UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

No. 08-MD-1928-MIDDLEBROOKS

IN RE: TRASYLOL PRODUCTS
LIABILITY LITIGATION

This document applies to:
ALL CASES

ORDER ON MOTIONS TO DISMISS

THIS CAUSE comes before the Court upon the Defendants' Motion to Dismiss Count V and VI of the Consolidated Amended Master Complaint (DE 221) and the Defendants' Motions to Dismiss Count IV in Cases No. 08-80880; 08-80881; and 08-80835 (DE 226, 227 & 234). The Court has reviewed the Motions and is otherwise fully informed of the premises.

Background

This MDL proceeding centers around a prescription medication aprotinin, trade name Trasylol®. The United States Food and Drug Administration (the "FDA") approved Trasylol for use in certain open-heart surgeries in 1993, and for all coronary artery bypass graft surgeries in 1998. The drug is intended to prevent peri-operative blood loss during surgery and reduce the need for blood transfusions.

In late 2007, early 2008, Plaintiffs began filing actions against the manufacturers of Trasylol for personal injury or death allegedly caused by the drug. The Judicial Panel on Multi-District Litigation found the actions appropriate for MDL treatment and transferred the instant actions to this Court commencing in April of 2007.

Since commencement of this MDL action, the Parties have diligently worked together to formulate a cooperative plan of general and case-specific discovery working towards prompt and efficient resolution of the underlying cases. As a part of that cooperative plan, I permitted the Plaintiffs to file an Amended Consolidated Complaint as well as abbreviated short form Complaints for the individual cases. The purpose of the consolidated proceedings is to ensure that these cases, which have nearly identical discovery requirements, are resolved in a just and consistent manner. Over three hundred cases have been transferred into this District pursuant to the MDL Transfer Order, with additional cases arriving weekly.

Legal Standard

It is well-settled that in ruling on a motion to dismiss, a federal court must view the complaint in the light most favorable to the plaintiff and take its well-pled allegations as true. *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 2232 (1984); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1965, 167 L.Ed.2d 929 (2007) (citation omitted); *Watts v. Fla. Int'l Univ.*, 495 f. 3d 1289, 1295 (11th Cir. 2007); *Hoffman-Pugh v. Ramsey*, 312 f.3d 1222, 1225 (11th Cir. 2002). In considering a motion to dismiss, it is necessary to assess the sufficiency of the complaint against the legal standard set forth in Rule 8: " a short and plain statement of the claim showing that the pleader is entitled to relief," but must also keep in mind that such short and plain statement "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1965, 167 L.Ed.2d 929 (2007) (citation omitted); *Watts v. Fla. Int'l Univ.*, 495 f. 3d 1289, 1295 (11th Cir. 2007).

Under the *Twombly* standard, factual allegations in a complaint need not be overly

detailed but "must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact). *Id.* at 1964-65 (citations omitted). "The Supreme Court's most recent formulation of the pleading specificity standard is that 'stating such a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element." *Watts*, 495 F.3d at 1295 (quoting *Twombly*, 127 S. Ct. at 1965). This does not mean to say that a Plaintiff must establish a probability of prevailing on a particular claim, but rather, the standard "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" of a required element. *Id.* "It is sufficient if the complaint succeeds in 'identifying facts that are suggestive enough to render [an element] plausible.'" *Watts*, 495 F.3d at 1296 (quoting *Twombly, id.*).

Additionally, when a claim for fraud is raised, "a party must state with particularity the circumstances constituting fraud . . . Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." *See* FED. R. CIV. P. 9(b). However, Rule 9 "must not be read to abrogate Rule 8," and a court, in "considering a motion to dismiss for failure to plead fraud with particularity should always be careful to harmonize the directives of rule 9(b) with the broader policy of notice pleading." *See Friedlander v. Nims,* 755 F.2d 810, 813 n.3 (11th Cir. 2001). With these standards in mind, I turn to the instant Motions.

The Motion to Dismiss Counts V (Fraud) and VI (Constructive Fraud) of Plaintiffs' Master Complaint and Related Short form Complaints

Defendants assert that dismissal of Count V and VI of the Master Complaint is warranted because both counts fail to plead fraud with particularity as required by Rule 9(b). Defendants also assert that dismissal of Count VI is required for the additional reason that it fails to allege

essential element of fiduciary or other special relationship between the Plaintiffs and the Defendants. I first turn to the Defendants' argument relating to Plaintiffs failure to plead fraud with particularity.

Count V alleges:

> 91. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
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> 92. Defendants are liable to Plaintiffs under the state common law and/or state Products Liability Acts for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ration of Trasylol, either compared to the use of alternative drug products in its class or compared to the use of no drug products, to Plaintiffs and to the health care providers that prescribed, recommended, ordered, and administered Trasylol to them.
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> 93. Through their actions and omissions in advertising, promoting, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians and consumers like Plaintiffs, concerning the character and safety of Trasylol, either compared to the use of alternative drug products in its class or compared to the use of no drug products.
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> 94. Defendants were entitled to provide consumers, like Plaintiffs and their health care providers, with scientific data which indicated an association between the use of Trasylol and the risk of kidney failure, renal injury, other injuries, and death. Defendants were able and entitled to compare Trasylol to alternative drug products in its class or to the use of no drug products, and were able to distribute such data to Plaintiffs and their physicians even if that information was not included in the Package Insert. Defendants were entitled to provided consumers, like Plaintiffs and their health care providers, with bona fide scientific data which indicated that Trasylol was unreasonably dangerous compared to alternative drug products in its class or to the use of no drug products, that there were no patients in whom the benefits of Trasylol outweighed the risks, and could have withdrawn Trasylol from the market at any time.
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> 95. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions further include, but are not

limited to, the following:

(1) Defendants failed to disclose that their pre-clinical and clinical testing and post-marketing surveillance were inadequate to determine the safety and side effects of Trasylol, compared to alternative drug products in its class or compared to the use of no drug products;

(2) Defendants failed to timely disclose, and/or intentionally concealed, data showing that Trasylol use dramatically increased the risk for renal failure and other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(3) Defendants failed to include adequate warnings with Trasylol about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure, other injuries and death, either compared to the use of no drug products;

(4) Defendants concealed and continue to conceal past and present facts - including that, as early as the mid-1990's, Defendants were aware of and concealed their knowledge of an association between the use of Trasylol and dangerous side effects, including renal failure and death - from the consuming public, including Plaintiffs;

(5) Defendants affirmatively represented to physicians and the public that "Trasylol had no adverse effect on renal function" when pre-approval clinical data confirmed the risk of renal impairment and Defendants had never performed any post-approval epidemiological studies to assess the risk of Trasylol on renal function.

96. Defendants' above-described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for Plaintiffs and the public.

97. Defendants knew or should have known that these representations were false and that Plaintiffs and their Physicians would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to

adequately and timely do so even after they were in possession of information concerning those risks. Defendants' representations that Trasylol was safe for its intended use, either compared to the use of alternative drug products in its class or compared to the use of no drug products, were false. Trasylol was, in fact, unreasonably dangerous to the health of Plaintiffs when used during surgery, and there were alternative products in the same class of drub products available that were less expensive, equally or more effective, and posed less risks.

98. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information they provided regarding the safe use of Trasylol and communicating that information to Plaintiffs and their physicians.

99. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiffs and their physicians were not aware of the falsity of the foregoing representations, nor were they aware that material facts concerning Trasylol had been concealed or omitted. In reliance upon Defendants' misrepresentations, Plaintiffs [sic] physicians were induced and did administer Trasylol to Plaintiffs before, during, and/or after surgery.

100. Defendants are obligated to provide consumers like Plaintiffs and their health care providers with scientific information and data regarding the association between exposure to Trasylol and the a [sic] risk of kidney failure, renal injury, other injuries and death and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the Package Insert. Defendants were obligated to provide consumers, like Plaintiffs and their health care providers, with scientific information and data which indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, either compared to the use of alternative drug products in its class or compared to the use of no drug products.

101. If Plaintiffs and their physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk or renal failure, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products, they would not have used Trasylol and would have used on of the alternatives in that class of products.

102. The reliance of Plaintiffs and their physicians upon Defendants' misrepresentations was justified, among other reasons, because said

misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasylol, while Plaintiffs and their physicians were not in a position to know the true facts. Defendants overstated the benefits and safety of Trasylol and concomitantly downplayed the risks in its use, compared to the use of alternative drug products in its class or compared to the use of no drug products, thereby inducing Plaintiffs' physicians to use Trasylol in lieu of other, safer alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew or should have known of, and ratified the acts of Defendants, as alleged herein.

103. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiffs to be administered Trasylol. Plaintiffs and their physicians did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendants when agreeing to utilize Trasylol.

104. As a direct and proximate result of the reliance of Plaintiffs and their physicians on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasylol, Plaintiffs suffered injuries and damages, as set forth in their individuals [sic] Complaints.

Count VI provides:

105. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein;

106. At the time Trasylol was manufactured, distributed, and sold by Defendants to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the drug product, which knowledge was not possessed by Plaintiffs or their physicians, and Defendants thereby held a position of superiority over Plaintiffs;

107. Through their unique knowledge and expertise regarding the defective nature of Trasylol, and through their marketing statements to physicians and patients in advertisements, promotion materials, and other communications, Defendants professed to Plaintiff' physicians that they were in possession of facts demonstrating that Trasylol was safe and effective for its intended use and was not defective;

108. Defendants' representations to Plaintiffs' physicians were made to induce the purchase of Trasylol, and Plaintiffs and their physicians relied upon

those statements when purchasing and administering Trasylol.

109. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

110. Plaintiffs and their physicians reasonably relied on Defendants' representations.

111. As a direct an proximate result of Defendants' constructive fraud, Plaintiffs have suffered injuries and damages, as set forth in their individual complaints.

In their Motions, the Defendants assert that Counts V and VI must be dismissed because they both fail to comply with Federal Rule of Civil Procedure 9(b) which provides, in pertinent part, that a plaintiff "alleging fraud . . . must state with particularity the circumstances constituting fraud." They further assert that Plaintiffs "incorporat[ion] by reference all preceding paragraphs as if fully set forth" within Count V and Count VI cannot satisfy Rule 9's particularity requirement.

In their discussion of Plaintiffs' lack of particularity, Defendants direct me to one of my prior rulings in which I interpreted Rule 9(b) to require Plaintiffs to, at a minimum, set forth: "(1) the exact statements or omissions made, (2) the time and place of each such statement and who made the statement or omission, (3) the substance of the statement and how it misled the plaintiff; and (4) the defendants' gain due to the alleged fraud." (Mot. Dismiss at 2)(citing *Jackson v. BellSouth Telecom., Inc.*, 181 F. Supp. 2d 1345, 1362 (S.D. Fla.) (Middlebrooks, J.). Defendants also present several cases wherein actions were dismissed for plaintiff's failure to aver fraud with sufficient particularity.

According to Defendants, under the appropriate test, Count V is deficient because it

vaguely "alleges that 'Defendants' – without specifying which defendant, when, or to whom the statement was directed – made unspecified 'innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ration of Trasylol . . . [and] concealed material facts from physicians and consumers . . . concerning the character and safety of Trasylol in their "advertising, promoting, and otherwise."

They further assert that Count VI's allegation that "[d]efendants professed to Plaintiffs' physicians that they were in possession of facts demonstrating that Trasylol was safe and effective for its intended use and was not defective, . . . and that Plaintiffs and their physicians relied upon those statements" is similarly insufficient under Rule 9(b) because it does not set forth the content of those alleged statements or when, by whom, to whom, or in what manner they allegedly were made.

Relying on *Wagner v. First Horizon Pharm. Corp*, Defendants lastly argue that the Consolidated Amended Master Complaint is a "shotgun pleading" which "incorporate[s] every antecedent allegation by reference into each subsequent claim for relief, and that it is therefore deficient because if fails to make any "connection between the substantive count and the factual predicates." 464 F.3d 1273, 1279 (11th Cir. 2006). *Wagner* involved a claim for securities fraud, and a Complaint with over 175 factual paragraphs which were in no way meaningfully connected with the substantive counts. I do not believe that the Consolidated Complaint to suffer from the infirmities of the *Wagner* complaint.

There is a difference between shotgun pleadings, where a party throws every fact into every claim and hopes that something sticks, and pleadings which contain "mere surplusage," or factual allegations that are incorporated to a particular count, but don't necessarily add anything

to the claim. "So long as [a complaint] is minimally sufficient to put a defendant on notice of the claims against him[, it] will not fail for mere surplusage. *See Bailey v. Janssen Pharmaceutica, Inc., et al.*, 2008 WL 2898214 (`11th Cir. 2008)(not selected for publication).

Defendants also offer *Ziemba v. Cascade Int'l., Inc.*, 256 F. 3d 1194 (11th Cir. 2001); *Allison v. McGhan Medical Corp.*, 184 F.3d 1300 (11th Cir. 1999); and *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, MDL No. 1718, 2007 WL 2421480 (E.D. Mich., Aug. 24, 2007) in support of the proposition that any fraud claims which fail to satisfy the pleading requirements of Rule 9(b) should be dismissed. This is a generally correct statement of the law, however, it is overly broad. As I stated in *Jackson*, Rule 9 "serves an important purpose in fraud actions by alerting defendants to the 'precise misconduct with which they are charged' and protecting defendants against 'spurious charges of immoral and fraudulent behavior." *Jackson,* 181 F. Supp. 2d at 1361 (quoting *Brooks v. Blue Cross Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1370-71 (11th Cir. 1997)(per curiam) and *Durham v. Business Mgmt. Assocs.*, 847 F.2d 1505, 1511 (11th Cir. 1988). However, "the strict application of [the Rule] must not be allowed to vitiate the overall concept of notice pleading." *Id.*

"[F]ocusing exclusively on [the particularity] language [of Rule 9] is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated" by the Federal Rules of Civil Procedure. Defendants reliance on the above cases is misplaced. The Parties have presented no, and the Court is unaware of any, case in which a strict application of Rule 9(b) has been applied in an MDL product liability claim such as this one. Each of the cases presented is either distinguishable, or non-controlling and non-persuasive under the facts presented and pled herein. In fact, I find that the cited cases present support for permitting the

Plaintiffs' claim for fraud to at least partially withstand Defendants' Motions to Dismiss.

For example, *Ziemba* is inapplicable here because it dealt with claims for securities fraud wherein a Company's shareholders brought against the Company's lawyers and accountants under Section 10(b) and Rule 10b-5 of the Securities Exchange Act, 15 U.S.C. §78j *et seq.* The case required analysis of Section 10(b) and Rule 10b-5's requirements for establishing fraud, which are even more stringent than those required under Rule 9 alone.

The district court in the matter dismissed the shareholder's claims predominantly because the plaintiffs had failed to establish required elements under the Securities Laws, however, the Court did discuss the interplay between the Securities Claims and Rule 9(b), and held that but those claims which generally averred that defendants' improper accounting practices, and reckless legal advice had led to the plaintiffs' damages, without more, were insufficient to state a claim for securities fraud against defendants acting in a merely advisory capacity under Section 10(b).

In re Sahlen & Associates, was another securities-based action wherein the district judge held that some of the plaintiffs had not averred specific financial documents upon which they relied., but also discussed that:

> while mere conclusory allegations of fraud will not satisfy Rule 9(b), allegations which provide a reasonable delineation of the underlying acts and transactions allegedly constituting the fraud are sufficient . . . *[t]he degree of specificity required by Rule 9(b) may vary according to the background of the parties and the information available to them at the time of pleading. In [some] cases . . . courts have determined that strict application of Rule 9(b) could result in substantial unfairness to private litigants who could not possibly have detailed knowledge of all the circumstances surrounding the alleged fraud.*

Sahlen, 773 F. Supp. at 352 (internal citations omitted)(emphasis added).

The *Sahlen* Court also discussed the difficulty presented by cases against large corporations where, because the defendants are largely in control of all of the information necessary to establish wrongful conduct, it is virtually impossible for plaintiffs to know exactly who said what or omitted to say what, or who, amongst several potential responsible parties is the one "at fault." The Court held that in corporate fraud cases involving group-published information, a plaintiff need only plead the alleged misrepresentations with particularity and, where possible, each individual defendant's role in the misrepresentations.

The Eleventh Circuit has stated that a fraud claim should include: (1) the precise statements which were made in what documents, or what oral representations or omissions were made; (2) the time and place of each such statement and the person responsible for making, or not making, the statement; (3) the content of each statement and the manner in which it misled the plaintiff; and (4) what the defendants obtained as a consequence of the fraud. *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1371 (11th cir. 1997).

In *Jackson,* the defendants argued, as do the Defendants herein, that the Plaintiffs' allegations of fraud did not meet the *Brooks* standard because they did not, within their claim for fraud, specify with sufficient particularity the facts underlying their claim. I looked at the *Jackson* Plaintiffs' claim and noted that it alleged that within the factual section of the Complaint, the plaintiffs had stated specific facts which could be "culled from the [Complaint]" thereby allowing for a finding that the plaintiffs had "met their pleading burden as clarified" in *Brooks.* I find a similar situation to exist here, and that the facts supporting the Claims for fraud are readily culled from the Complaint.

The reality of this case is thus. There are well in excess of four hundred separate cases

that have either been filed in, or transferred into, this district. Many of those cases are filed on behalf of more than one individual. Each and every one of the complaints assert that the Defendants: (1) had evidence establishing that from as far back as 1993that there was a problem with Trasylol, (2) knew that the drug presented risks of substantial and serious harm, and (3) failed to bring that information to the attention of the FDA, providers or plaintiffs. The Complaints further allege times when the Defendants knew or should have known about the potential medical risks presented by Trasylol, and that he Defendants failed to bring that information to the FDA's attention at any time during the relevant time frame, and specifically at an advisory meeting held with the FDA. Further, the Complaints go into detail about the dates of certain investigations, publications and/or inquiries wherein the Defendants had control over the transmission of crucial information to Plaintiffs or their healthcare providers. What information the corporate defendants did or did not have relating to clinical studies and/or safety is largely, if not totally, within the possession and/or control of the Defendants. In response to questioning at oral argument, the Defendants admitted that their packaging and marketing materials were subject to an internal approval process and that they are keenly aware of the information contained within these materials.

The four hundred plus cases in this MDL consist of cases from various states throughout the Country, each containing claims under the common and/or statutory law of their home states. These cases were transferred to this Court for consolidated discovery proceedings in order to assure an efficient, just and consistent resolution to the issues presented herein. If I dismiss the claims presented in Count V and Count VI for failure to plead with specificity at this juncture, I believe that I will be ill-serving these goals.

As I stated previously, for the most part, 'the information missing from the plaintiffs' complaint[s] in this case . . . is outweighed by the sufficiency of the description of the claim[s] against the defendants." *In re Welding Fume Products Liability Litigation*, Case No. 03-17000 (MDL 1535 N.D. Ohio) . The Court cannot envision the task of adequately pleading the consolidated master complaint in a manner which would satisfy Defendants, without completely removing the compromise and attempt at efficiency the Parties and I had in mind in allowing the filing of the Consolidated Master Complaint. At this stage of the litigation I prefer to assess the sufficiency of plaintiffs' claims with substantial leniency, especially when the information that may or may not support Plaintiffs' claims is largely within the control of the Defendants. This is not the type of "fishing expedition" that Rule 9 seeks to prevent. I find the interests of justice best served in allowing the claims in Count V and Count VI to go forward in part,[1] and to be more appropriately addressed at the summary judgment stage in the near future.

However, leniency must not overreach so as to effect a negation of the policy behind Rule 9. I recognize that the Plaintiffs' claims of fraud, if allowed to proceed exactly as stated, are somewhat overly broad. Specifically, I find that Plaintiffs have minimally stated enough to allow discovery into what information Defendants possessed regarding clinical studies and the safety of Trasylol from 1993 forward as compared to information set forth in their packaging inserts or marketing materials. However, a broad claim that a Plaintiff or a Plaintiffs' physician's relied on fraudulent or misleading statements made directly to them, absent some recitation of what oral or written statement a particular drug representative made to a specific physician at what

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[1] While include both Counts V and VI as going forward despite a Rule 9(b) challenge, Count VI is due to be dismissed for other reasons as discussed *infra.*

particular point in time, is an insufficient basis for allowing Plaintiffs to proceed with a claim for fraud premised on any such alleged statements.[2]

Unlike clinical drug studies and corporate marketing strategies, the information relating to this type of alleged misrepresentation, if any, lies largely in the possession of Plaintiffs' physicians, and so, any allegation of fraud based on such statements must be pled with particularity in the individual Plaintiff's complaint, and be subject to discovery during the case-specific discovery stage if, and only if, properly alleged.

Before I discuss Defendants specific assertion that Count VI of the Master Complaint must be dismissed due to Plaintiffs' failure to adequately allege a fiduciary duty between they and the Defendants, I turn to the Motions to Dismiss Count IV's claims for fraud in the Individual Complaints.

The Motions to Dismiss Count IV of the Individual Complaints

Each of the individual case-related Motions to Dismiss are identical and seek dismissal of Count IV of the Complaints in 08-80880, 08-80881, and 08-80835.[3] Count IV of the individual complaints are indistinguishable from Count V in the Master Complaint.

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[2] At oral argument, the Parties agreed that to the best of their knowledge, any false or misleading written or oral statements made were made to Plaintiffs' physicians, and not directly to patients.

[3] I note that the Master Docket reflects the filing of only three specific Motions to Dismiss directed at cases 08-80880; 08-80881; and 08-80835. However, the Master Docket also reflects the filing of a response in opposition to Defendants' Motion to Dismiss Count V and VI of Plaintiffs' Master Complaint and Related Short Form Complaints filed on behalf of the Plaintiffs in Cases No.08-80640;08-80834; 08-08639; 08-80642; 08-80710; 08-80868; and 08-80760. The Docket does not reflect any Motions to Dismiss directed at these specific cases.

Count IV in 08-80880; 08-80881; 08-80835 allege:[4]

74. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

75. Defendants are liable to Plaintiff under the CPLA, Conn. Gen. Stat §52-272m *et seq.* for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ration of Trasylol, either compared to the use of alternative drug products in its class or compared to the use of no drug products, to Plaintiff's Decedent and to the health care providers that prescribed, recommended, ordered, and administered Trasylol to her [sic].

76. Through their actions and omissions in advertising, promoting, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians and consumers like Plaintiff's Decedent, concerning the character and safety of Trasylol, either compared to the use of alternative drug products in its class or compared to the use of no drug products.

77. Defendants were entitled to provide consumers, like Plaintiff's Decedent and his health care providers, with scientific data which indicated an association between the use of Trasylol and the risk of kidney failure, renal injury, other injuries, and death. Defendants were able and entitled to compare Trasylol to alternative drug products in its class or to the use of no drug products, and were able to distribute such data to Plaintiff's Decedent and his physicians even if that information was not included in the Package Insert. Defendants were entitled to provided consumers, like Plaintiff's Decedent and his health care providers, with bona fide scientific data which indicated that Trasylol was unreasonably dangerous compared to alternative drug products in its class or to the use of no drug products, that there were no patients in whom the benefits of Trasylol outweighed the risks, and could have withdrawn Trasylol from the market at any time.

78. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint.

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[4] There are minor differences in Count IV of the three Complaints. For example, the Plaintiffs in 08-80880 and 08-80835 are pursuing claims for the injuries and deaths of their spouses, while the Plaintiff in 08-80881 is seeking damages for his own personal injuries. There are also some minor differences in numbering. These disparities are of no consequence for the purposes the Motions to Dismiss.

Those misrepresentations and omissions further include, but are not limited to, the following:

(1) Defendants failed to disclose that their pre-clinical and clinical testing and post-marketing surveillance were inadequate to determine the safety and side effects of Trasylol, compared to alternative drug products in its class or compared to the use of no drug products;

(2) Defendants failed to timely disclose, and/or intentionally concealed, data showing that Trasylol use dramatically increased the risk for renal failure and other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(3) Defendants failed to include adequate warnings with Trasylol about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure, other injuries and death, either compared to the use of no drug products;

(4) Defendants concealed and continue to conceal past and present facts - including that, as early as the mid-1990's, Defendants were aware of and concealed their knowledge of an association between the use of Trasylol and dangerous side effects, including renal failure and death - from the consuming public, including Plaintiffs Decedent [sic];

79. Defendants' above-described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for Plaintiff's Decedent and the public.

80. Defendants knew or should have known that these representations were false and that Plaintiff's Decedent and his Physicians would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after they were in possession of information concerning those risks. Defendants' representations that Trasylol was safe for its intended use, either compared to the use of alternative drug products in its class or compared to the use of no drug products, were false. Trasylol was, in fact, unreasonably dangerous to the health of Plaintiff's Decedent when used during surgery, and there were

alternative products in the same class of drub products available that were less expensive, equally or more effective, and posed less risks.

81. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information they provided regarding the safe use of Trasylol and communicating that information to Plaintiff's Decedent and his physicians.

82. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiff's Decedent and his physicians were not aware of the falsity of the foregoing representations, nor were they aware that material facts concerning Trasylol had been concealed or omitted. In reliance upon Defendants' misrepresentations, Plaintiff's Decedent physicians were induced and did administer Trasylol to Plaintiff's Decedent before, during, and/or after surgery.

83. Defendants are entitled to provide consumers like Plaintiff's Decedent, and his health care providers with scientific information and data regarding the association between exposure to Trasylol and the a [sic] risk of kidney failure, renal injury, other injuries and death and could have distributed that information to Plaintiff's Decedent and his physicians even if that information was not included in the Package Insert. Defendants were entitled to provide consumers, like Plaintiff's Decedent, and his health care providers, with scientific information and data which indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, either compared to the use of alternative drug products in its class or compared to the use of no drug products.

84. If Plaintiff's Decedent and his physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk or renal failure, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products, they would not have used Trasylol and would have used on of the alternatives in that class of products.

85. The reliance of Plaintiff's Decedent and his physicians upon Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasylol, while Plaintiff's Decedent and his physicians were not in a position to know the true facts. Defendants overstated the benefits and safety of Trasylol and concomitantly downplayed the risks in its use, compared to the use of

alternative drug products in its class or compared to the use of no drug products, thereby inducing Plaintiff's Decedent' physicians to use Trasylol in lieu of other, safer alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew or should have known of, and ratified the acts of Defendants, as alleged herein.

86. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiff's Decedent to be administered Trasylol. Plaintiff's Decedent and his physicians did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendants when agreeing to utilize Trasylol.

87. As a direct and proximate result of the reliance of Plaintiff's Decedent and his physicians on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasylol, Plaintiff's Decedent suffered injuries and death.

It is apparent that Count IV in these individual Complaints is indistinguishable from Count V of the Consolidated Master Complaint. The factual allegations in the individual Complaints are similarly indistinguishable from those set forth in the Consolidated Master Complaint. For the reasons set forth above, I find that these claims are minimally sufficiently alleged, and are more appropriately addressed at the summary judgment stage for the most part. However, as I previously stated, to the extent that any plaintiff asserts reliance by their physician on a fraudulent statement made directly to them or their physician by a drug salesman or other person as a basis of their individual fraud claim, then such plaintiff must amend his or her individual complaint to set forth the basis of that fraud with the particularity required by Rule 9.

The Motion to Dismiss Count VI of the Consolidated Master Complaint

Defendants assert that Count VI should be dismissed because it does not adequately allege the required element of a "confidential" or otherwise "special" relationship between the

Defendants and the Plaintiffs. Such relationship may be premised on "a statute, a contract, or a trust," but, according to Defendants, at a minimum must reflect an express or implied arrangement in which one party has undertaken to act on the other's behalf and for his or her benefit. C.J.S. *Fraud* § 5 (2008); *Larson v. Correct Craft, Inc.*, 537 F. Supp. 2d 1264, 1270 (M.D. Fla. 2008).

Plaintiffs concede that they must plead a special relationship to withstand the Defendants' Motion to Dismiss. However, they, the Plaintiffs, assert that their burden is satisfied if they are able to set forth a plausible entitlement to relief for constructive fraud. They assert that the following facts establish a plausible entitlement to relief by establishing that Bayer's unique position of authority and strength as the manufacturer of a drug places it in a special relationship with the Plaintiffs:

* From 1994 to 2007, Bayer sold Trasylol in the United States. Mast. Comp. At ¶ 14.

* Plaintiffs bring these civil actions for equitable relief, monetary restitution and/or compensatory and punitive damages for injuries and/or wrongful deaths suffered as a direct result of their exposure to Trasylol during major surgery. *Id.* at ¶ 3.

* At the time Trasylol was manufactured, distributed, and sold by Defendants to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the drug product, which knowledge was not possessed by Plaintiffs or their physicians, and Defendants thereby held a position of superiority over Plaintiffs. *Id.* at ¶ 106.

* Through their unique knowledge and expertise regarding the defective nature of Trasylol, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiffs' physicians that they were in possession of facts demonstrating that Trasylol was safe and effective for its intended use and was not defective. *Id.* at ¶ 107

* Defendants' representations to Plaintiffs physicians were made to induce the purchase of Trasylol, and Plaintiffs and their physicians relied upon those statements when purchasing and administering Trasylol. *Id.* at ¶ 108

* Defendants' representations that Trasylol was safe for its intended use, either compared to the use of alternative drug products in its class or compared to the use of no drug products, were false. *Id.* at ¶ 97

"Constructive fraud is . . . a term applied to a great variety of transactions which equity regards as wrongful. *American Fidelity & Cas. Co. v. Greyhound Corp.*, 258 f.2d 709 (5th Cir. 1958)(citing *Douglas v. Ogle*, 80 Fla. 42, 85 (Fla. 1920)). Constructive fraud arises when a confidential or fiduciary relationship has been used to take advantage of the party seeking affirmative relief. *Shuler v. State*, 502 So. 2d 46 (Fla. 2nd DCA 1987). The mere fact that one party places trust or confidence in another does not create the type of confidential or special relationship envisioned by traditional interpretations of fiduciary responsibility. *See Optimum Technologies, Inc. v. Henkel Consumer Adhesives, Inc.*, 496 F.3d 1231, 1249 (11th Cir. 2007).

"A confidential relationship must be shown by proof and that burden of proof rests on the party claiming such a relationship exists." *Wilchombe v. TeeVee Toons, Inc.*, __ F.3d.__ (11th Cir. 2009), 2009 WL 129714. The Plaintiffs have presented no, and the Court is unaware of any, case establishing that a simply producing drugs which will inevitably be ingested by an end-consumer patient, absent anything further, creates a fiduciary relationship and duty between a manufacturer and a patient. I "can draw no inferences consistent with the facts stated in the amended complaint to support the existence of a fiduciary duty, which is a material element of any claim for constructive fraud." *Id.* Absent analogous authority, I decline to create a duty where previously none has existed. Accordingly, Count VI is due to be dismissed.

For the above-stated reasons, it is hereby

ORDERED and ADJUDGED that the Defendants' Motion to Dismiss Count V and Count VI of the Consolidated Amended Complaint (DE 221) be, and is hereby, GRANTED in PART and DENIED in PART in accordance with the above. Count V remains pending as it relates to Bayer's knowledge of evidence establishing the risk of renal and other personal injury damage by Trasylol which was not consistent with the information set forth in its contemporaneous marketing materials. To the extent that Count V specifically relies on any statement other than packaging or marketing materials that was made by Defendants marketing representatives to an individual plaintiff or treating physician, then such statements must be set forth with the particularity required by Rule 9. Count VI is DISMISSED. It is further

ORDERED and ADJUDGED that the Defendants' Motions to Dismiss directed at Count IV of the specified individual Complaints (DE 226; 227 & 234 of the Master Docket) be, and is hereby, GRANTED in PART and DENIED in PART in accordance with the above. Count IV remains pending as it relates to Bayer's knowledge of evidence establishing the risk of renal and other personal injury damage by Trasylol which was not consistent with the information set forth in its contemporaneous marketing materials. To the extent that Count IV specifically relies on any statement other than packaging or marketing materials that was made by Defendants marketing representatives to an individual plaintiff or treating physician, then such allegations must be stated with the particularity required by Rule 9.

Plaintiffs shall have thirty (30) days from the date of this Order within which to amend Count V of the Master Complaint or Count IV of the individual Complaints to set forth any claim for fraud premised on any oral or written statement, other than packaging or marketing materials,

made to a Plaintiff or Plaintiff physician with the specificity required of Rule 9.[5]

DONE and ORDERED in Chambers, at West Palm Beach, Florida this 4th day of March, 2009.

DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT JUDGE

[5] In the event that an individual Plaintiff becomes aware of a basis for setting forth a specific fraud claim as contemplated herein after this thirty (30) day period, that Plaintiff may file a Motion for Leave to Amend. However, Plaintiff, in any such Motion, must set forth good cause as to why such information was not reasonably available to Plaintiff previously.