

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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MOSCINSKI, DAVID and SHARON,	:	
	:	Civil Action No. 06-6055 (FLW)
Plaintiff,	:	
v.	:	
	:	<b>OPINION</b>
BRISTOL-MYERS SQUIBB CO., <u>et al.</u> ,	:	
	:	
Defendants.	:	

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**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”). Plaintiffs David and Sharon Moscinski, husband and wife, (collectively, “Plaintiffs”) bring this suit against Defendants because they allege that they 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, Plaintiffs’ First Amended Complaint (“Amended Complaint”) asserts various Wisconsin state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim; Count VI, i.e., fraud claim pursuant to the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq. For the reasons that follow, Defendants’ motion to dismiss these counts is granted.

## BACKGROUND FACTS

### I. Procedural History

On December 18, 2006, Plaintiffs, citizens of Wisconsin, 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. (December 18, 2006 Complaint ¶¶ 6-8.) Plaintiffs are among the individual claimants<sup>1</sup> that lodged separate complaints<sup>2</sup> against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

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

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<sup>1</sup> 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.

<sup>2</sup> A number of the twenty-three claimants were joined in their actions by spouses asserting claims for loss of consortium.

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

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

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<sup>3</sup> 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' motions to dismiss Plaintiffs' Counts V and VI that this Court now considers.

## **II. Factual Background**

The following version of events assumes Plaintiffs' allegations in their 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 the present matter.

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. Plaintiffs allege 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, Plaintiffs point 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.<sup>4</sup> Id., ¶ 19. Plaintiffs also point 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. 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, Plaintiffs point 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 Plaintiffs, 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”<sup>5</sup>). Id.

As further evidence of Defendants’ allegedly false and misleading promotional practices, Plaintiffs point 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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<sup>4</sup> 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.

<sup>5</sup> 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 Plaintiffs, 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, Plaintiffs point 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.

Plaintiffs allege 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, Plaintiffs contend 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. Plaintiffs point 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. Plaintiffs additionally cite 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, Plaintiffs contend 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, Plaintiffs assert, inter alia, fraud claim pursuant to the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq. ("WDTP" or the "Act"), and a Wisconsin state common law claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiffs allege that Mr. Moscinski "began 'dual therapy'—Plavix plus aspirin, in July 2005 after he had required a cardiac catheterization and stenting procedure." On or around December 18, 2005, David Moscinski was rushed to the hospital because he passed out from vomiting uncontrollably. "It was found that he had suffered a severe subarachnoid hemorrhage." As a result of the alleged injuries, Plaintiffs allege that Mr. Moscinski was "unable to walk, talk, chew food, swallow, or breathe unaided." In that connection, Plaintiffs allege that Ms. Moscinski "had to spend her time caring for David and dealing alone with the

everyday matters in which her husband normally provided assistance.” Am. Compl., ¶31.

As result of the alleged injuries, Plaintiffs, in Count VI of their Amended Complaints, allege that Defendants violated the WDTP by making “untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff, concerning the use and safety of Plavix.” Am. Compl., ¶ 97. In that connection, Plaintiffs allege that “Defendants knew and should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects.” Am. Compl., ¶ 94. Specifically, Plaintiffs allege that “Defendant’s practice of promoting Plavix placed and continues to place all consumers of Plavix at risk of serious injury and potentially lethal side effects.” Am. Compl., ¶ 99. Plaintiffs further allege that “Defendants’ statements and omissions were made with the intent that the Plaintiff, and Plaintiff’s prescribing physician, would rely on them.” Am. Compl., ¶ 100. As a result of the alleged illegal practices, Plaintiffs claim that they have “suffered severe and permanent physical injuries.” Am. Compl., ¶ 104.

Similarly, Count V alleges that “Defendants falsely represented to Plaintiffs in direct to consumer advertising and indirectly through misrepresentations 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 Plaintiffs’ health.” Am. Compl., ¶ 80. Plaintiffs claim that “[a]t the time the representations were made, Defendants concealed from Plaintiffs and their 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.” Am. Compl., ¶ 81. In that regard, Plaintiffs allege that Defendants’ misrepresentations “were made by Defendants with the intent to induce Plaintiffs to use



Plavix, to Plaintiffs' detriment." Am. Compl., ¶ 82. Plaintiffs further allege that "Plaintiffs and Plaintiffs' healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Plaintiffs' ingestion of Plavix was to their detriment." Am. Compl., ¶ 85.

Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the WDTP claim, of the Amended Complaint. The Court will now 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).<sup>6</sup> "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 Plaintiffs' 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, Plaintiffs supply 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.

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<sup>6</sup> 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.

Additionally, 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 motion to dismiss.

## **II. The WDTP Claim**

To state a claim under the WDTP, Defendants contend that Plaintiffs’ pleading in this context must conform to the rigors of Rule 9(b). To support their contention, Defendants rely upon Budgetel Inns v. Micros Sys., 8 F.Supp. 2d 1137, 1149 (D. Wis. 1998), for the general proposition that Rule 9(b) typically applies to allegations of fraud or misrepresentation. In response, Plaintiffs contend that Budgetel Inn involved fraud claims arising from common law, not a statutory claim pursuant to the WDTP; therefore, the case has no application here. Moreover, Plaintiffs submit that while there is no case law in Wisconsin, federal or state, directly addressing this issue, the Wisconsin Supreme Court in Novell v. Migliaccio, 2008 WI 132 ( 2008), has interpreted the WDTP as a separate statutory remedy distinct from a common law claim of fraudulent misrepresentation; therefore, Plaintiffs suggest that their WDTP claim need not meet the requirements of Rule 9(b). The Court disagrees.

Having surveyed federal and state cases interpreting the WDTP, it appears the courts are silent as to whether a heightened pleading requirement is required when asserting a fraud claim under this statute. However, it is well-settled in the Seventh Circuit that in general, for fraud claims

brought in federal court a higher threshold of specificity is required; under Federal Rule of Civil Procedure 9(b), a claim based upon fraudulent conduct must be plead with particularity. See Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., 536 F.3d 663, 669 (7<sup>th</sup> Cir. 2008); see also GE Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1078 (7<sup>th</sup> Cir. 1997). To that end, while no Wisconsin state court has had the occasion to address whether a heightened pleading standard applies to fraud claims under the WDTP, since Plaintiff is asserting his state claim in a federal forum, the Court will apply Rule 9(b) to Plaintiff's WDTP claim.<sup>7</sup>

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

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<sup>7</sup>Indeed, Plaintiff tacitly conceded that Rule 9(b) applies to his WDTP 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." As stated earlier, because his WDTP claim involves allegations of fraud, the Court will apply Rule 9(b).

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 Seventh Circuit precedent. GE Capital Corp., 128 F.3d at 1078 (“[t]he circumstances of fraud or mistake include the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff” (citations and quotations omitted)).

To prevail on a claim under the WDTP, a plaintiff must prove three elements: (1) with the intent to induce an obligation, the defendant made a representation to "the public," see Wis. Stat. § 100.18(1); (2) the representation was untrue, deceptive or misleading, Id.; (3) the representation caused the plaintiff a pecuniary loss, Wis. Stat. § 100.18(11)(b)(2); see Schmidt v. Bassett Furniture Indus., No. 08-1035, 2009 U.S. Dist. LEXIS 103490, at \*23 (E.D. Wis. Oct. 20, 2009); K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc., 301 Wis. 2d 109, 121-22 (2007).

Section 100.18(11)(b)(2) of the WDTP provides that “[a]ny person suffering pecuniary loss because of a violation of this section by any other person may sue in any court of competent jurisdiction and shall recover such pecuniary loss.” While a plaintiff need not show or plead reasonable reliance, this section requires a causal connection between the untrue, deceptive, or misleading representation and the pecuniary loss. K&S Tool, 301 Wis. 2d at 129 (“a plaintiff does not have the burden of proving reasonable reliance; unlike common law causes of action for misrepresentations, reasonable reliance is not the standard for a DTPA claim because the legislature created a distinct cause of action” (citations omitted)); Tim Torres Enters., Inc. v. Linscott, 142 Wis. 2d 56, 70 (Ct. App. 1987). However, “[b]ecause the purpose of the [WDTP] includes protecting

Wisconsin residents from untrue, deceptive, or misleading representation made to induce action . . . proving causation in the context of [WDTP] requires a showing of material inducement.” K&S Tool, 301 Wis. 2d at 129.

In the Amended Complaint, Plaintiffs allege a unified course of fraudulent conduct and they rely entirely on that as the basis of their WDTP claim. More specifically, as noted above, Plaintiffs allege that Defendants “knew or should have known, that Plavix was unreasonably dangerous or defective, and had a propensity to cause serious potentially life threatening side effects.”<sup>8</sup> Plaintiffs further allege that despite their knowledge, “Defendants omitted material facts in the disclosures they made to the public, the medical community and consumers, including the Plaintiffs herein, concerning the safety of Plavix.” Am. Compl., ¶ 95. As a result, Plaintiffs allege that Defendants violated the WDTP “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[s], concerning the use and safety of Plavix.” Plaintiffs’ allegations fall short of complying with Rule 9(b).

Arguing the contrary, Plaintiffs contend that the Amended Complaint asserts sufficient facts to satisfy Rule 9(b). In particular, Plaintiffs point to ¶¶ 19-22; 27; 29-30; and 90-107 of the Amended Complaint to support their assertion that they have pled the so-called “newspaper requirements” of Rule 9(b). Summarizing their points, Plaintiffs state (1) that they have alleged who made the misleading statements - Defendants; (2) that they have alleged what was misleading about Defendants’ statements - Defendants advertised Plavix as safe and effective in “dual therapy”

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<sup>8</sup>Since the Court is restating these allegations that were previously set forth in this Opinion, the Court will not repeat the citations to the record here.

treatments, off-label use, and more effective than aspirin; (3) that they have 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 they have 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 they have 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, Plaintiffs also suggest that under the circumstances of this case, because information regarding their allegations of fraud are within Defendants' control, less specificity of pleading is required pending discovery.

Although Plaintiffs have arguably pled with particularity with respect to the first and second element of a WDTP claim, they have failed to sufficiently plead the third element - the representation caused Plaintiffs a pecuniary loss. Indeed, Plaintiffs made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies; however, the Amended Complaint fails to allege with specificity the connection between Defendants' conduct and Plaintiffs' resultant injury. Plaintiffs' only allegations particular to their circumstances that support their WDTP fraud claim can be found in ¶ 31 of the Amended Complaint, wherein Plaintiffs set forth when Mr. Moscinski was prescribed Plavix and the health issues he suffered as a result of taking Plavix. These allegations are insufficient to meet the rigors of Rule 9(b).

Plaintiffs fail to identify any specific advertisements they viewed, how they were misled by

these advertisements, how these advertisements affected Mr. Moscinski's prescriptions 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 Plaintiffs, and if they were, when these materials were viewed and how they were relied upon. More simply stated, Plaintiffs have failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. See Krittley 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, Plaintiffs fail to allege that Mr. Moscinski's physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to Mr. Moscinski.<sup>9</sup> Rather, Plaintiffs allege only generally that Defendants "omitted material facts in the disclosures they made to the public, the medical community and to consumers,

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<sup>9</sup> Plaintiffs' Amended Complaint does not provide the names of Mr. Moscinski's prescribing physicians.



including the Plaintiff, concerning the use and safety of Plavix,” and these “statements and omissions were made with the intent that the Plaintiffs herein, and [Mr. Moscinski’s] prescribing physician, would rely on them.” Although the Amended Complaint also 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, Plaintiffs have not identified the representatives, what was said, when it was said, to whom it was said and how these statements relate to Mr. Moscinski’s prescriptions 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, Mr. Moscinski and his physicians are within Plaintiffs’ ken, but are nowhere to be found within Plaintiffs’ Amended Complaint.<sup>10</sup>

The deficiencies of Plaintiffs’ Amended Complaints 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

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<sup>10</sup>Indeed, in that connection, Mr. Moscinski 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, Plaintiffs must still “accompany their legal theory with factual allegations that make their theoretically viable claim plausible.” In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to “avoid dismissal,” a complaint must also delineate at least the nature and the scope of a plaintiff’s efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiffs have failed to comply with these requirements. The Amended Complaint contains no allegation that the information required for Plaintiffs to meet their Rule 9(b) obligation is solely within Defendants’ control.

defendants “orchestrated a campaign to illegally market and promote the Subject Drugs for off label uses . . . and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs that they would not have purchased but for the illicit marketing scheme.” Id. at \*7. Similar to Defendants’ response here, the defendants there filed a motion to dismiss, among other claims, plaintiffs’ fraud and negligent misrepresentation claims.

In dismissing these two specific claims, the court, in a well-reasoned opinion, found that plaintiffs made “sweeping allegations” regarding defendants’ alleged promotion, yet they did not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs. Id. at \*117. In addition, the court explained that plaintiffs’ common law fraud and negligent misrepresentation claims also failed to state a claim because plaintiffs did not allege a causal connection between their injury and defendants’ conduct. Id. at \*119. While In re Schering-Plough dealt with New Jersey’s common law claims, the same reasoning applies here since the fraud theory of that case parallels the instant actions. See Suarez v. Playtex Products, Inc., No. 08-2703, 2009 U.S. Dist. LEXIS 63774, at \*8-10 (N.D. Ill. Jul. 24, 2009)(plaintiffs failed to allege with specificity “whether or when they relied on, or even saw, these [misrepresentations] prior to purchasing the coolers”). Accordingly, Plaintiffs fail to inject precision and some measure of substantiation to support their WDTP claim, and therefore, it is dismissed.

As a final note, Plaintiffs have also failed to properly plead their damages under the WDTP. Although actual damages are recoverable under the DTPA, they are limited to the recovery of pecuniary loss, together with costs, including reasonable attorneys’ fees. Calnin v. Hilliard, No. 05-694, 2008 U.S. Dist. LEXIS 8590, at \*35 (E.D. Wis. Feb. 5, 2008); Wis. Stat. §

100.18(11)(b)(2)(this section allows “[a]ny person suffering pecuniary loss because of a violation of this section by any other person,” to “recover such pecuniary loss, together with costs, including reasonable attorney fees . . .”). Plaintiffs may move to amend this claim to cure the deficiencies set forth herein.

### **III. Negligent Misrepresentation**

The Court notes at the outset that Plaintiffs do not dispute that they must plead with particularity pursuant to Rule 9(b) with respect to their Negligent Misrepresentation claims. Indeed, courts in Wisconsin have required compliance with Rule 9(b) when asserting a negligent misrepresentation claim grounded, or sounds, in fraud. See Krider Pharmacy & Gifts, Inc. v. Medi-Care Data Sys., Inc., 791 F. Supp. 221, 226-27 (E.D. Wis. 1992); Green Spring Farms v. Kersten, 136 Wis. 2d 304, 319 (1987). Because Plaintiffs’ WDTP claim brims with allegations of fraud, it must be pled with particularity.

In Wisconsin, the common law elements of a negligent misrepresentation claim are: (1) a duty of care or voluntary assumption of a duty on the part of the defendant; (2) a breach of that duty, i.e., failure to exercise ordinary care in making the representation or in ascertaining the facts; (3) a causal link between the conduct and the injury; and (4) actual loss or damage as a result of the injury. Hatleberg v. Norwest Bank Wis., 283 Wis. 2d 234, 255 (2005).

Here, in order to support their negligent misrepresentation claims, Plaintiffs first allege that “Defendants having undertaken the manufacturing, marketing distribution, and/or promotion of Plavix owed a duty to provide accurate and complete information regarding Plavix.” Am. Compl., ¶ 79. However, breaching that duty, “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. Plaintiffs further allege 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. Plaintiffs also point to the same allegations used to support their WDTP claim in ¶¶ 19-22; 27; 29-30; and 90-107 of the Amended Complaint to substantiate their claim here.

Viewing the allegations in combination, Plaintiffs have failed to allege with the requisite specificity a claim for negligent misrepresentation. While Plaintiff may have arguably alleged with specificity elements (1), (2) and (4), Plaintiffs fail to allege specific facts with respect to element (3) of the claim - a causal link between the conduct and the injury. In this regard, Plaintiffs' Negligent Misrepresentation claim fails to state a claim for the same reasons why Plaintiffs' WDTP 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 Plaintiffs; when they were made to Plaintiffs; the substance of the alleged misrepresentations; the name of Mr. Moscinski's prescribing physician; the substance of the alleged misrepresentation made to his prescribing physician; and when the false representation was made. While the Court does not suggest that Plaintiffs must plead every single fact listed above, Plaintiffs simply do not state with the requisite particularity the circumstances of the alleged fraud or otherwise inject precision into their allegations of how they 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, Plaintiffs' Negligent

Misrepresentation claim is dismissed without prejudice.

As a final note, Defendants move to dismiss Plaintiffs' request for punitive damages in connection with their Negligent Misrepresentation claim because Wisconsin law does not support such an award. Plaintiffs do not dispute this contention and thus, voluntarily withdraw their request for punitive damages under their Negligent Misrepresentation claim.

### **CONCLUSION**

Based upon the foregoing reasons, Defendants' motion to dismiss Counts V and VI of the Amended Complaint is granted. However, Plaintiffs may file a motion to amend the Complaint as to these Counts, if they intend 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