Bayer Healthcare Pharm., Inc.*, No. 3:13-CV-00656-JHM, 2013 WL 5656111, at *2-3 (W.D. Ky. Oct. 16, 2013) (declining to provide an advisory opinion, foregoing analysis, reserving ruling on Bayer's motion dismiss, and granting plaintiff leave to amend). As it does here, Bayer argued in

each of the Kentucky cases that the plaintiff's complaint was globally insufficient. When presented with this same global deficiency argument, the court in *Houston v. Bayer Healthcare Pharm. Inc*., found the unpublished Kentucky cases, including *Bosch* (on which Bayer primarily relies here), particularly "unpersuasive" because the case has "no holding that this court can discern, as the court there declined to analyze the complaint before it on the grounds that doing so would provide the plaintiff's an advisory opinion." --- F. Supp. 2d ----, No. 2:14-CV-00035-WMA, 2014 WL 1330906 (N.D. Ala. Mar. 28, 2014) (citing *Bosch*, 2013 WL 5656111, at *4). The court railed against Bayer's logic, stating that "the court disagrees that there exists an abstract sufficiency hurdle, contained in the Federal Rule, that is entirely separate from any substantive law." *Id.*

In the instant action, Bayer encourages the Court to ignore *Houston*, but offers no analysis. Rather, Bayer cryptically nods to the case's application of Alabama law. Yet state law had no role in or impact on the *Houston* court's analysis of federal procedural requirements. *See generally* 2014 WL 1330906. This Court, like that in *Houston*, finds that *Bosch*, *Hardwick* and *Smith* simply do not stand for the proposition that a case can be dismissed in its entirety with prejudice, without any substantive analysis of the required elements of the claims, as Bayer argues. *Id.*

Ultimately, Bayer's global deficiency argument is unavailing. At this early stage, Patterson's failure to include *some* facts in the Complaint is not fatal to the *entire* action. Rule 8(a) does not operate in a vacuum. Rather, the Court must examine factual omissions in context of the elements of the causes of action to determine whether these particular facts are required to state a claim. *See, e.g.*, *Houston* 2014 WL 1330906 ("the question is whether [a plaintiff] has alleged **facts to support that cause of action**, not simply whether he has alleged facts") (original emphasis) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009) ("In *Twombly*, [. . .] the Court found it necessary first to discuss the antitrust principles implicated by the complaint. Here too we begin by taking note of the elements a plaintiff must plead to state a claim . . . ."). In Bayer's discussion of this

issue, it ignores the most similar case from within the Ninth Circuit (about which Bayer must have known because Bayer had the same counsel in that case as it does here). *See Baker v. Bayer Healthcare Pharm., Inc*., No. C13-0490 TEH, 2013 WL 6698653, at *1 (N.D. Cal. Dec. 19, 2013). Like the instant action, *Baker* is a product liability case related to Mirena use. *Id.* The court in *Baker* reviewed the factual allegations in context of the individual elements of the causes of action, ultimately granting Bayer's motion to dismiss plaintiff's strict liability – manufacturing and design defect claims, but denying the motion as to negligence, strict liability – failure to warn, breach of implied warranty, and breach of express warranty claims. *Id.* Determining whether the elements of negligence are satisfied,[2] for example, does not turn on the name of Patterson's doctor or the dates of her procedures.[3] In other words, "detailed factual allegations," some of which Bayer emphasizes are absent here, are not required. *Twombly*, 550 U.S. at 555. Following the *Twombly* and *Iqbal* standard, as it must, the Court therefore declines Bayer's invitation to embrace a new global sufficiency standard.

In support of dismissal of Patterson's claims for Negligence (Claim I), Strict Liability – Failure to Warn (Claim III), and Strict Liability – Misrepresentation[4] (Claim IV), Bayer's sole argument is the failed global deficiency theory and it otherwise offers no basis for dismissal grounded in the elements of the causes of action or Patterson's factual allegations. Accordingly, the Court will deny the motion to dismiss as to Claims I, III and IV.

II. Motion to Dismiss for Failure to State Plausible Claims for Relief

[2] When a court sits in diversity, it must ordinarily apply the substantive law of the forum in which it is located. *Erie R.R. Co. v.* Tompkins, 304 U.S. 64, 78 (1938). Substantive California law therefore governs the instant action.

[3] To state a claim for negligence under California law, a plaintiff must allege that a defendant owed a legal duty, breached it, and that the breach proximately caused plaintiff's injury. *See Garcia v. W & W Cmty. Dev., Inc.*, 186 Cal. App. 4th 1038, 1044 (2010).

[4] Patterson does not bring a defective manufacturing claim, as Bayer suggests. Rather, she brings an action for strict liability – misrepresentation. *See* Compl. ¶¶ 163-197; Plaintiff's Opp. to Defendant's Motion to Dismiss (Doc. 12, p. 4) ("Plaintiff is not pursuing a manufacturing defect claim."). As such, the Court need not address Bayer's motion to dismiss the nonexistent claim.

In the alternative, Bayer argues that Patterson's cause of action for strict liability – design defect (Claim II) is prohibited under California law; that the breach of implied/express warranty claims (Claims V, VI) fail for lack of privity; and that the claims sounding in fraud (Claims VII-IX) fail under Rule 9(b) for lack of particularity. The Court will examine the claims in turn and whether, with respect to each, Patterson makes sufficient factual allegations.

Claim II: Strict Liability—Design Defect

Patterson alleges that Bayer is strictly liable for her injuries under a design defect theory. California recognizes strict liability for three types of product defects—manufacturing defects, warning defects (inadequate warnings or failure to warn), and design defects. *Lucas v. City of Visalia,* 726 F. Supp. 2d 1149, 1154 (E.D. Cal. 2010) (citing *Anderson v. Owens-Corning Fiberglas Co.,* 53 Cal. 3d 987, 995 (1991)). A design defect exists where a product is built in accordance with its intended specifications, but the design itself is inherently defective. *Tucker v. Wright Med. Tech., Inc.*, No. 11-CV-03086-YGR, 2013 WL 1149717, at *4 (N.D. Cal. Mar. 19, 2013) (citing *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 429 (1978)). Controlling California authority unequivocally prohibits strict liability claims for design defect against manufacturers of prescription drugs. *See Brown v. Superior Court,* 44 Cal.3d 1049, 1069 (1988) (holding that no manufacturer strict liability exists for design defect injuries caused by a prescription drug); *Tucker,* 2013 WL 1149717, at * 6 (collecting cases in accord and dismissing strict liability claim based on design defect as precluded by California law). The California Court of Appeal has also specifically held that a manufacturer of intrauterine devices cannot be held strictly liable for design defect. *Plenger v. Alza Corp.,* 11 Cal. App. 4th 349, 360-61 (1992). Because the instant action for design defect relates to an intrauterine device's administration of levonorgestrel – a prescription drug – the claim is precluded as a matter of law. Accordingly, the Court will grant Defendant's motion to

dismiss as to Patterson's cause of action for strict liability – design defect (Claim II), without leave to amend.

Claim V: Breach of Implied Warranty

To maintain a claim for breach of implied warranty, a plaintiff must allege (1) that she intended to use the product for a particular purpose; (2) that the defendant had reason to know of this purpose; (3) that the plaintiff relied on defendant's skill or judgment to provide a product suitable for this purpose; (4) that the defendant had reason to know that buyers relied on its skill or judgment; and (5) that the product was unfit for the purpose for which it was purchased and that it subsequently damaged the plaintiff. *Frisby-Cadillo v. Mylan, Inc.,* No. C 09–05816 SI, 2010 WL 1838729, at *3 (N.D. Cal. May 5, 2010) (Illston, J.) (citing *Keith v. Buchanan,* 173 Cal.App.3d 13, 25 (1985)).

The Court finds that Patterson has adequately stated a claim for breach of an implied warranty. Patterson alleges that she used Mirena for its ordinary purpose, contraception, which is the purpose for which it was designed, manufactured, prescribed, and intended by Bayer, Compl. ¶ 8, 13, 15, 17, 75, 199, 200, 202; that in choosing to use Mirena, she relied on Bayer's skill and judgment as it is in the business of designing, manufacturing, advertising and distributing birth control, *id.* ¶ 199-200; and that Bayer knew or had reason to know that she and other consumers so relied, *id*. ¶ 199, 201, 205-06. She further alleges that Mirena was unfit for its intended purpose for which it was purchased and used "because it causes and/or contributes to the development of IIH/PTC, a foreseeable risk, which Defendant knew or should have known of," *id.* ¶ 203, and because Bayer "inadequately warned of the risks of developing IIH/PTC and/or papilledema, and/or that the Mirena should be removed once these conditions, and/or symptoms of these conditions, develop." *Id.* ¶ 204. Finally, Patterson alleges that she was damaged by this unfitness in that Mirena use proximately caused her PTC/IIH, and that as a direct result, she suffered from severe

headaches and vision problems, among other injuries, *id.* ¶¶ 80, 81, 83, 84, 207; *Baker*, 2013 WL 6698653, at *6 (finding allegations of unfitness coupled with contention that plaintiff "subsequently suffered from infections, a cyst and abdominal pain as a result of Mirena," sufficient to meet fifth element of a breach of implied warrant claim). Against the backdrop of the requisite elements, the Court concludes that, brevity notwithstanding, Patterson's factual allegations are sufficient to state a claim. *See Frisby-Cadillo*, 2010 WL 1838729, at *4.

Bayer also contends that Patterson's breach of implied warranty claim fails because she was not in contractual privity with Bayer. *See Blanco v. Baxter Healthcare Corp.*, 158 Cal.App. 4th 1039, 1058-59 (2008). However, in breach of warranty claims relative to food or drug products, there is an exception to the privity requirement. *See, e.g., Baker,* 2013 WL 6698653, at *6 (applying exception in nearly identical circumstances to the instant case, and finding plaintiff had adequately stated a claim for breach of implied warranty) (citing *Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 271423, at *5 (N.D. Cal. Jan. 20, 2010) (citing *Gottsdanker v. Cutter Labs.*, 182 Cal.App.2d 602 (1960))); *see also Arnold v. Dow Chem. Co.*, 91 Cal. App. 4th 698, 720 (2001) (citing *Gottsdanker* with approval). Recognized in California, the exception allows an implied warranty to run from the manufacturer to the ultimate consumer in these circumstances. *Aaronson v. Vital Pharm., Inc.*, No. 09-CV-1333 W(CAB), 2010 WL 625337, at *5 (S.D. Cal. Feb. 17, 2010) (citing *Windham at Carmel Mtn. Ranch Assn. v. Superior Court*, 109 Cal. App. 4th 1162, 1168-70 (2003)). Consequently, contrary to Bayer's argument, lack of privity does not bar Patterson's implied breach of warranty claim as a matter of law. *Baker*, 2013 WL 6698653, at *6. Accordingly, the Court will deny Bayer's motion to dismiss Patterson's cause of action for breach of implied warranty (Claim V).

Claim VI: Breach of Express Warranty

California courts use a three-step approach to determine whether an express warranty was breached. *NuCal Foods, Inc. v. Quality Egg LLC*, 918 F. Supp. 2d 1023, 1034 (E.D. Cal. 2013) (citing *McDonnell Douglas Corp. v. Thiokol Corp.*, 124 F.3d 1173, 1176 (9th Cir. 1997) (citing *Keith*, 173 Cal. App. 3d at 19)). To maintain a breach of express warranty action, the plaintiff "must allege the exact terms of the warranty, plaintiff's reasonable reliance thereon, and a breach of that warranty which proximately causes plaintiff injury." *Frisby-Cadillo*, 2010 WL 1838729, at *4 (citing *Williams v. Beechnut Nutrition Corp.*, 185 Cal. App. 3d 135, 142 (1986)). As Judge Illston recognized in *Frisby-Cadillo*, however, a plaintiff need not quote the exact terms of the warranty when she has alleged that defendant "utilized the advertising media to urge the use and application of [the subject product] and expressly warranted to the general public including plaintiff herein, that said product was effective, proper and safe for its intended use." *Id.* (quotation marks omitted). A seller does not need to use formal words such as "warrant" or "guarantee," or have a specific intention to make a warranty. *Houston v. Medtronic, Inc.*, No. 2:13-CV-01679-SVW, 2014 WL 1364455, at *10 (C.D. Cal. Apr. 2, 2014) (citing Cal. Com. Code § 2313(2)). Rather, "[c]ourts have liberally construed affirmations of quality made by sellers in favor of injured consumers." *Id.* (citing *Keith*, 173 Cal. App. 3d at 21 (citing *Hauter v. Zogarts*, 14 Cal. 3d 104, 112 (1975)). Indeed, "[p]roduct advertisements, brochures, or packaging can serve to create part of an express warranty." *Rosales v. FitFlop USA, LLC*, 882 F. Supp. 2d 1168, 1178 (S.D. Cal. 2012) (citing Cal. Com. Code § 2313(1)(b) (2002)). Moreover, "[i]t has even been suggested that in an age of consumerism all seller's statements, except the most blatant sales pitch, may give rise to an express warranty." *Id.* (citation and internal quotation marks omitted). While a plaintiff need not have relied on the individual advertisements, plaintiff must have actually been exposed to the advertising. *See In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Products Liab. Litig.*, 754 F. Supp. 2d 1145, 1183 (C.D. Cal. 2010).

In the instant action, Patterson sufficiently pleads a breach of express warranty claim. First, she alleges that she received Bayer's advertising about Mirena, such as its Patient Information Booklet, labels, and brochures, which failed to adequately warn about the potential health risks of Mirena and which promoted it as safe for use, and that she read them. Compl. ¶¶ 27-29, 76-78, 199, 200. From this, the Court can draw a plausible inference that Patterson knew about Bayer's claims that Mirena was safe and effective for use by the public at large. *Id.* ¶ 199. Second, Patterson alleges that having received and read the Booklet as well as other Bayer materials, she reasonably relied on these warranties in choosing Mirena, *id.* ¶¶ 76, 77, thus obviating the requirement to show privity in a breach of express warranty claim. *See Baker*, 2013 WL 6698653, at *7 (citing *Fieldstone Co. v. Briggs Plumbing Products, Inc.,* 54 Cal. App. 4th 357, 369 n. 10 (1997), *superseded by statute on other grounds as stated in Greystone Homes, Inc. v. Midtec, Inc.,* 168 Cal.App. 4th 1194, 1213 (2008) (an exception to the general rule that privity of contract is a required element of an express breach of warranty cause of action exists where a plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials)). Third, Plaintiff alleged that a breach of the express warranty proximately caused her injuries and she suffered from PTC/IIH and its symptoms, caused by Mirena. *Id.* ¶¶ 79-81, 207.

For the purposes of stating a claim upon which relief can be granted, Patterson has alleged sufficient facts to establish that she reasonably relied upon an express warranty and thus has plausibly stated a claim for breach of express warranty. Accordingly, the Court will deny Bayer's motion to dismiss her cause of action for breach of express warranty (Claim VI).

Claim VII: Negligent Misrepresentation

A negligent misrepresentation is "[t]he assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true." Cal. Civ. Code § 1710. Negligent

misrepresentation differs from fraud in that it "allows recovery in the absence of scienter or intent to defraud." *Waldo v. Eli Lilly & Co.*, No. CIV. S-13-0789 LKK, 2013 WL 5554623, at *8 (E.D. Cal. Oct. 8, 2013) (quoting *Los Angeles Unified School Dist. v. Great Am. Ins. Co.*, 49 Cal. 4th 739, 750 n. 5 (2010)). Still, negligent misrepresentation requires a "positive assertion, in a manner not warranted by the information of the person making it, of that which is not true, though he believes it to be true." *Mitsui O.S.K. Lines, Ltd. v. SeaMaster Logistics, Inc.*, 913 F. Supp. 2d 780, 789 (N.D. Cal. 2012) (citing *Small v. Fritz Companies, Inc.*, 30 Cal. 4th 167, 174 (2003) (quoting Cal. Civ. Code §§ 1710(2), 1572(2)) (alterations in original; citations omitted)). In other words, mere omissions or nondisclosures "cannot give rise to liability for negligent misrepresentation." *Mitsui O.S.K. Lines, Ltd.*, 913 F. Supp. 2d at 789 (citing *Lopez v. Nissan N. Am., Inc.*, 201 Cal. App. 4th 572, 596 (2011), *reh'g denied* (Dec. 30, 2011), *review withdrawn* (Mar. 14, 2012); *Wilson v. Century 21 Great W. Realty*, 15 Cal. App. 4th 298, 306 (1993)).

Bayer moves to dismiss Patterson's seventh cause of action for negligent misrepresentation for failure to meet the particularity requirement of Rule 9(b). The Court agrees that the Complaint does not make allegations of misrepresentations with sufficient particularity. The basis for Patterson's allegation that Bayer is liable for negligent misrepresentation is her contention that Bayer omitted adequate warnings from its promotional materials, brochures, and labels. Although Patterson implies that Bayer made positive assertions that Mirena was safe, this conclusory statement rehashes allegations of Bayer's omissions and nondisclosures. In the absence of any evidence that Bayer made positive assertions and not merely omissions, the factual allegations are insufficient to state a plausible claim for negligent misrepresentation.

Accordingly, the Court will grant Bayer's motion to dismiss with respect to Patterson's seventh cause of action for negligent misrepresentation. Because such deficiencies could be cured in a well-pleaded complaint, the Court will grant leave to amend.

Claims VIII and IX: Fraud Based Claims

Under California law, "[t]he elements of fraud, which gives rise to the tort action for deceit, are (a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or 'scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage." *Waldo*, 2013 WL 5554623, at *7 (citing *Small*, 30 Cal. 4th at 173 (quoting *Lazar v. Superior Court*, 12 Cal. 4th 631, 638 (1996))).

Bayer argues that Patterson's fraud claims should be dismissed for failure to meet the particularity requirement of Rule 9(b). The Court agrees. Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." In order to plead fraud with particularity, the complaint must allege the time, place, and content of the fraudulent representation; conclusory allegations do not suffice. *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Claims made on information and belief are not usually sufficiently particular, unless they accompany a statement of facts on which the belief is founded. *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993).

The Court acknowledges Patterson's relevant factual allegations: that Mirena's Booklet, advertisements, and label fail to warn about PTC/IIH; that Bayer has a history of overstating the efficacy of Mirena while understating the potential safety concerns, for instance, that Bayer made fraudulent representations regarding Mirena in December 2009 in their "Mirena Simple Style Statements Program," and made misrepresentations regarding Mirena's propensity to cause serious physical harm. Absent from these otherwise sufficient factual allegations is where or when Patterson was exposed to the Booklet or other materials. Discovery issues notwithstanding, Patterson fails to include the information in her pleading thus does not meet Rule 9(b)'s heightened pleading standard. Accordingly, the Court will grant the motion to dismiss as to the causes of

action sounding in fraud (Claims VIII and IX) with leave to amend, as such omissions may be cured.

III. CONCLUSION AND ORDER

For the foregoing reasons, **IT IS HEREBY ORDERED** that Defendant's Motion to Dismiss Plaintiff's Complaint (Doc. 9) is **GRANTED IN PART** and **DENIED IN PART**, as follows:

(1) Insofar as Plaintiff's First Cause of Action for Negligence, the motion is **DENIED**;

(2) The motion to dismiss Plaintiff's Second Cause of Action for Strict Liability – Design Defect is **GRANTED**; and because a strict liability – design defect claim is not cognizable under California law, the claim is **DISMISSED WITHOUT LEAVE TO AMEND**.

(3) The motion to dismiss Plaintiff's Third Cause of Action for Strict Liability – Failure to Warn is **DENIED**;

(4) The motion to dismiss Plaintiff's Fourth Cause of Action for Strict Liability – Misrepresentation is **DENIED**;

(5) The motion to dismiss Plaintiff's Fifth Cause of Action for Breach of Implied Warranty is **DENIED**;

(6) The motion to dismiss Plaintiff's Sixth Cause of Action for Breach of Express Warranty is **DENIED**;

(7) Insofar as Plaintiff's Seventh Cause of Action for Negligent Misrepresentation, Eighth Cause of Action for Fraudulent Misrepresentation, and Ninth Cause of Action for Fraud by Suppression and Concealment, the motion to dismiss is **GRANTED**, with leave to amend.

Should Plaintiff amend the complaint, any amended pleading shall be filed no later than **15 days from the date of this Order**.

IT IS SO ORDERED.

Dated: **February 24, 2015**

/s/ Lawrence J. O'Neill
UNITED STATES DISTRICT JUDGE