UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

COOPER, DEMPSEY,	:	
		Civil Action No. 07-885 (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 Rule 12(b)(6) and Rule 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 Dempsey Eugene Cooper ("Plaintiff") brings the instant suit against Defendants because he alleges that he 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 Alabama state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim and Count VI, i.e., fraud claim pursuant to the Alabama Deceptive Trade Practices Act, Ala. Code 1975 § 8-19-1, et seq. For the reasons that follow, Counts V and VI are dismissed without prejudice.

BACKGROUND FACTS

I. Procedural History

On February 23, 2007, Plaintiff, an Alabama 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 23, 2007 Complaint ¶¶ 6-8.) Plaintiff is one of the individual claimants[1] that lodged separate complaints[2] against Defendants in this district between December 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 February 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 V and VI 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 Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1, et seq. ("DTPA" or the "Act"), and a claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiff alleges that he "was prescribed Plavix from September 4, [2004] to February 22, 2005 for cardiac risks following quadruple bypass surgery." Plaintiff further alleges that "[o]n February 22, 2005, Plaintiff, Dempsey Eugene Cooper suffered a stroke, requiring medical attention and treatment." Id., ¶ 31.

As result of the alleged injury, Plaintiff, in Count VI of the Amended Complaint, alleges that Defendants violated the DTPA by making "untrue, deceptive and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff

herein, concerning the use and safety of Plavix." Id., ¶ 97. In that regard, Plaintiff alleges that "Defendants knew or should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects." Id., ¶ 94. Plaintiff further alleges that "Defendants' statements and omissions were made with the intent that the Plaintiff herein, and his prescribing physicians, would rely on such statements and omissions" in connection with the sale or advertisement of merchandise or services by Defendants in violation of the DTPA. Id., ¶¶ 100, 102. As a result, Plaintiff alleges that he suffered, inter alia, "ascertainable loss –economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff for treble and actual damages ." Id., ¶¶ 103, 104.

In similar fashion, Count V alleges that "Defendants falsely represented to Plaintiff in direct to consumer advertising and indirectly through misrepresentation to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's health." Id., ¶ 80. Plaintiff further alleges that "[a]t the time the aforesaid representations were made, Defendants concealed from Plaintiff and his prescribing physician information about the propensity of Plavix to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information regarding the same." Id., ¶ 81. Due to these misrepresentations, Plaintiff alleges that he suffered injuries by taking Plavix and thus, he initiated the instant action.

Now, Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the DTPA 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, 127 S.Ct. at 1965).

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 DTPA Claim

A. Notice

At the outset, Defendant submits that Plaintiff's DTPA claim should be dismissed for his failure to comply with the notice requirements set forth in Ala. Code § 8-19-10(e). Indeed, under this section, a plaintiff must give notice of a DTPA claim to a defendant before filing suit. It provides:

> At least 15 days prior to the filing of any action under this section, a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive act or practice relied upon and the injury suffered, shall be communicated to any prospective respondent by placing in the United States mail or otherwise . . . . The demand requirements of this subsection shall not apply if the prospective respondent does not maintain a place of business or does not keep assets within the state, but such respondent may otherwise employ the provisions of this section by making a written offer of relief and paying the rejected tender into court as soon as practicable after receiving notice of an action commenced under this section.

Ala. Code § 8-19-10(e)(emphasis added); see Nimbus Techs., Inc. v. SunnData Prods., No. 04-312, 2005 U.S. Dist. LEXIS 46509, at *61 (N.D. Ala. Dec. 7, 2005). The notice letter cannot be considered sufficient notice if it fails to reasonably describe the alleged unfair or deceptive practice or the injury suffered. Givens v. Rent-A-Center, Inc., 720 F.Supp. 160, 162 (S.D. Ala. 1988).

Relying on the plain language of the statute, Plaintiff retorts that the notice provision is inapplicable in this instance because Defendants do not maintain a place of business or keep assets within Alabama. Rather than addressing this issue, Defendants respond to Plaintiff's alternative grounds for complying with the notice provision, i.e., that Defendants have had ample notice of Plaintiff's claim and that the Mediation Letter, dated March 12, 2009, serves as a valid notice. In

fact, in their response, Defendants ignore the section of the notice provision that clearly sets forth the exemption. The Court can only presume in the absence of any indication in the Amended Complaint identifying Defendants' ties to Alabama and in the face of Defendants' silence as to the application of this provision, that Defendants neither maintain a place of business in Alabama nor maintain assets therein. Accordingly, this Court finds the notice provision inapplicable in this case.

B. Sufficiency of the Pleadings

To state a claim under the DTPA, Defendants contend that Plaintiff's pleading in this context must conform to the rigors of Rule 9(b). To support their contention, Defendants rely upon Bodie v. Purdue Pharma Co., 236 Fed. Appx. 511, 524 (11th Cir. 2007), for the general proposition that Rule 9(b) typically applies to allegations of fraud or misrepresentation. In response, Plaintiff contends Bodie involved fraud claims arising from common law, not a statutory claim pursuant to the DTPA; therefore, Bodie has no application here. However, in so arguing, Plaintiff does not cite to any authority, federal or state, to support his contention that Rule 9(b) does not apply to DTPA claims in Alabama.

Having surveyed federal and state cases interpreting the DTPA, it appears the courts are silent as to whether a heightened pleading requirement is required when asserting a fraud claim under the DTPA. However, it is well-settled in the Eleventh Circuit that, in general, "[f]or fraud claims brought in federal court . . . a higher threshold of specificity is required; under Federal Rule of Civil Procedure 9(b), 'the circumstances constituting fraud or mistake shall be stated with particularity.'" Bodie, 236 Fed. Appx. at 524 (citing Clausen v. Lab Corp. of America, Inc., 290 F.3d 1301, 1310 (11th Cir. 2002)). To that end, while no Alabama state court has had the occasion to address whether a heightened pleading standard applies to fraud claims under the DTPA, since Plaintiff is asserting

his state claim in a federal forum, the Court will apply Rule 9(b) to Plaintiff's DTPA claim.[7]

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 the Eleventh Circuit. Clausen, 290 F.3d at 1310.

The DTPA, § 8-19-1 et seq., is a consumer protection statute designed to punish persons that engage in deceptive trade practices. Sam v. Beaird, 685 So. 2d 742, 744 (Ala. Civ. App. 1996). The

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[7]Indeed, Plaintiff tacitly conceded that Rule 9(b) applies to his DTPA claim. Plaintiff acknowledges that he is "aware that FRCP 9(b)'s reach is not confined to pure fraud causes of action. Rule 9(b) applies to averments of fraud, not claims of fraud, so whether the rule applies will depend on the plaintiff's factual allegations." Plaintiff's Opposition Brief, p. 7. As stated earlier, because his DTPA claim involves allegations of fraud, the Court will apply Rule 9(b).

statute provides a cause of action for a "consumer," Ala. Code § 8-19-10, who is defined as a person "who buys goods or services for personal, family or household use." Ala. Code § 8-19-3(2); Deerman v. Federal Home Loan Mortg. Corp., 955 F. Supp. 1393, 1399 (N.D. Ala. 1997). In the statute, "goods" are defined as including but not limited to: "any property, tangible or intangible, real, personal, or any combination thereof, and any franchise, license, distributorship, or other similar right, privilege, or interest." Ala. Code § 8-19-3(3). Section 8-19-5 the DTPA is intended to limit the scope of the statute as the Alabama legislature enacted the DTPA to replace common law and statutory actions for fraud only in specifically designated situations. Sam, 685 So. 2d at 744.

As a preliminary matter, Defendants argue that Plaintiff's DTPA claim should be dismissed because he fails to identify which unlawful conduct, if any, delineated in § 8-19-5 apply to his fraud claim. This Court has not found any decisions in Alabama dismissing a DTPA claim for failing to identify the section of the DTPA upon which the claim is premised. Regardless, Plaintiff has sufficiently identify the alleged unlawful acts enumerated in the statute. Section 8-19-5 prohibits Defendants from "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have," and from "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Ala. Code § 8-19-5(5), (6), (7). In that connection, the Amended Complaint specifically claims that Defendants violated the DTPA by falsely representing that Plavix "had sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which [it] did not have . . . ." Am. Compl., ¶ 96. Accordingly, Defendants' argument is without merit on this basis. Nevertheless, Plaintiff fails to state a DTPA claim.

In the Amended Complaint, Plaintiff alleges a unified course of fraudulent conduct and he

relies entirely on that as the basis for his DTPA claim. More specifically, Plaintiff alleges that Defendants violated the DTPA for the following reasons:

> a. Defendants' business practices caused confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
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> b. Defendants' business practices caused confusion or misunderstanding as to affiliation, connection, or association with or certification by another;
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> c. [Defendants] represented that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has sponsorship, approval, status, affiliation, or connection which it did not[; and]
>
> d. [Defendants] represented that goods or services were of a particular standard, quality, or grade, or that goods of a particular style or model, when they were of another.

Am. Comp., ¶ 96. Plaintiff further alleges that Defendants violated the DTPA "in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff herein, concerning the use and safety of Plavix." Id., ¶ 97. However, these allegations fall short of complying with the strictures of Rule 9(b).

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 his assertion that he has pled the so-called "newspaper requirements" of Rule 9(b). Summarizing his points, Plaintiff states (1) that he has alleged who made the misleading statements - Defendants; (2) that he 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 he 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 he 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 he 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 he viewed, how he was misled by these advertisements, how these advertisements affected his prescription for Plavix and how these advertisements caused any of his 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 his physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to Plaintiff.[8] Rather, Plaintiff alleges only generally that the "Defendants' statements and omissions were made with the intent that the Plaintiff herein, and his prescribing physician, would rely on such statements and omissions." Am. Compl., ¶ 99. 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 physicians – 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 his physicians are within Plaintiff's

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

ken, but are nowhere to be found within the Amended Complaint.[9]

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, 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 in 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

[9]Indeed, in that connection, Plaintiff is uniquely equipped to determine from his physician whether the physician received such promotional literature. Even where factual information may be within the domain or control of Defendants, such as the identities of the doctors who received promotional information, Plaintiff 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 his Rule 9(b) obligation is solely within Defendants' control.

misrepresentation 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, the court held that plaintiffs failed to allege with specificity "whether or when [plaintiffs] relied on, or even saw, these [misrepresentations] prior to purchasing the coolers"). Accordingly, Plaintiff fails to inject precision and some measure of substantiation to support his DTPA claim, and therefore, it is dismissed without prejudice. However, Plaintiff may move to amend the Amended Complaint with respect to this claim.

III. Negligent Misrepresentation

The Court notes at the outset that Plaintiff does not dispute that he must plead with particularity pursuant to Rule 9(b) with respect to his Negligent Misrepresentation claim. Indeed, district courts in Alabama have applied the standard of Rule 9(b) to negligent misrepresentation claims. See Preis v. Lexington Ins. Co., No. 06-360, 2006 U.S. Dist. LEXIS 57913, at *2 (S.D. Ala. Aug. 15, 2006); Abrams v. Ciba Specialty Chems. Corp., No. 08-68, 2008 U.S. Dist. LEXIS 68897, at *35-40 (S.D. Ala. Sep. 10, 2008). As such, Plaintiff must plead with particularity with respect to his Negligent Misrepresentation claim.

Before the Court discusses the elements of negligent misrepresentation, Defendants argue that in Alabama in order to sustain a negligent misrepresentation claim, a defendant must owe or voluntarily assume a duty to the plaintiff. For support, Defendants cite Grady Bros. Invs., LLC v. GMAC, No. 07-747, 2007 U.S. Dist. LEXIS 94589, at *15 (S.D. Ala. Dec. 26, 2007), for such a

proposition. This case is inapposite. The Alabama Supreme Court has instructed that liability for negligent misrepresentation is predicated upon the existence of a duty "in cases involving negligent misrepresentations relied upon by third parties, or parties who were not in privity of contract with the person making the misrepresentation." Fisher v. Comer Plantation, Inc., 772 So. 2d 455, 461 (Ala. 2000). Here, Plaintiff brings an action against Defendants, the manufacturer of Plavix, and in that regard, he alleges that "Defendants having undertaken the manufacturing, marketing distribution, and/or promotion of Plavix owed a duty to provide accurate and complete information regrading Plavix." Am. Compl., ¶ 79. Because of the allegation of a direct relationship between Plaintiff and Defendants, Defendants' argument is without merit.

In Alabama, the elements of a cause of action for negligent misrepresentation are:

> (a) a false representation of an existing material fact; (b) a representation (1) that the speaker knew was false when made, (2) that was made recklessly and without regard to its truth or falsity, or (3) that was made by telling the listener that the speaker had knowledge that the representation was true while having no such knowledge; (c) reliance by the listener on the representation, coupled with deception by it; (d) the reasonableness of that reliance under the circumstances; and (e) damage to the listener proximately resulting from his or her reasonable reliance. Cato v. Lowder Realty Co., 630 So. 2d 378, 381-82 (Ala. 1993); Foremost Ins. Co. v. Parham, 693 So. 2d 409 (Ala. 1997) (readopting the "reasonable reliance" standard). Reasonable reliance is shown "if the circumstances are such that a reasonably prudent person who exercised ordinary care would have discovered the true facts." Torres v. State Farm Fire & Cas. Co., 438 So. 2d 757, 759 (Ala. 1983).

City of Prattville v. Carter, 831 So. 2d 622 , 628-29 (Ala. Civ. App. 2002); see also Preis v. Lexington Ins. Co., No. 06-0360, 2006 U.S. Dist. LEXIS 57913, at *2 (S.D. Ala. Aug. 15, 2006). Here, in order to support his negligent misrepresentation claim, Plaintiff alleges that "Defendants falsely represented to Plaintiff in direct to consumer advertising and indirectly through misrepresentation to the prescribing physician, that Plavix was safe and effective. The

representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's health." Am. Compl., ¶ 80. Plaintiff further alleges that "[a]t the time the aforesaid representations were made, Defendants concealed from Plaintiff and his prescribing physician information about the propensity of Plavix to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information regarding the same." Id., ¶ 81. Plaintiff also points to the same allegations used to support his DTPA claim in ¶¶ 19-22, 27 and 29-30 of the Amended Complaint to substantiate his claim here.

Viewing the allegations in combination, Plaintiff has failed to allege with the requisite specificity a claim for negligent misrepresentation. While Plaintiff may have arguably alleged with specificity elements (a), (b) and (d), Plaintiff fails to allege specific facts with respect to elements (c) and (e) of the claim - reliance by the listener on the representation, coupled with deception by it and damage to the listener proximately resulting from his reasonable reliance. In this regard, Plaintiff's Negligent Misrepresentation claim fails to state a claim for the same reasons why Plaintiff's DTPA 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 his allegations of how he relied upon Defendants' misrepresentations in connection with 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 Counts V and VI of the Amended Complaint is granted. However, Plaintiff may file a motion to amend the Complaint as to these Counts, if he intends to pursue those claims 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