UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

ANGELA WALDO, individually and as Natural Parent of D.P., Plaintiff, v. ELI LILLY & COMPANY, Defendant.	No. CIV. S-13-0789 LKK/EFB **ORDER**

Plaintiff Angela Waldo, in her individual capacity and on behalf of her son, D.P., sues defendant Eli Lilly and Company, alleging that D.P. was born with various heart defects as a result of Waldo's ingestion of Prozac during pregnancy.

Eli Lilly moves to dismiss two of Waldo's causes of action under Federal Rule of Civil Procedure 12(b)(6).

For the reasons set forth below, Eli Lilly's motion will be denied as to the cause of action for fraud, and granted as to the cause of action for negligent misrepresentation.

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I. BACKGROUND

A. Procedural Background

Waldo filed this lawsuit on April 22, 2013. Eli Lilly moved to dismiss her complaint under Rule 12(b)(6). (ECF No. 18.) By order dated October 8, 2013, the court granted Eli Lilly's motion in part and denied it in part. (Order, ECF No. 35.)

Waldo then filed a first amended complaint, alleging nine causes of action under California law, sounding in strict liability, negligence, warranty, and fraud. ("FAC," ECF No. 36.)

On November 12, 2013, Eli Lilly answered the FAC, and simultaneously moved to dismiss Waldo's eighth (fraud) and ninth (negligent misrepresentation) causes of action, contending that these were not pled with sufficient specificity under Rule 9(b). (ECF Nos. 37, 38.) Eli Lilly's answer does not respond to the allegations which comprise these two causes of action.

B. Factual Background

The following allegations are taken from the FAC.

In 2001, Waldo was prescribed and took Prozac for depression. She stopped taking Prozac when she discovered she was pregnant. (FAC ¶ 20.)

On March 1, 2002, after 35 weeks' gestation, Waldo gave birth to D.P. at Mercy Folsom Hospital in Folsom, California. (Id. ¶ 21.) D.P. was diagnosed with a ventricular septal defect, a hole in the bottom of the heart chamber, and a heart murmur. (Id. ¶ 22.)

On February 27, 2007, D.P. underwent surgery to repair the hole in his heart chamber. (Id. ¶ 23.)

In January 2011, D.P was diagnosed with leaking of the aortic valve. (Id. ¶ 24.)

Due to these birth defects, D.P. regularly visits a cardiologist and other health care specialists. (Id. ¶ 25.)

Prozac is a selective serotonin reuptake inhibitor marketed primarily as an antidepressant medication. Eli Lilly designed, manufactures, and markets Prozac. (Id. ¶¶ 14, 16.)

When ingested during pregnancy, Prozac can cause serious birth defects, including, but not limited to, heart defects, lung defects, ventricular septal defects, limb deformations, spina bifida, cleft palates, and persistent pulmonary hypertension of the newborn. (Id. ¶ 26.)

Eli Lilly conducted animal studies both before and after initial approval of Prozac in 1987. These studies suggested that (i) dangerous birth defects might be associated with use of Prozac during pregnancy, (ii) the deaths of baby animals during the studies were due to developmental abnormalities caused by Prozac, and (iii) a human fetus might be affected by the mother's ingestion of Prozac during pregnancy, though the mother might not show any noticeable signs therefrom. (Id. ¶¶ 27-30.)

Shortly after Prozac's approval, Eli Lilly began receiving adverse event reports which also reflected birth defects associated with Prozac use during pregnancy. (Id. ¶ 28.)

Eli Lilly did not test Prozac for safety or efficacy in pregnant women. In its promotional activities, Eli Lilly did not discourage pregnant women from using Prozac. Through a variety of methods, Eli Lilly encouraged doctors to prescribe Prozac to

women of childbearing age, women who were trying to conceive, and to pregnant women. (Id. ¶ 32.)

Eli Lilly knew, or should have known, about the adverse side effects of Prozac as early as 1987, but failed to adequately warn consumers, physicians, and the U.S. Food and Drug Administration. (Id. ¶ 27.)

In 2001 (the same year in which Waldo started taking Prozac), studies were published showing that drugs in the same class as Prozac increased the risks of major congenital malformations, premature birth, and toxic effects on the fetus. (Id. ¶ 43.)

Eli Lilly did not add a warning regarding cardiovascular birth defects to the Prozac label until 2011. (Id. ¶ 36.) This label modification only referenced cardiac defects, not the other birth defects for which babies were at risk if their mothers ingested Prozac while pregnant. (Id. ¶ 41.)

II. STANDARD

A dismissal motion under Rule 12(b)(6) challenges a complaint's compliance with the federal pleading requirements. Under Rule 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The complaint must give the defendant "'fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atlantic v. Twombly, 550 U.S. 544, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)).

To meet this requirement, the complaint must be supported by factual allegations. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Moreover, this court "must accept as true all of the factual

allegations contained in the complaint." Erickson v. Pardus, 551 U.S. 89, 94 (2007).[1]

"While legal conclusions can provide the framework of a complaint," neither legal conclusions nor conclusory statements are themselves sufficient, and such statements are not entitled to a presumption of truth. Iqbal, 556 U.S. at 679. Iqbal and Twombly therefore prescribe a two-step process for evaluation of motions to dismiss. The court first identifies the non-conclusory factual allegations, and then determines whether these allegations, taken as true and construed in the light most favorable to the plaintiff, "plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

"Plausibility," as it is used in Twombly and Iqbal, does not refer to the likelihood that a pleader will succeed in proving the allegations. Instead, it refers to whether the non-conclusory factual allegations, when assumed to be true, "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Twombly, 550 U.S. at 557).[2] A

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[1] Citing Twombly, 550 U.S. at 555-56, Neitzke v. Williams, 490 U.S. 319, 327 (1989) ("What Rule 12(b)(6) does not countenance are dismissals based on a judge's disbelief of a complaint's factual allegations"), and Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ("[I]t may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test" under Rule 12(b)(6)).

[2] Twombly imposed an apparently new "plausibility" gloss on the previously well-known Rule 8(a) standard, and retired the long-established "no set of facts" standard of Conley v. Gibson, 355 U.S. 41 (1957), although it did not overrule that case

complaint may fail to show a right to relief either by lacking a cognizable legal theory or by lacking sufficient facts alleged under a cognizable legal theory. Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1990).

III. ANALYSIS

When the 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). California substantive law therefore governs.

Waldo's eighth cause of action alleges fraud, and its ninth, negligent misrepresentation. Eli Lilly argues that these causes of action should be dismissed for failure to meet the particularity requirement of Rule 9(b).

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

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outright. See Moss v. U.S. Secret Service, 572 F.3d 962, 968 (9th Cir. 2009) (the Twombly Court "cautioned that it was not outright overruling Conley[,]" although it was retiring the "no set of facts" language from Conley). The Ninth Circuit has acknowledged the difficulty of applying the resulting standard, given the "perplexing" mix of standards the Supreme Court has applied in recent cases. See Starr v. Baca, 652 F.3d 1202, 1215 (9th Cir. 2011) (comparing the Court's application of the "original, more lenient version of Rule 8(a)" in Swierkiewicz v. Sorema N.A., 534 U.S. 506 (2002) and Erickson v. Pardus, 551 U.S. 89 (2007) (per curiam), with the seemingly "higher pleading standard" in Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336 (2005), Twombly and Iqbal), cert. denied, 132 S. Ct. 2101 (2012). See also Cook v. Brewer, 637 F.3d 1002, 1004 (9th Cir. 2011) (applying the "no set of facts" standard to a Section 1983 case).

allegations do not suffice. Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989).[3] 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).

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." Small v. Fritz Companies, Inc., 30 Cal.

[3] Several courts in the Northern District of California have held that plaintiffs may plead fraud-by-omission with less specificity than fraud-by-misrepresentation, noting that such a plaintiff "will not be able to specify the time, place, and specific content of an omission as precisely as would a plaintiff in a false representation claim." Falk v. Gen. Motors Corp., 496 F. Supp 2d. 1088, 1098-99 (N.D. Cal. 2007) (Alsup, J.) Accord Washington v. Baenziger, 673 F. Supp. 1478, 1482 (N.D. Cal. 1987) (Weigel, J.) ("Where the fraud consists of omissions on the part of the defendants, the plaintiff may find alternative ways to plead the particular circumstances of the fraud . . . a plaintiff cannot plead either the specific time of the omission or the place, as he is not alleging an act, but a failure to act.") (internal citation omitted); Stickrath v. Globalstar, Inc., 527 F. Supp. 2d 992, 998 (N.D. Cal. 2007) (Henderson, J.) ("[W]here allegations rest on claims of omission, this standard is relaxed . . . ."); In re Apple & AT & TM Antitrust Litigation, 596 F.Supp.2d 1288 (N.D. Cal. 2008) (Ware, J.) ("Where the claim is one of fraud by omission, however, the pleading standard is lowered on account of the reduced ability in an omission suit "to specify the time, place, and specific content" relative to a claim involving affirmative misrepresentations") (internal citation and quotation omitted). The court finds the reasoning in these cases to be sound; plaintiffs need not allege fraudulent concealment or nondisclosure under Rule 9(b) with the level of specificity required to allege fraudulent misrepresentation.

4th 167, 173 (2003) (quoting Lazar v. Superior Court, 12 Cal. 4th 631, 638 (1996)).

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." Los Angeles Unified School Dist. v. Great Am. Ins. Co., 49 Cal. 4th 739, 750 n. 5 (2010).

A. Misrepresentation or omission

The court previously dismissed both causes of action without prejudice. Its Order identified the following pleading defect: Waldo did not "identify the specific fraudulent representations at issue, the medium through which they were conveyed, and whom they were directed to." (Order 16.)

Eli Lilly contends that Waldo has again failed to meet this standard in the FAC.

Waldo has alleged that labeling information included with Prozac during her pregnancy provided as follows:

> *Pregnancy—Pregnancy Category C*: In embryo-fetal development studies in rats and rabbits, there was no evidence of teratogenicity following administration of up to 12.5 and 15 mg/kg/day, respectively (1.5 and 3.6 times, respectively, the maximum recommended human dose [MRHD] of 80 mg on a mg/m^2 basis) throughout organogenesis. However, in rat reproduction studies, an increase in stillborn pups, a decrease in pup weight, and an increase in pup deaths during the first 7 days postpartum occurred following maternal exposure to 12 mg/kg/day (1.5 times the MRHD on a mg/m^2 basis) during gestation or 7.5 mg/kg/day (0.9 times the

> MRHD on a mg/m^2 basis) during gestation and lactation. There was no evidence of developmental neurotoxicity in the surviving offspring of rats treated with 12 mg/kg/day during gestation. The no-effect dose for rat pup mortality was 5 mg/kd/day (0.6 times the MRHD on a mg/m^2 basis). Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (FAC ¶¶ 111, 124.)

According to Waldo, the statement herein that "there was no evidence of teratogenicity[4] following administration of up to . . . 1.5 and 3.6 times . . . the maximum recommended human dose" is an actionable misrepresentation, as the FAC elsewhere alleges that Eli Lilly knew, as early as 1987, that animal studies showed the risk of birth defects associated with Prozac. (FAC ¶¶ 27-31.)

Waldo also contends that Eli Lilly fraudulently omitted information regarding (i) the aforementioned animal studies, (ii) studies conducted in the 1990s which "did not provide sufficient data to rule out the teratogenic risk exhibited by [Eli] Lilly's animal studies," and (iii) studies published in 2001 showing that Prozac-class drugs increase the risk of birth defects. (FAC ¶¶ 28-30, 33, 34.) She claims that Eli Lilly failed to warn her, her physician, and other consumers and physicians of these risks. (FAC ¶¶ 42, 106, 111, 120, 124.)

Eli Lilly's response is two-fold. First, it argues that the labeling information quoted above is not an actionable misrepresentation, as it specifically identifies Prozac as a

[4] In her opposition, Waldo defines "teratogenicity" as "birth defects." Webster's Third New International Dictionary (1976) defines the term as "tending to cause developmental malformations and monstrosities."

"Pregnancy Category C" drug. Under regulations promulgated by the FDA:

> Pregnancy Category C. If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling must state: "Pregnancy Category C. (Name of drug) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (name(s) of species) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (Name of drug) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." The labeling must contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: "Pregnancy Category C. Animal reproduction studies have not been conducted with (name of drug). It is also not known whether (name of drug) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (Name of drug) should be given to a pregnant woman only if clearly needed." The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

21 C.F.R. § 201.57(c)(9)(i)(A)(3).[5] In other words, according to Eli Lilly, the fact that Prozac was identified as a "Pregnancy Category C" drug meant that "physicians were on notice that its use during pregnancy was not without risk." (Motion 5, ECF

[5] According to Eli Lilly, this regulation was in effect in 2001, when Waldo became pregnant. At that time, it was codified at 21 C.F.R. § 201.57(a)(6)(i)(c).

No. 38-1.) However, Eli Lilly does not cite authority for the proposition that conformance with FDA labeling regulations insulates drug manufacturers from liability for fraud or negligent misrepresentation. Moreover, the quoted labelling language does not appear to conform to the FDA regulation in question, as it does not include the statement that "There are no adequate and well-controlled studies in pregnant women."

Eli Lilly also contends that its statement, in the Prozac product labeling, that "Fluoxetine [*i.e.*, Prozac] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus" contradicts Waldo's allegation that the company fraudulently represented that Prozac was safe for use during pregnancy. (Motion 5-6.)

Waldo responds, "Irrespective of whether Prozac is classified as a Category C drug, and whether or not the Insert identified that the drug's use is contingent upon its benefit outweighing any potential risk, [Eli] Lilly failed to include information that Prozac was known to cause birth defects and overtly misrepresented that 'there was no evidence of teratogenicity' when Lilly knew that such evidence did in fact exist." (Opposition 6, ECF No. 40.) In support, Waldo cites Frisby-Cadillo v. Mylan, Inc., No. C 09-05816 SI, 2010 WL 1838729, 2010 U.S. Dist. LEXIS 43868 (N.D. Cal. May 5, 2010) (Illston, J.), a wrongful death action against various pharmaceutical firms. Defendants therein sought to dismiss a negligent misrepresentation claim on the basis that the alleged misrepresentations appeared in FDA-approved labeling. Judge Illston denied the motion, reasoning that, by quoting the label's

language, plaintiff had provided sufficient notice under Rule 9(b) for defendants to answer.

Judge Illston's reasoning is sound, and applies equally to this case, particularly as the labelling in question appears to omit language called for by the FDA regulation cited by Eli Lilly.

Eli Lilly's motion to dismiss on this ground is therefore denied.

B. Justifiable reliance

Eli Lilly also argues that Waldo has failed to properly allege her justifiable reliance on its alleged misrepresentations and/or fraudulent omissions.

"To establish this element of fraud, plaintiffs must show (1) that they actually relied on the defendant's misrepresentations, and (2) that they were reasonable in doing so." OCM Principal Opportunities Fund v. CIBC World Markets Corp., 157 Cal. App. 4th 835, 864 (2007). To show actual reliance, a plaintiff must "'establish a complete causal relationship' between the alleged misrepresentations and the harm claimed to have resulted therefrom." Mirkin v. Wasserman, 5 Cal. 4th 1082, 1092 (1993) (quoting Garcia v. Superior Court, 50 Cal. 3d 728, 737 (1990)). "[R]eliance upon the truth of the fraudulent misrepresentation [need not] be the sole or even the predominant or decisive factor in influencing [plaintiff's] conduct . . . . It is enough that the representation has . . . been a substantial factor, in influencing his decision." Engalla v. Permanente Med. Grp., 15 Cal. 4th 951, 976–7 (1997) (quoting Restatement (Second) of Torts § 546). Reasonableness of reliance

on the alleged misrepresentation is demonstrated if "circumstances were such to make it reasonable for the plaintiff to accept the defendant's statements without an independent inquiry or investigation. [Reasonableness] is judged by reference to the plaintiff's knowledge and experience." OCM Principal Opportunities Fund, 157 Cal. App. 4th at 864 (internal quotations and citations omitted).

A. Fraud

Waldo has satisfactorily pled justifiable reliance with respect to her cause of action for fraud.

She has alleged the "complete causal relationship" required to show actual reliance. Waldo took Prozac during pregnancy. (FAC ¶ 20.) Prozac labeling provided that 'there was no evidence of teratogenicity,' despite Eli Lilly's knowledge that such evidence did in fact exist. (FAC ¶¶ 27-30, 111.) Causation is alleged: "as a direct and proximate result" of Eli Lilly's conduct "[a]s alleged herein," Waldo and her son "suffered severe and permanent physical and emotional injuries including, but not limited to, [her son's] VSD." (FAC ¶ 45.) Finally, according to Waldo:

- "Had [she] been aware of the hazards associated with the use of Prozac during pregnancy, she would not have purchased and/or consumed the products that lead [*sic*] proximately to the . . . injuries as alleged herein." (FAC ¶ 112.)
- "Defendant's . . . labeling regarding Prozac made material misrepresentations and omissions Defendant knew to be false, for the purpose of fraudulently inducing consumers, such as Angela Waldo, to purchase Prozac. Angela Waldo relied on

these material misrepresentations in deciding to purchase and consume Prozac . . . .” (FAC ¶ 113.)

These statements demonstrate that that Eli Lilly’s misrepresentations and nondisclosure were “a substantial factor, in influencing [Waldo’s] decision” to take Prozac. Engalla, 15 Cal. 4th at 977.

Waldo’s reliance was reasonable. Pharmaceutical consumers are in no position to conduct an “independent inquiry or investigation” into the accuracy or truthfulness of pharmaceutical manufacturers’ representations. OCM Principal Opportunities Fund, 157 Cal. App. 4th at 864. Most lack the “knowledge and experience” necessary to review and weigh published studies into drugs’ efficacy and side effects. Id. And, to the extent that Waldo’s claims rest on Eli Lilly’s failure to disclose the results of animal studies to the public (FAC ¶ 110), no consumer would have been in a position to learn the relevant information.

Eli Lilly counters with the following:

> As set forth in Plaintiff’s Amended Complaint, the package insert makes clear that there was no statement to the effect that Prozac was safe for use in pregnancy. Instead, doctors were specifically advised that Prozac should be used during pregnancy “only” if any potential benefit “justifies the potential risk to the fetus.” As a “potential risk to the fetus” was specifically disclosed, Plaintiff cannot plausibly allege that she or her physician justifiably relied on the Prozac package insert to conclude that the medicine was “safe . . . for use during pregnancy.” (Motion 6) (quoting FAC ¶ 108).

Eli Lilly is asking the court to find that the statement "Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus" is sufficiently clear so as to render unreasonable Waldo's reliance on the prior statement regarding "there was no evidence of teratogenicity[6] following administration of up to . . . 1.5 and 3.6 times . . . the maximum recommended human dose." This is a factual determination that is inappropriate on a 12(b)(6) motion to dismiss. Waldo's pleading allows the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. No more is necessary.

Eli Lilly's motion to dismiss Waldo's eighth cause of action, for fraud, is therefore denied.

B. Negligent Misrepresentation

Waldo has not satisfactorily pled justifiable reliance with respect to her cause of action for negligent misrepresentation.

She pleads her reliance as follows:

- "Angela Waldo and her healthcare providers justifiably relied on Defendant's misrepresentations." (FAC ¶ 126.)
- "Defendant's negligent misrepresentations proximately caused the Plaintiff and Minor Plaintiff's injuries and monetary losses." (FAC ¶ 127.)

In the absence of further factual development, Iqbal and Twombly disallow this sort of "formulaic recitation of the elements of a

[6] In her opposition, Waldo defines "teratogenicity" as "birth defects." Webster's Third New International Dictionary (1976) defines the term as "tending to cause developmental malformations and monstrosities."

cause of action." Iqbal, 556 U.S. 662, 678 (quoting Twombly, 550 U.S at 555). The pleading of the causal relationship between Eli Lilly's alleged misrepresentations and Waldo's actions lacks the factual specificity with which the cause of action for fraud was pled. Accordingly, this cause of action will be dismissed, though the court will grant Waldo leave to amend.

IV. CONCLUSION

Based on the foregoing, the court hereby orders as follows:

[1] Plaintiff's ninth cause of action is DISMISSED WITHOUT PREJUDICE.

[3] The remainder of defendant's motion to dismiss is DENIED.

[3] Plaintiff is GRANTED leave to file an amended complaint no more than twenty-one (21) days after entry of this order.

IT IS SO ORDERED.

DATED: January 14, 2014.

LAWRENCE K. KARLTON
SENIOR JUDGE
UNITED STATES DISTRICT COURT