NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PHILIP BARGE, Plaintiff, 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-00783 (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 Philip Barge's First Amended Complaint asserts claims against Defendants for: (1) Strict Liability - Defective Product (Count I); (2) Strict Liability - Failure to Warn (Count II); (3) negligence (Count IV)[1]; (4) negligent misrepresentation (Count V); and (5) violations of Georgia's Fair Business Practices Act ("GFBPA") (Count VI). 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 Count VI of Plaintiff's Complaint. For the reasons that follow, Defendants' motion to dismiss Count VI

[1] Plaintiff's First Amended Complaint does not set forth a Third Count.

is granted.

I. Procedural History

On February 15, 2007, Plaintiff, a Georgia 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. (Feb. 15, 2007 Complaint ¶¶ 6-8.) Plaintiff is one of twenty-three individual claimants[2] that lodged separate complaints[3] 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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[2] 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.

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

4965 (hereinafter, "Skilstaff"),[4] 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,

[4] 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 Count 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.[5] 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"[6]). FAC at ¶ 20; DiMartino Cert. at ¶ 3, Ex. B.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiff points to a December 1998 letter from the FDA, wherein the FDA

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[5] 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.

[6] 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.

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 contends that he "was prescribed Plavix, to be taken in combination with aspirin (known as 'dual therapy') on or around October, 2003 in connection with his heart disease after suffering a heart attack. On or around February 16, 2005, he went to the hospital and was told he had a bleeding ulcer and was given six pints of blood to replace

the blood he had lost." 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).[7] "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 March 12, 2009 letter from Plaintiff's counsel to Defendants' counsel. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. While

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[7] 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.

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 which were relied upon by Plaintiff in drafting the FAC are properly before the Court on the instant motion to dismiss. The only exhibit not referenced in, or integral to, the FAC is the March 12, 2009 letter from Plaintiff's counsel regarding mediation. However, in light of this Court's determination, infra, that the *ante litem* notice provision is inapplicable to Plaintiff's statutory consumer fraud claim, the Court need not consider the letter.

IV. Plaintiff's Claim Under Georgia's Fair Business Practices Act

In Count VI of Plaintiff's FAC, Plaintiff asserts violations of Georgia's Fair Business Practices Act ("GFBPA"), O.C.G.A. §§ 10-1-390 *et seq*. Defendants seek dismissal of Plaintiff's GFBPA claim, arguing that the claim fails as a matter of law because they are exempt from liability pursuant to O.C.G.A. 10-1-396(1). Additionally, Defendants contend that Plaintiff has failed to plead the requisite elements of the GFBPA claim and, further, that the claim lacks the particularity required by Fed.R.Civ.P. 9(b). Finally, Defendants argue that Plaintiff cannot maintain the GFBPA claim because Plaintiff failed to provide notice of the claim as required by O.C.G.A. § 10-1-399(b).

The Court turns first to Defendants' contention that the GFBPA claim must be dismissed based upon Plaintiff's failure to give the statutorily required notice set forth in O.C.G.A. § 10-1-399(b). Notice pursuant to O.C.G.A. § 10-1-399(b) is indeed a prerequisite to the filing of a claim under the GFBPA. In accordance with O.C.G.A. § 10-1-399(b), "[a]t

least 30 days prior to the filing of any such action, 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 delivered to any prospective respondent." Plaintiff contends that the notice requirement is satisfied by virtue of the filing of the original Complaint.[8] Plaintiff reasons that because he filed the FAC "some two and one-half years after Plaintiff's original complaint," Defendants have had notice of the allegations for at least thirty (30) months. Pl. Br. at 11. In other words, the earlier Complaint identifying Plaintiff's claim under New Jersey's consumer protection statute, serves as the requisite notice prior to the May 2009 filing of the FAC bringing the claim under Georgia's consumer protection statute. A district court considering a similar argument under O.C.G.A. § 10-1-399(b), rejected the notion that the statutorily required notice can be satisfied by the filing of a complaint, prior to an amended complaint. See In re New Motor Vehicles Canadian Export Antitrust Litigation, 350 F.Supp.2d 160, 183 (D.ME 2004). Notwithstanding the fact that the GFBPA is to be liberally construed, the New Motor Vehicles court found that "[t]o hold that a complaint filed in a court suffices as notice if it is later amended to add a consumer protection claim flies in the face of both the statutory language and its policy." Id.

Alternatively, Plaintiffs contend that a March, 2009 letter sent from Plaintiff's counsel to counsel for Defendants seeking to resolve the instant litigation via mediation following this Court's reinstatement of the case satisfies the notice requirement. Pl. Br. at

[8] In citing to the filing of the initial Complaint in this matter, Plaintiff references Case No. 05-203 and an original filing date of October 30, 2006. Pl. Br. at 11. The Court can only presume that this is in error as the docket number for the instant case is, and always has been, No. 07-783, and the original filing date was February 15, 2007.

11. This Court is not convinced that notice given after the filing of the original complaint can satisfy the requirements of O.C.G.A. § 10-1-399(b). However, the Court need not reach the issue of whether the foregoing conduct by Plaintiff satisfies the statutory notice requirement because, as Plaintiff points out, the notice provisions are inapplicable. O.C.G.A. § 10-1-399(b) expressly provides that "[t]he 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." This Court can only presume in the absence of any facts in the FAC indicating Defendants' ties to Georgia and in the face of Defendants' silence as to the application of this provision, that Defendants neither maintain a place of business in Georgia nor maintain assets therein. Accordingly, this Court finds the *ante litem* notice provision inapplicable.

Next, Defendants contend that Plaintiff's GFBPA claim fails as a matter of law because Defendants are exempt from liability pursuant to O.C.G.A. § 10-1-396(1). The purpose of the GFBPA is

> to protect consumers and legitimate business enterprises from unfair or deceptive practices in the conduct of any trade or commerce in part or wholly in the state. It is the intent of the General Assembly that such practices be swiftly stopped, and this part shall be liberally construed and applied to promote its underlying purposes and policies."

O.C.G.A. § 10-1-391(a). The GFBPA proscribes "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful." O.C.G.A. § 10-1-393(a). The exemption language in the GFBPA at issue states that "[n]othing in this part shall apply to . . . [a]ctions or transactions specifically authorized under laws administered by or rules and regulations promulgated by any regulatory agency of this state or the United States." O.C.G.A. § 10-1-396(1).

Plaintiff contends that the exemption cannot be read to protect Defendants' conduct. According to Plaintiff, "[t]he fact that Plavix was approved by the (FDA) and underwent regulatory review by the FDA does not mean that Defendants are exempt from liability under the GFBPA. Certainly, even though the FDA approved Plavix, it certainly did not specifically authorize Defendants to engage in unfair, deceptive and/or unconscionable consumer sales practices." Pl. Br. at 6. Plaintiff argues that there is no federal statute preempting claims against pharmaceutical companies for making false or misleading statements about their products. Citing Wyeth v. Levine, __ U.S. __, 129 S.Ct. 1187, 1202, 173 L.Ed.2d 51 (2009), for the proposition that "state law is a complementary form of drug regulation", Plaintiff contends that the Supreme Court has acknowledged that claims against pharmaceutical manufacturers for misleading or incomplete warnings are not preempted. Pl. Br. at 6-7. Plaintiff's arguments miss the mark. The issue is not whether Plaintiff's claim is preempted by federal law, but, rather, whether the claim is exempted by O.C.G.A. § 10-1-396(1). *Emphasis added*. Moreover, this Court declines to adopt Plaintiff's narrow reading of the GFBPA's exemption provision.

Although relatively few Georgia courts have addressed precisely what is meant by the "specifically authorized" language of O.C.G.A. § 10-1-396(1), a district court addressing the issue noted that the language engenders two possible interpretations:

> The first interpretation would exempt from the Act conduct that was specifically authorized. The second interpretation would exempt conduct that is being regulated by an administrative agency. While in the abstract it is possible to envision a regulatory agency's permitting of "activities which do not conflict with the interests which that agency is charged to protect, with no pretense of concern whether those activities might harm other interests," practically speaking, the court perceives that an interpretation of [§ 10-1-396(1)] that would exempt conduct authorized specifically by an agency as anomalous, for what administrative agency would authorize an unfair trade practice? In

> light of the purpose of the [GFBPA] as well as a judicial construction of [§ 10-1-396(1)], the court reads the second interpretation as proper.

Taylor v. Bear Stearns & Co., 572 F.Supp. 667, 674 (N.D.Ga. 1983) (quoting Rothschild, *A Guide to Georgia's Fair Business Practices Act of 1975*, 10 Ga.L.Rev. 917, 922-29 (1976)(internal citation omitted)). Citing Ferguson v. United Insurance Co., 193 S.E.2d 736 (Ga.App. 1982), the Taylor court noted that "to the extent that a remedy is available to an injured consumer in a regulated industry . . . the [GFBPA] has no application." Taylor, 572 F.Supp. at 675. The Taylor court concluded

> the phrase 'specifically authorized' in [§ 10-1-396(1)]is construed to mean specifically regulated. Therefore, in a situation where a consumer remedy exists, with no need to fill in a legal gap or create a consumer right, and where the industry which is the subject matter of the situation explicitly defines wrongful conduct or unfair and deceptive practices, the [GFBPA] has no application.

Id.

Again, in Brogdon v. National Healthcare Corp., 103 F.Supp. 2d 1322, 1336 (N.D.Ga. 2000), a district court considering the meaning of the "specifically authorized" language of O.C.G.A. § 10-1-396(1) noted

> the [GFBPA] does not apply in extensively regulated areas of the marketplace such as investment account transactions, finance charges and required disclosures by lenders, and insurance transactions. Taylor v. Bear Stearns & Co., 572 F.Supp. 667, 675 (N.D.Ga. 1983) (holding allegations of unauthorized trades or churning not cognizable under FBPA); [Chancellor v. Gateway Lincoln-Mercury, Inc., 233 Ga.App. 38, 45 (1998)] ("area of finance charges, disclosure, and truth in lending falls outside the FBPA, except where expressly covered"); Ferguson v. United Ins. Co. of Am., 163 Ga.App. 282, 283, 293 S.E.2d 736 (1982) ("[I]nsurance transactions are among those types of transactions which are exempt from the Fair Business Practices Act.").

The Brogdon court determined that O.C.G.A. § 10-1-396(1) exempted the plaintiffs' claims,

which set forth allegations regarding the deficient level of care provided by the defendant health care facility, reasoning that because the facility participated in the Medicare and Medicaid programs, state and federal agencies regulate the precise conduct about which plaintiffs complained. Brogdon, 103 F.Supp. at 1336-37.

To avoid application of the exemption provision, Plaintiff argues that although the FDA "approved and regulated Plavix, it did not approve every action or practice undertaken by Defendants and certainly did not approve misrepresentations and omissions." Pl. Br. at 8. In support of his contention that the FDA did not authorize Defendants' actions at issue, Plaintiff points to the allegations in the FAC which set forth instances in which Defendants were admonished for misrepresentations. Id. However, Plaintiff's argument in this regard actually undercuts his position. It is clear that while the FDA may not have authorized the purported deceptive practices at issue here, the admonishments Plaintiff cites evidence the fact that the FDA does indeed regulate the marketing and sale of prescription drugs.

The inquiry, however, does not end there. As Plaintiff points out, 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. However, 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 GFBPA should not be dismissed on this basis.

The Court now turns to Defendant's contention that Plaintiff has failed to sufficiently plead a cause of action under the GFBPA. To establish a cause of action under the GFBPA, a plaintiff must satisfy the following elements: (1) violation of the Act; (2) causation; and (3) injury. Johnson v. GAPVT Motors, Inc., 292 Ga.App. 79, 84 (Ga.Ct.App. 2008) (citing Campbell v. Beak, 256 Ga. App. 493, 497-98 (Ga.Ct.App. 2002)). Although the GFBPA "differs from common law fraud in that it eliminates two of the five required elements of fraud: scienter and intent to deceive," Johnson, 292 Ga.App. at 84, n.3 (citation omitted), it does incorporate "the 'reliance' element of the common law tort of misrepresentation into the causation element of an individual claim under the [GFBPA]." Campbell, 256 Ga. App. at 497 (quoting Zeeman v. Black, 156 Ga.App. 82 (Ga.Ct.App. 1980).

Defendants argue that Plaintiff has failed to demonstrate in the FAC that his injury was caused by Defendants' conduct, which was a violation of the GFBPA. Specifically, Defendants contend that not only does the FAC fail to "identify the 'untrue, deceptive or misleading advertisements' that were allegedly made, but it also fails to allege that

Plaintiff heard or relied upon these statements in filling his prescription for Plavix." Def. Br. at 5. Defendants also contend that Plaintiff's damage claim is not properly plead under the GFBPA because, although actual damages are recoverable, they are limited to the actual injury suffered.[9] Id. (citing Regency Nissan v. Taylor, 194 Ga. App. 645, 649 (Ga. Ct. App. 1990). Additionally, Defendants argue that Plaintiff's GFBPA claim lacks the particularity required by Fed.R.Civ.P. 9(b).

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 GFBPA 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.

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[9] Plaintiff notes that he seeks only those damages which are afforded by the GFBPA. Pl.Br. 10.

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 GFBPA 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 after suffering a heart attack. 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. While Plaintiff identifies the specific provisions of the GFBPA under which he brings his claim, and generally references the paragraphs in Section III of the FAC, which arguably set forth the deceptive practices complained of, the FAC is silent as to causation and reliance, requisite components of his GFBPA claim. This proves fatal to Plaintiff's claim.

Plaintiff identifies Paragraphs 82 and 83 of the FAC as supportive of the fact that he has plead reliance. Those Paragraphs provide:

> 82. The Defendants' statements and omissions were made with the intent that Plaintiff herein, and his prescribing physician, would rely on such statements.
>
> 83. The Plaintiff purchased and used Plavix for personal, family or household purposes and suffered ascertainable losses of money as a

> result of the Defendants' use or employment of the methods, acts, or practices.

The conclusory nature of Plaintiff's allegations mandates dismissal. Plaintiff never identifies which of the allegedly deceptive promotional materials upon which he or his prescribing physician relied or that were it not for Defendants' deceptive practices Plaintiff would not have taken Plavix or his physician would not have prescribed the drug to Plaintiff. Significantly, Plaintiff does not even identify the name of his prescribing physician. Accordingly, Plaintiff has failed to state a claim upon which relief can be granted.

VI. Conclusion

For the foregoing reasons, Defendants' motion to dismiss Count VI of Plaintiff's FAC is granted. Plaintiff's GFBPA claim is dismissed without prejudice.

Dated: December 30, 2009

/s/ Freda L. Wolfson
United States District Judge