UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MATTSON, SHARON,	:	
		Civil Action No. 07-908 (FLW)
Plaintiff,	:	
v.		
	:	**OPINION**
BRISTOL-MYERS SQUIBB CO., et al.,		
	:	
Defendants.		
	:	

WOLFSON, District Judge:

This matter comes before the Court on a motion to dismiss pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure brought by defendants Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiff Sharon Mattson ("Plaintiff") brings the instant suit against Defendants because she alleges that she suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix. In that respect, Plaintiff's First Amended Complaint ("Amended Complaint") asserts various California state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count IV, i.e., negligent misrepresentation claim and Count V, i.e., fraud claim pursuant to the California Consumer Legal Remedies Act, Cal Civ. Code § 1750. For the reasons that follow, Defendants' motion to dismiss is granted.

BACKGROUND FACTS

I. Procedural History

On February 26, 2007, Plaintiff, a California resident, filed a Complaint against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq., the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, et seq., the New Jersey Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. (February 26, 2007 Complaint ¶¶ 6-8.) Plaintiff is one of the individual claimants[1] that lodged separate complaints[2] against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, prior to the filing of the instant action, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter,

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[1] Initially, claims were filed in twenty-four individual cases, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

[2] A number of the twenty-three claimants were joined in their actions by spouses asserting claims for loss of consortium.

"Skilstaff")[3], and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of

[3] The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motion to dismiss Counts IV and V with regard to this Plaintiff that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiff's allegations in the Amended Complaint to be true because Defendants move pursuant to Fed. Civ. R. P. 12(b)(6). The Court will recount only those facts relevant to this Motion.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. See Amended Complaint ("Am. Compl."), ¶¶ 2-5. In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id., ¶ 12. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id., ¶ 14. Plaintiff alleges that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id., ¶ 15.

As evidence that Defendants' were indeed aware of their false and misleading promotion of Plavix, Plaintiff points to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.[4] Id., ¶ 19. Plaintiff also points to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. Id., ¶ 19. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id., ¶ 20. In particular, Plaintiff points to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as "dual therapy") when, in fact, its safety had not been established. Id. According to Plaintiff, Defendants' claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the "CHARISMA Study"[5]). Id.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiff points to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. Id., ¶ 21. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001,

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[4] As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

[5] The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. Id., ¶ 22. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven to be significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiff, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which Plavix is safe and FDA approved. Id., ¶ 23. Specifically, Plaintiff points to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id., ¶ 24.

Plaintiff alleges that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id., ¶ 26. Citing a study published in The New England Journal of Medicine in January 2005, entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the "Chan Study"), Plaintiff notes the dangers of Plavix. Specifically, Plaintiff contends that the Chan Study demonstrates the fallacy of Defendants' assertions that Plavix is safer and more effective

for patients suffering from gastrointestinal intolerance to aspirin. Id., ¶ 27. Plaintiff points out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiff additionally points to the Chan Study's finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id., ¶28. Finally, citing the CHARISMA Study, Plaintiff contends that Plavix plus aspirin ("dual therapy") is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id., ¶ 29.

Due to these alleged illegal practices, Plaintiff asserts, inter alia, a fraud claim pursuant to the California Consumer Legal Remedies Act, Cal Civ. Code § 1750 ("CLRA" the "Act"), and a California state common law claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiff alleges that she "was prescribed Plavix, to be taken in combination with aspirin on around March 2005 in connection with a stent placement." Plaintiff further alleges that on or about December 30, 2005, "she went to the hospital complaining of rectal bleeding." Thereafter, she was "transfused and taken off Plavix . . . [and] stayed in the hospital for nearly a week and continues to have health problems." Am. Compl., ¶ 31.

As result of the alleged injury, Plaintiff, in Count V of the Amended Complaint, alleges that Defendants violated the CLRA by intentionally misrepresenting "the source, approval, or

certification of Plavix," and that Defendants represented that Plavix has "sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that it does not have." Id., ¶ 58. Plaintiff further alleges that Defendants misrepresented that "Plavix is of a particular standard, quality or grade." Id.

Similarly, Count IV alleges that "Defendants, each of them, represented to Plaintiff Sharon Mattson and her physicians that the Plavix was safe to use knowing that the Plavix was defective and dangerous and caused the injuries described [in the Amended Complaint]." Id., ¶ 52. In addition, Plaintiff alleges that Defendants had "no reasonable ground for believing them to be true when Defendants', and each of their, own data showed that Plavix was defective and dangerous when used in the intended manner." Id., ¶ 53. Importantly, Plaintiff submits that "the aforesaid representations were made to the physicians prescribing Plavix prior to the date it was prescribed to Plaintiff and her physicians with the intent that Plaintiff and her physicians would rely upon such misrepresentations about the safety and efficacy of Plavix . . . ." Id., ¶ 54. Plaintiff alleges that she and her physicians "did reasonably rely upon [Defendants'] representations that [Plavix] . . . was safe for use to aid in her treatment following placement of cardiac stents." Id. Due to these intentional misrepresentations, Plaintiff alleges that she suffered injuries by taking Plavix and thus, she initiated the instant action.

Now, Defendants move to dismiss Count IV, the negligent misrepresentation claim, and Count V, the CLRA claim, of the Amended Complaint. The Court will turn to address the sufficiency of these claims.

DISCUSSION

I. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating … a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (quoting Twombly, 530 U.S. at 556).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S.

Ct. 1937, 1949 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).[6] "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiff's claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). As previously referenced in this Court's discussion of the Factual Background, Plaintiff supplies this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; (5) the Chan Study; and (6) a Mediation Letter dated March 12, 2009. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are "integral to or explicitly relied upon in the complaint" may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant

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[6] The Court notes that because the briefing in this matter was filed shortly after the United States Supreme Court's decision in Ashcroft, counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

motion to dismiss.

II. The CLRA Claim

A. Notice

At the outset, Defendant submits that Plaintiff's CLRA claim should be dismissed for her failure to comply with the notice requirements set forth in Cal. Civ. Code § 1782. Indeed, prior to the commencement of an action seeking damages pursuant to the CLRA, Plaintiff should have furnished Defendants with notice of the particular alleged violations of § 1770 of the California Civil Code. See Cal. Civ. Code § 1782. The Code provides that:

> (a) Thirty days or more prior to the commencement of an action for damages pursuant to this title, the consumer shall do the following:
>
> > (1) Notify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770 of the particular alleged violations of Section 1770.
> >
> > (2) Demand that the person correct, repair, replace, or otherwise rectify the goods or services alleged to be in violation of Section 1770.
>
> The notice shall be in writing and shall be sent by certified or registered mail, return receipt requested, to the place where the transaction occurred or to the person's principal place of business within California.

Cal. Civ. Code § 1782(a); see also Roybal v. Equifax, No. 05-1207, 2008 U.S. Dist. LEXIS 79789, at *29-30 (E.D. Cal. Oct. 9, 2008); Cattie v. Wal-Mart Stores, Inc., 504 F.Supp. 2d 939, 949-950 (S.D. Cal. 2007).

The overarching purpose of the notice requirement is "to give the manufacturer or vendor sufficient notice of alleged defects to permit appropriate corrections or replacements." Stickrath v. Globalstar, Inc., 527 F. Supp. 2d 992, 1001-1002 (N.D. Cal. 2007) (citations and quotations omitted). In that regard, the statutory requirements "facilitate pre-complaint settlements of consumer

actions wherever possible." Von Grabe v. Sprint PCS, 312 F.Supp.2d 1285, 1303-1304 (S.D. Cal. 2003). California courts have cautioned that even liberally construing the CLRA "does not permit [the courts] to disregard or enlarge the plain provisions of the statute, nor does it go beyond the meaning of the words used when they are clear and unambiguous." Outboard Marine Corp. v. Superior Court, 52 Cal. App.3d 30, 40 (1975) (citing 45 Cal. Jur. 2d, Statutes, § 180, p. 680; People v. Cruz, 12 Cal.3d 562, 566 (1974); Richardson v. City of San Diego, 193 Cal. App.2d 648, 651 (1961)). Because "section 1782, subdivision (a), is clear and unambiguous, not requiring interpretation," see id., "strict application of the [notice] requirement [is] necessary." Von Grabe 312 F.Supp.2d at 1304; Cattie, 504 F.Supp. 2d at 950 ("[t]he Outboard Marine court was adamant: insisting on a 'literal application of the notice provisions' was the only way to accomplish the CLRA's purposes").

Citing the last paragraph of section 1782(a), Plaintiff first argues that the notice requirement of the CLRA is inapplicable because this case does not involve the "place" where the transaction occurred and that no defendant maintains a principal place of business in California. A similar argument was recently raised, and rejected, in Shein v. Canon U.S.A., Inc., No. 08-7323, 2009 U.S. Dist. LEXIS 94109, at *18-20 (C.D. Cal. Sep. 22, 2009). The court there held that the plaintiffs complied with the section 1782(a) notice provision by sending the statutorily-required demand letter to defendant's headquarter in New York, even though the defendant did not maintain its principal place of business in California. Implicit in that determination, is that the notice provisions apply even if a defendant does not have its principal place of business in California, because as the court explained that "strictly applying the plain language of section 1782(a) . . . would contravene the goals of the CLRA notice provision which is to facilitate remediation of consumer actions." Id. at

*22-23. Thus, here, Plaintiff was required by the CLRA to send a demand letter to the principal place of business of each Defendant, irrespective of the fact that none of the Defendants maintained their principal place of business in California. In fact, in her Amended Complaint, Plaintiff acknowledges the need to comply with the notice provision of the CLRA by stating: "In compliance with the CLRA provision in California Civil Code § 1782, Plaintiff [has] given written notice to each Defendant named in this Complaint of [her] intention to file an action for damages under Civil Code § 1750, et seq." Am. Compl., ¶59. Accordingly, the Court rejects Plaintiff's argument that the notice requirement of § 1782 is inapplicable in this case.

Next, Plaintiff contends that she has complied with the notice provision of the CLRA because Defendants had sufficient notice of the nature of the claims asserted. Plaintiff reasons that the present case was brought in February 2007, and it has been administratively terminated pending the outcome of the Supreme Court's decision in Wyeth v. Levin. In that regard, Plaintiff maintains that given the procedural history of this case, Defendants had ample notice. In addition, Plaintiff also points to a mediation letter sent to Defendants on March 12, 2009, wherein Plaintiff expressed her intention to reinstate this case, which at that time was administratively dismissed by the Court.

Having surveyed the decisions of California state and federal courts in this context, the Court is constrained by prior case law and must strictly enforce the notice provision of § 1782. Here, Plaintiff does not dispute that she did not submit a demand letter thirty days prior to the filing of the Original Complaint on February 26, 2007. Indeed, Plaintiff did not originally assert a claim under the CLRA and thus, she was not required to send a notice to Defendants when she filed her Original Complaint. Consequently, and more importantly, the Original Complaint cannot constitute as valid notice under the CLRA because it asserted only New Jersey state law claims. Accordingly, Plaintiff

was required to send a notice thirty days prior to filing her Amended Complaint which asserts a claim under the CLRA. She did not do so.

Nonetheless, Plaintiff contends that Defendants had ample notice of the claim because a significant amount of time has lapsed between the initial filing of the Original Complaint and the Amended Complaint. However, this passage of time, due to the court-ordered termination, cannot excuse Plaintiff's failure to comply with the CLRA. While Plaintiff also suggests that the mediation letter sent to Defendants on March 12, 2009, satisfies the notice requirement, the letter plainly does not meet the requirements of § 1782. Specifically, it did not advise Defendants of the particular alleged violations itemized in § 1770 of the CLRA. More importantly, the letter does not even mention this particular Plaintiff, or any of the statutory requirements under the CLRA. Accordingly, Count V of the Amended Complaint is dismissed for Plaintiff's failure to comply with the notice requirements of Cal. Civ. Code § 1782.

B. Sufficiency of the Pleadings

Plaintiff's CLRA claim is also dismissed for the additional reason that she fails to state a claim. As a preliminary matter, Plaintiff maintains that the heightened pleading standard of Rule 9(b) does not apply to the CLRA, and that even if it did, the Amended Complaint "does not generally describe fraud at all and fails to even use the word 'fraud'." Plaintiff's arguments in this regard lack merit. In fact, the same argument was advanced recently in Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009), wherein the Ninth Circuit rejected the position that Rule 9(b) does not apply to the CLRA, if the claim is grounded in, or sounds in, fraud. Id.

The Kearns court explained:

> [Plaintiff's] first argument--that Rule 9(b) does not apply to California's consumer protection statutes because California courts have not applied Rule 9(b) to the Consumer Protection Statutes, which include the CLRA and UCL--is unavailing. It is well-settled that the Federal Rules of Civil Procedure apply in federal court, "irrespective of the source of the subject matter jurisdiction, and irrespective of whether the substantive law at issue is state or federal." See [Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1102 (9th Cir. 2003)] (citing Hanna v. Plumer, 380 U.S. 460 (1965)). "'[W]hile a federal court will examine state law to determine whether the elements of fraud have been pled sufficiently to state a cause of action, the Rule 9(b) requirement that the circumstances of the fraud must be stated with particularity is a federally imposed rule.'" Vess, 317 F.3d at 1103 (quoting Hayduk v. Lanna, 775 F.2d 441, 443 (1st Cir. 1985) (emphasis omitted, brackets in original)).

Kearns, 567 F.3d at 1125. Because the CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale . . . of goods or services to any consumer," Cal. Civ. Code § 1770, in the Ninth Circuit, the particularity requirement of Rule 9(b) applies to claims for violations of the CLRA that are grounded in, or sound in, fraud. Vess, 317 F.3d at 1102-05; Kearns, 567 F.3d at 1125.

Moreover, "while fraud is not a necessary element of a claim under the CLRA . . . a plaintiff may nonetheless allege that the defendant engaged in fraudulent conduct." Kearns, 567 F.3d at 1125 (citations omitted). "A plaintiff may allege a unified course of fraudulent conduct and rely entirely on that course of conduct as the basis of that claim. In that event, the claim is said to be 'grounded in fraud' or to 'sound in fraud,' and the pleading . . . as a whole must satisfy the particularity requirement of Rule 9(b)." Id. (citations and quotations omitted).

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated the heightened pleading standard under Rule 9(b):

> Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." To satisfy this standard, the

> plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (internal citations omitted); In re Supreme Specialties, Inc. Sec. Litig., 438 F.3d 256, 276-77 (3d Cir. 2006)(the Third Circuit advised that pursuant to Rule 9(b), at a minimum, a plaintiff must support his/her allegations of fraud with all the essential factual background that would accompany "'the first paragraph of any newspaper story' – that is, the 'who what, when, where and how' of the events at issue"(citations omitted)). Moreover, a complaint must do more than assert generalized facts, it must allege facts specific to the plaintiff. Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658-59 (3d Cir. 1998)(where the complaint failed to allege "what actually happened to either" of the plaintiffs, the complaint did not plead "fraud with the specificity required by Rule 9(b)"). This type of heightened pleading requirement is in accord with Ninth Circuit precedent. See Kearns, 567 F.3d at 1124 ("Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged" (citations and quotations omitted)).

In the Amended Complaint, Plaintiff alleges a unified course of fraudulent conduct and she relies entirely on that as the basis of her CLRA claim. More specifically, Plaintiff alleges that Defendants misrepresented certain information regarding Plavix in violation of Cal. Civ. Code §§ 1770(a)(2), (a)(5) and (a)(7). See Am. Compl., ¶ 58. Plaintiff further alleges that Defendants' policies, acts and practices in marketing Plavix "were intended to result in the sale of Plavix to Plaintiff Sharon Mattson and the general public," see id., and Defendants had "no reasonable ground for believing" that the representations in connection with the sale of Plavix were true. Id., ¶ 53. In fact, the Amended Complaint brims with allegations of intentional conduct. See, e.g., Am. Compl,., ¶¶ 19-22, 27 and 29-30. In this respect, Plaintiff's allegations regarding Defendants' wrongdoing

are clearly based upon intentional, fraudulent conduct. Accordingly, Plaintiff must plead her CLRA claim in accordance with the heightened pleading requirements of Rule 9(b). However, Plaintiff's allegations fall short of complying with that Rule.

Arguing the contrary, Plaintiff contends that the Amended Complaint asserts sufficient facts to satisfy Rule 9(b). In particular, Plaintiff points to ¶¶ 19-22, 27 and 29-30 (as noted above) of the Amended Complaint to support her assertion that she has pled the so-called "newspaper requirements" of Rule 9(b). Summarizing her points, Plaintiff states (1) that she has alleged who made the misleading statements - Defendants; (2) that she has alleged what was misleading about Defendants' statements - Defendants advertised Plavix as safe and effective in "dual therapy" treatments, off-label use, and more effective than aspirin; (3) that she has alleged that Defendants' statements were known to be misleading or should have been known when made - multiple FDA warnings against deceptive advertising of Plavix's safety and use in certain treatments, as well as scientific studies, both internal and external, refuting Defendants' wrongful advertising of Plavix; (4) that she has alleged what Defendants' misrepresentations were - the safety and effectiveness of Plavix as advertised in the face of both FDA warnings to the contrary and numerous scientific studies; and (5) that she has alleged why Defendants' misrepresentations were misleading - concealment of the risks associated with the use of Plavix, promotion of the safe and beneficial use of Plavix for off-label use in patients receiving arterial stents, even though the FDA and scientific studies warned against such use. Nevertheless, Plaintiff also suggests that under the circumstances of this case, because Plaintiff's allegations of fraud are within Defendants' control, less specificity of pleading is required pending discovery.

While Plaintiff made exhaustive allegations regarding Defendants' alleged illegal practices

by relying on FDA correspondence and scientific studies, the Amended Complaint fails to allege with specificity the connection between Defendants' conduct and Plaintiff's resultant injury. Specifically, Plaintiff fails to identify any specific advertisements she viewed, how she was misled by these advertisements, how these advertisements affected her prescription for Plavix and how these advertisements caused any of her injuries. In other words, the Amended Complaint fails to identify which, if any, of the promotional or marketing materials were received, viewed or relied upon by Plaintiff, and if they were, when these materials were viewed and how they were relied upon. More simply stated, Plaintiff has failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. See Kritley v. Wadekar, No. 05-5383, 2006 U.S. Dist. LEXIS 60309, at *9-10 (D.N.J. Aug. 25, 2006)("Plaintiffs offer only general, conclusory statements that Plaintiffs purchased pharmaceutical products manufactured by the company that Defendants were officers and directors of, and that Defendants marketed the products using false representations, with fraudulent scienter." Plaintiffs do not allege with particularity any of the facts that would be expected to be within their knowledge: exactly who bought exactly what product when, relying on what false representations made when by whom"); Guilbealt v. R.J. Reynolds Tobacco Co., 84 F.Supp. 2d 263, 269 (D.R.I. 2000)(when a plaintiff claims that a product advertisement or promotion led to injuries, he or she must "identify specific advertising he [or she has] seen and how it ha[s] affected" him or her to comply with Rule 9(b)'s requirements).

Likewise, Plaintiff fails to allege that her physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to

Plaintiff.[7] Rather, Plaintiff alleges only generally that the "representations were made to the physicians prescribing Plavix prior to the date it was prescribed to Plaintiff and her physicians." Am. Compl., ¶ 54. Although the Amended Complaint alleges that Defendants' drug representatives have misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved, Plaintiff has not identified the representatives, what was said, when it was said, to whom it was said – whether it was communicated to Plaintiff's physician – and how these statements relate to Plaintiff's prescription of Plavix.

Moreover, these factual allegations are not the type of facts that are within the control of, and therefore subject to concealment by Defendants. Instead, these important details regarding misrepresentations made to, and relied upon by, Plaintiff and her physicians are within Plaintiff's ken, but are nowhere to be found within the Amended Complaint.[8]

The deficiencies of Plaintiff's Amended Complaint in this context were recently discussed by the court in In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774,

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[7] Plaintiff's Amended Complaint does not provide the name of her prescribing physician.

[8] Indeed, in that connection, Plaintiff is uniquely equipped to determine from her physician whether the physician received such promotional literature. Even where factual information may be within the domain or control Defendants, such as the identities of the doctors who received promotional information, Plaintiffs must still "accompany their legal theory with factual allegations that make their theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiff has failed to comply with these requirements. Plaintiff's Amended Complaint makes no allegations that the information required for Plaintiff to meet her Rule 9(b) obligation is solely within Defendants' control.

2009 U.S. Dist. LEXIS 58900 (D.N.J. Jul. 10, 2009) (Chesler, J.) In that case, plaintiffs filed a class action complaint alleging, inter alia, that defendants "engaged in improper and illegal off-label promotion of Intron-A, PEG-Intron, Rebetol and Temodar." Id. at *6. Plaintiffs further alleged that defendants "orchestrated a campaign to illegally market and promote the Subject Drugs for off label uses . . . and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs that they would not have purchased but for the illicit marketing scheme." Id. at *7. Similar to Defendants' response here, the defendants there filed a motion to dismiss, among other claims, plaintiffs' fraud and negligent misrepresentation claims.

In dismissing these two specific claims, the court, in a well-reasoned opinion, found that plaintiffs made "sweeping allegations" regarding defendants' alleged promotion, yet they did not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs. Id. at *117. In addition, the court explained that plaintiffs' common law fraud and negligent misrepresentation claims also failed to state a claim because plaintiffs did not allege a causal connection between their injury and defendants' conduct. Id. at *119. While In re Schering-Plough dealt with New Jersey's common law claims, the same reasoning applies here since the fraud theory of that case parallels the instant action. See Suarez v. Playtex Products, Inc., No. 08-2703, 2009 U.S. Dist. LEXIS 63774, at *8-10 (N.D. Ill. Jul. 24, 2009)(in determining whether plaintiffs sufficiently plead consumer fraud claims under Cal Civ. Code §§ 17200 and 17500, the court, relying on Ninth Circuit case law, held that plaintiffs failed to allege with specificity "whether or when [plaintiffs] relied on, or even saw, these [misrepresentations] prior to purchasing the coolers"); Vess, 317 F.3d at 1102. Accordingly, Plaintiff fails to inject precision and some measure of substantiation to

support her CLRA claim, and therefore, it is dismissed without prejudice. Plaintiff may move to amend the Amended Complaint after complying with the notice requirements of the TDTP.

III. Negligent Misrepresentation

The Court notes at the outset that Plaintiff does not dispute that she must plead with particularity pursuant to Rule 9(b) with respect to her Negligent Misrepresentation claim. Indeed, it is well-established in the Ninth Circuit that a claim for negligent misrepresentation must also meet Rule 9(b)'s particularity requirements. Neilson v. Union Bank of California, NA, 290 F.Supp. 2d 1101, 1141 (C.D. Cal. 2003)("the elements of a cause of action for negligent misrepresentation are the same as those of a claim for fraud, with the exception that the defendant need not actually know the representation is false"). Accordingly, a claim for negligent misrepresentation must be pled with specificity. Glen Holly Entm't, Inc. v. Tektronix, Inc., 100 F. Supp. 2d 1086, 1093 (C.D. Cal. 1999).

In California, negligent misrepresentation is a form of deceit, the elements of which consist of (1) a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the truth and justifiable reliance thereon by the party to whom the misrepresentation was directed, and (5) damages. B.L.M. v. Sabo & Deitsch, 55 Cal. App. 4th 823, 834 (1997); see also Glenn K. Jackson Inc. v. Roe, 273 F.3d 1192, 1201, n. 2 (9th Cir. 2001); Firoozye v. Earthlink Network, 153 F. Supp. 2d 1115, 1128 (N.D. Cal. 2001).

Here, in order to support her negligent misrepresentation claim, Plaintiff alleges that (1) Defendants' represented to both her and her physicians that Plavix was safe to use knowing that Plavix was defective and dangerous; (2) Defendants made the representations with no reasonable ground for believing them to be true when Defendants "own data showed Plavix was defective and

dangerous when used in the intended manner;" and (3) the representations "were made to the physicians prescribing Plavix prior to the date it was prescribed to Plaintiff . . . with the intent that Plaintiff and her physicians would rely upon such misrepresentations about the safety and efficacy of Plavix . . . [and that] Plaintiff and her physicians did reasonably rely upon such representations that [Plavix] was safe for use to aid in her treatment following placement of cardiac stents." Plaintiff also points to the same allegations used to support her CLRA claim in ¶¶ 19-22, 27 and 29-30 to substantiate her claim here.

Viewing the allegations in combination, Plaintiff has failed to allege with the requisite specificity to state a claim for negligent misrepresentation. While Plaintiff may have arguably alleged with specificity elements one, two, three and five, Plaintiff fails to allege specific facts with respect to the fourth element of the claim - ignorance of the truth and justifiable reliance thereon by the party to whom the misrepresentation was directed. In this regard, Plaintiff's Negligent Misrepresentation claims fails to state a claim for the same reasons why Plaintiff's CLRA claim fails. No plaintiff-specific facts were pled in connection with this claim. The Amended Complaint fails to allege what specific misrepresentation were made to Plaintiff; when they were made to Plaintiff; the substance of the alleged misrepresentations; the name of Plaintiff's prescribing physician; the substance of the alleged misrepresentation made to Plaintiff's prescribing physician; and when the false representation was made. While the Court does not suggest that Plaintiff must plead every single fact listed above, Plaintiff simply does not state with the requisite particularity the circumstances of the alleged fraud or otherwise inject precision into her allegations of how she relied upon Defendants' misrepresentations in connection with her taking the prescription drug Plavix. See In re Schering-Plough, 2009 U.S. Dist. LEXIS 58900 at *117-119. Accordingly, Plaintiff's

Negligent Misrepresentation claim is dismissed without prejudice.

CONCLUSION

Based upon the foregoing reasons, Defendants' motion to dismiss Count IV and Count V of the Amended Complaint is granted. However, Plaintiff may file a motion to amend the Complaint as to Count IV, i.e., the Negligent Misrepresentation claim, if she intends to pursue that claim and can cure the deficiencies outlined by the Court.

DATE: December 30, 2009

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge