NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DALE MONEY, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC., Defendants.	Civil Action No. 3:07-cv-1100 (FLW) **OPINION**

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 Dale Money's First Amended Complaint asserts claims against Defendants for: (1) products liability - defective design (Count I); (2) products liability - manufacturing defect (Count II); (3) products liability - failure to warn (Count III); (4) products liability - negligence (Count IV); (5) negligent misrepresentation (Count V); (6) violations of Oklahoma's Consumer Protection Act (Count VI); and (7) punitive damages (Count VII). Plaintiff alleges that he was injured 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®. Defendants' motion to dismiss is limited to Counts V and VI of Plaintiff's Complaint. For the reasons that follow, Counts V and VI are dismissed without prejudice.

I. Procedural History

On March 8, 2007, Plaintiff, an Oklahoma 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*., New Jersey's 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. (March 8, 2007 Complaint ¶¶ 6-9.) Plaintiff is one of twenty-three 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-

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[1] Initially, claims were filed on behalf of twenty-four individual claimants, 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.

4965 (hereinafter, "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,

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[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.

173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of 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 First Amended Complaint ("FAC") 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. FAC ¶¶ 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. at ¶ 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. at ¶ 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. at ¶ 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. at ¶ 19; Certification of Michele A. DiMartino, Esq. ("DiMartino Cert.") at ¶ 4, Ex. C. 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. FAC at ¶ 19; DiMartino Cert. ¶ 4, Ex. C. 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. at ¶ 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]). FAC at ¶ 20; DiMartino Cert. at ¶ 3, Ex. B.

As further evidence of Defendants' allegedly false and misleading promotional

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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.

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 more effective than aspirin. FAC at ¶ 21; DiMartino Cert. at ¶ 2, Ex. A. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. FAC at ¶ 22; DiMartino Cert. at ¶ 5, Ex. D. 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 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. FAC at ¶ 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. at ¶ 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. at ¶ 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. at ¶ 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. at ¶ 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. at ¶ 29.

Plaintiff Dale Money contends that he "was prescribed Plavix, to be taken in combination with Aspirin (known as "dual therapy") on or about April 1, 2005, in connection with stent placement. On or about August 1, 2005, Plaintiff went to the

hospital complaining of a headache. CAT scans revealed an acute subdural hematoma. He was taken off Plavix and given six units of blood. An operation was necessary to place a cranial bur hole. Plaintiff spent two weeks in the hospital and continues to have health problems as a result of his Plavix ingestion." Id. at ¶ 31. With regard to his own experiences, or those of his prescribing physician, in connection with Defendants' purported false and misleading promotional materials and practices, Plaintiff's limited discussion of those facts will be discussed more fully infra.

III. 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, 550 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, 173 L.Ed. 2d 868 (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.; and

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[6] The Court notes that because the briefing in this matter was filed only shortly after the United States Supreme Court's decision in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), 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.

(5) the Chan Study. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. 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 motion to dismiss.

IV. Plaintiff's Claim Under Oklahoma's Consumer Protection Act

In Count VI of Plaintiff's FAC, Plaintiff asserts violations of Oklahoma's Consumer Protection Act ("OCPA"), Okla. Stat. tit. 15, § 751 *et seq*. Defendants seek dismissal of Plaintiff's OCPA claim, arguing that the claim fails as a matter of law because Defendants are exempt from liability pursuant to Okla. Stat. tit. 15, § 754(2). Additionally, Defendants contend that Plaintiff has failed to plead the requisite elements of the OCPA claim and, further, that the claim lacks the particularity required by Fed.R.Civ.P. 9(b).

The Court turns first to Defendants' contention that Plaintiff's OCPA claim fails as a matter of law because Defendants are exempt from liability pursuant to Okla. Stat. tit. 15, § 754(2). The exemption language at issue states that:

> Nothing in this Act shall apply to . . .
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> 2. Actions or transactions regulated under laws administered by the Corporation Commission or any other regulatory body or officer acting under statutory authority of this state or the United States, or to acts done by retailers or other persons acting in good faith on the basis of information or matter supplied by others and without knowledge of the deceptive character of such information or matter.

Okla. Stat. tit. 15, § 754.

Defendants argue that the alleged deceptive statements identified by Plaintiff in the FAC fall under § 754(2) and are exempted because FDA authorization of those statements is undisputed in this case. Defendants reason that Plavix was approved by the FDA in November 1997 and, therefore, any advertisements in relation to its marketing would also have been authorized by the FDA. Because Plaintiff concedes in the FAC that Plavix was reviewed by the FDA so that it could be brought to market in 1997, Defendants contend that this Court must necessarily find that the statutory exemption applies. Def. Br. at 7. Citing Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 246 (3d Cir. Del. 2007), vacated on other grounds, 129 S.Ct. 1578 (2009), Defendants assert that Congress has expressly given the FDA authority over prescription drug advertising in the Federal Food, Drug & Cosmetic Act. Defendants reason that the FDA, in turn, authorizes pharmaceutical companies to market and sell their products. Def. Rep. Br. at 3 (citing 21 U.S.C. § 355; 21 U.S.C. § 352(n)).

Plaintiff counters that the purpose of § 754(2) is to exempt from OCPA coverage areas where another state or federal agency could adequately address and remedy a plaintiff's claims. Citing In re General Motors Corp., No. 04-1600, 2005 WL 1924335, *3 (W.D. Okla. Aug. 8, 2005) and Williams v. CSC Credit Services, No. 07-0255(CVE), 2007 WL 1959219, *3 (N.D. Okla. Jun. 29, 2007), Plaintiff argues that in determining whether § 754(2) applies, a court must examine the purposes of the conflicting regulatory scheme and determine whether the conflicting regulatory scheme can properly address and remedy the dispute underlying a plaintiff's OCPA claim. Pl. Br. at 11. Plaintiff asserts that the FDA is unable to adequately address and remedy Plaintiff's claims, despite the agency's

recognition that Defendants' conduct is deserving of chastisement. Plaintiff reasons that 21 U.S.C.A. § 335b limits the reach of the FDA to fraud actions. Because the OCPA is broader in scope than the regulatory powers of the FDA under § 335b, and because the OCPA covers deceptive trade practices that do not require the element that a defendant act "knowingly" as is required by § 335b , Plaintiff argues that the exemption is inapplicable. Moreover, Plaintiff cites to 21 U.S.C.A. § 336, which Plaintiff argues gives the Secretary of the FDA discretion in regulatory prosecution leaving "vulnerable citizens such as Plaintiff" where the FDA has chosen, as in this matter, not to pursue legal action. Pl. Br. at 12. Finally, citing 21 U.S.C.A. § 337, Plaintiff notes that there is no private right of action under the Food, Drug and Cosmetic Act ("FDCA"). Id.

"The OCPA was enacted to protect consumers from unfair and deceptive trade practices." Williams v. CSC Credit Services, Inc., No. 07-0255(CVE), 2007 WL 1959219, *1 (Jun. 29, 2007). Similarly, "Congress enacted the FDCA to bolster consumer protection against harmful products." Levine v. Wyeth, 129 S.Ct. at 1199. "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." Id. Accordingly, while the purpose of the FDCA may indeed be similar to that of the OCPA, i.e. consumer protection, Plaintiff may not bring a private cause of action. Contrary to Plaintiff's suggestion, that fact is not a *fait accompli* to the inapplicability of § 754(2). Indeed, while an individual consumer remedy in the form of a private right of action may be unavailable under the federal regulatory scheme, that scheme exists to afford protection to consumers, which may indeed be sufficient remedy.

Nevertheless, this Court is not prepared at this stage in the litigation to engage in the legal analysis necessary to determine the applicability of § 754(2). While this Court's interpretation of the meaning of § 754(2) is a question of law, Defendants' assertions that their conduct was authorized by the FDA necessarily interjects an analysis of the regulatory scheme applicable to the alleged deceptive promotional materials that has not been adequately briefed by the parties on this motion. Defendants have provided the Court with no support or authority for its bald assertion that "any action involving Plavix® would be authorized or administered by FDA." Def. Br. at 4. The fact that the FDA regulates the labeling and marketing of pharmaceuticals is not a *fait accompli* to the application of the exemption. While the FDA may indeed regulate the promotion and marketing of Plavix, the parties have failed to provide the Court with any factual information or legal analysis involving the regulatory scheme at issue. The issue for this Court's determination is whether the promotional materials that Plaintiff identifies as deceptive were nevertheless in compliance with FDA regulations governing those materials. If indeed Defendants were compliant, then the Court could find the statutory exemption applicable. If, however, Defendants' promotional materials were not authorized by the FDA's regulatory scheme in that they were either not in compliance or are not among the type of materials that the FDA monitors then the statutory exemption would be inapplicable. The Court rejects Defendants' assertion that the exemption is applicable merely because the promotion and marketing of prescription drugs are generally regulated by the FDA. In the absence of adequate briefing from the parties as to these issues the Court is not in a position at this juncture to make a ruling on the issue. Accordingly, this Court finds that Plaintiff's claim under the OCPA should not be dismissed on this basis.

The Court now turns to Defendants' contention that Plaintiff's FAC must be dismissed because he has failed to plead the requisite elements of the OCPA claim and, further, that the claim lacks the particularity required by Fed.R.Civ.P. 9(b). "[T]o state a claim under the OCPA, a plaintiff must allege four elements: (1) the defendant engaged in an unlawful practice under Okla. Stat. tit. 15, § 753; (2) the unlawful practice occurred in the course of the defendant's business operations; (3) the plaintiff, in his capacity as a consumer, was injured; and (4) the defendant's unlawful practice caused the plaintiff's injury. Williams v. CSC Credit Services, Inc., 2007 WL 1959219, at *1.

At the outset, the Court notes that while the parties dispute the applicability of Rule 9(b) to Plaintiff's statutory consumer fraud claim, the Court need not address the issue as Plaintiff's OCPA claim does not even satisfy the more lenient standards of Rule 8(a). Last year, addressing the clarifications as to a litigant's pleading requirement stated by the United States Supreme Court in Twombly, 550 U.S. 544, the Court of Appeals for the Third Circuit provided the district courts with guidance as to what pleadings are sufficient to pass muster under Rule 8. See Phillips v. County of Allegheny, 515 F.3d at 230-34. Specifically, the Third Circuit, quoting Twombly, observed as follows:

> "[W]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's [Rule 8] obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." . . . "[T]he threshold requirement of Rule 8(a)(2) [is] that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'" . . . "Factual allegations must be enough to raise a right to relief above the speculative level."

Phillips 515 F.3d at 231-32 (quoting Twombly 550 U.S. at 555). As previously noted, this pleading standard was further refined by the United States Supreme Court in Ashcroft v.

Iqbal, 129 S. Ct. 1949 wherein the Supreme Court held that in all civil actions:

> [T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . 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. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"
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> Two working principles underlie [the] decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief." Fed. Rule Civ. Proc. 8(a)(2).
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> . . . .
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> Rule 8 does not empower [a claimant] to plead the bare elements of his cause of action, affix the label "general allegation," and expect his complaint to survive a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-54 (quoting Twombly 550 U.S. at 555-57). Since Iqbal, the Third Circuit has required the district courts to conduct, with regard to Rule 8 allegations, a two-part analysis when presented with a motion to dismiss:

> First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. [See Iqbal, 129 S.Ct. at 1949-50]. Second, a District Court must then determine whether the facts alleged

> in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief" [in light of the definition of "plausibility" provided in Iqbal.] In other words, a complaint must do *more than allege the plaintiff's entitlement to relief*. A complaint has to "show" such an entitlement with its facts. See Phillips, 515 F.3d at 234-35. As the Supreme Court instructed in Iqbal, "[w]here the well-pleaded facts do not permit the court to infer more than the *mere possibility of misconduct, the complaint has alleged-but it has not 'show [n]'-'that the pleader is entitled to relief.'"* Iqbal, 129 S.Ct. at 1949-50. This "plausibility" determination will be "a context-specific task that *requires the reviewing court to draw on its judicial experience and common sense."* Id.

Fowler, 578 F.3d at 210-11 (emphasis supplied).

This Court finds that Plaintiff has failed to plead anything other than bald conclusory allegations in support of his OCPA claim. The only factual allegations in the FAC which are not boilerplate and which provide details with regard to this particular Plaintiff are those in Paragraph 31, wherein Plaintiff describes the fact that he was prescribed Plavix to be taken in combination with aspirin in connection with stent placement. FAC at ¶ 31. With regard to his own experiences, or those of his prescribing physician, in connection with Defendants' purported false and misleading promotional materials and practices, Plaintiff is silent. Even if this Court were to find that Plaintiff has plead facts sufficient to support the first three elements of his claim, it is clear that the FAC does not set forth sufficient facts to support the fourth element – that Defendants' unlawful practice caused his injury. The FAC sets forth the following allegations with regard to causation:

> 103. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff has suffered 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 his actual damages, punitive damages, and civil penalties.

> 104. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff further suffered severe and permanent physical injuries, including but not limited [sic] those described in paragraph No. 31.

The conclusory nature of Plaintiff's allegations mandates dismissal. Plaintiff has failed to plead any facts which could support a finding of causation, i.e. that his damages were actually caused by the conduct which Plaintiff asserts was a violation of the OCPA. While Plaintiff made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies, the FAC fails to allege any facts linking Defendants' conduct with Plaintiff's resultant injury. Plaintiff fails to identify any specific advertisements viewed by himself or his prescribing physician. In fact, Plaintiff fails to even identify his prescribing physician. The necessary factual allegations to support Plaintiff's claim are not the sort that are within the control of, and therefore subject to concealment by Defendants.[7] Accordingly, Plaintiff has failed to state a claim upon which relief can be granted.

V. Plaintiff's Negligent Misrepresentation Claim

Oklahoma has adopted the formulation for the tort of negligent misrepresentation set forth in the Restatement (Second) of Torts § 552. Accordingly, "[o]ne who, in the course of his

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[7] Indeed, in that connection, Plaintiff is uniquely equipped to determine from his prescribing physician, whether the physician received such promotional literature or information from Defendants' sales representatives. Even where factual information may be within the domain or control of Defendants, Plaintiff must still "accompany [his] legal theory with factual allegations that make [his] 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 FAC makes no allegations that the information required for Plaintiff to meet his Rule 9(b) obligation is solely within Defendants' control.

. . . profession . . . supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information . . . ." Stroud v. Arthur Andersen & Co., 37 P.3d 783, 794 (Okla. 2001) (*quoting* Restatement (Second) of Torts § 552).

Defendants contend that Plaintiff's negligent misrepresentation claim is subject to the particularity requirements of Rule 9(b). Defendants cite no support for this contention, and Plaintiff appears to accept the application of Rule 9(b) without argument. The Court can only presume, that the parties' application of Rule 9(b) is based upon the fact that Plaintiff's negligent misrepresentation claim in Count V sounds in fraud rather than negligence. See In re Suprema Specialities, Inc. Securities Litig., 438 F.3d 256, 270 (3d Cir. 2006) (noting that where "plaintiff grounds [his claims] in allegations of fraud - and the claims thus 'sound in fraud' - the heightened pleading requirements of Rule 9(b) apply").

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated what must be alleged to satisfy the heightened pleading standard of 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). The Court finds the FAC woefully deficient. As previously noted, Paragraph 31 of the FAC is the only paragraph in the entire FAC that provides specific details regarding Plaintiff and the allegations therein are limited to a description of Plaintiff's injuries. The remaining factual allegations in the FAC are boilerplate allegations that appear in all twenty-three of the amended complaints filed by the personal

injury Plavix plaintiffs in this district. The allegations within Count V of the FAC do not remedy the deficiency. The allegations amount to nothing more than conclusory allegations purporting to set forth the elements of a negligent misrepresentation claim. There is absolutely no plaintiff-specific information identified in Count V.

In opposition to the motion, Plaintiff argues only that his "Negligent Misrepresentation claim is plead with sufficient particularity as Plaintiff's Complaint at 19-22; 27; 29-30; and 78-89 details the 'who', 'what', 'when', 'where', and 'why' requirements . . . ." Pl. Br. at 10. The Court disagrees. The FAC lacks any allegations regarding which misrepresentations were made to Plaintiff or his prescribing physician, and what misrepresentations Plaintiff or his prescribing physician relied upon in connection with Plaintiff's decision to take Plavix. Without this information, Plaintiff's allegation in Paragraph 85(e) of the FAC that "Plaintiff and his healthcare provider justifiably relied on Defendants' misrepresentations" amounts to mere legal conclusion that does not state a plausible claim upon which relief may be granted. Accordingly, Plaintiff's negligent misrepresentation claim cannot withstand the instant motion to dismiss.[8]

VI. Conclusion

For the foregoing reasons, Defendants' motion to dismiss Counts V and VI of Plaintiff's FAC is granted. Plaintiff shall have leave to file a motion to amend the complaint if he seeks

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[8] Citing case law from Illinois and Ohio, Defendants raise for the first time in their Reply Brief that Plaintiff's negligent misrepresentation claim additionally fails as a matter of law because Defendants are not in the business of supplying information, i.e., the end product manufactured and sold is a tangible object. To the extent that Plaintiff moves for leave to amend the Complaint, Defendants can raise the issue in response to Plaintiff's motion to amend, however, the Court declines to address the issue here because Defendants raise it for the first time in their Reply Brief. See Merling v. Horizon Blue Cross Blue Shield of New Jersey, No. 04-4026, 2009 WL 2382319, *10, n.5 (D.N.J. Jul. 31, 2009) (declining to address issue raised for first time in reply brief).

to assert the claims, but he must cure the deficiencies as outlined by the Court herein.

Dated: December 30, 2009

___/s/ Freda L. Wolfson
United States District Judge