UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

OCTAVIA L. MOORE, individually, and as next friend and guardian for and on behalf of GEORGE L. FRAZIER, JR., et al.,	:	
Plaintiffs,	:	CIVIL ACTION NO.
v.	:	1:11-CV-03037-MHS
MYLAN INC. f/k/a MYLAN LABORATORIES INC., et al.,	:	
Defendants.	:	

ORDER

Presently before the Court are defendants' motions to dismiss. The Court's rulings and conclusions are set forth below.

Background

This is a personal injury and products liability suit brought against the drug manufacturers of the prescription medication phenytoin, sold under the brand name Dilantin. According to the complaint, decedent George L. Frazier was prescribed and ingested phenytoin products, and as a result, he suffered severe and adverse complications, eventually resulting in his death.

The plaintiffs in this case are as follows: (1) Octavia L. Moore, individually and as the next friend and guardian of decedent's son, George L. Frazier, Jr.; (2) Jonathan A. Frazier, the decedent's son;[1] (3) Johnnie May Frazier, the decedent's widow; (4) Tanya Cephus, the decedent's sister; and (5) the estate of the decedent.

The defendants in this case are the makers and sellers of phenytoin and Dilantin. Defendants Mylan, Inc. f/k/a Mylan Laboratories, Inc.; Mylan Bertek Pharmaceuticals, Inc.; and Mylan Pharmaceuticals, Inc. (collectively "Mylan") were engaged in the business of manufacturing, packaging, marketing, distributing, promoting, and selling extended phenytoin sodium capsules. Defendants Pharmacia Corporation, Pfizer, Inc.; Parke-Davis; and Warmer-Lambert Company LLC (collectively "Pfizer") were engaged in the business of the testing, manufacturing, packaging, marketing, labeling, adverse drug event reporting or non-reporting, distributing, promoting, and/or selling Dilantin.

[1] Octavia Moore is the biological mother of decedent's sons, Jonathan A. Frazier and George L. Frazier, Jr.

On January 20, 2011, plaintiffs filed a complaint against the Mylan defendants in the State Court of Fulton County. Plaintiffs voluntarily dismissed the complaint without prejudice on February 10, 2011. On August 9, 2011, plaintiffs filed another complaint, this time naming both Mylan and Pfizer as defendants, in the State Court of Fulton County. Defendants removed the case to this Court on September 12, 2011, based on federal diversity jurisdiction.

According to the complaint, phenytoin is a generic for the drug Dilantin, and the generic phenytoin was approved as a bioequivalent by the FDA in December 1998.[2] Plaintiffs allege that the decedent was prescribed and ingested phenytoin products. Decedent allegedly used phenytoin, a seizure medication,[3] and suffered an adverse reaction constituting one or more of the following, sometimes overlapping, severe skin conditions:

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[2] The Court will use phenytoin throughout the complaint to refer to both the generic and brand name versions of phenytoin. The Court will differentiate between the brand name Dilantin and the generic version of phenytoin where necessary.

[3] Phenytoin is an anticonvulsant or antiepileptic drug used to prevent and control seizures. "Drugs & Medications - Dilantin Oral," Web MD, available at http://www.webmd.com/drugs/mono-57-PHENYTOIN+EXTENDED+CAPSULES+-+ORAL.aspx?drugid=4157&drugname=Dilantin+Oral.

erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Toxic Epidermal Necrolysis ("TEN") and Stevens-Johnson Syndrome ("SJS").

According to the complaint, decedent was admitted to the University Health Center on December 30, 2008, in Augusta, Georgia. His hospital course was complicated by "diffuse rash thought to be secondary to Dilantin, and progressive renal insufficiency." Compl. at ¶ 18. On January 23, 2009, Mr. Frazier died at the University Health Center at the age of 51, allegedly as a result of TEN and other health issues, many of which are associated with complications of TEN. Plaintiffs allege that at all times Mylan and Pfizer were engaged in the business of the testing, manufacturing, packaging, marketing, labeling, adverse drug event reporting or non-reporting, distributing, promoting and/or selling phenytoin. Plaintiffs contend that the decedent's conditions and the resulting injuries were caused by the decedent's ingestion of defendants' phenytoin products.

Plaintiffs bring the following claims in their complaint: Count One, Strict Product Liability - Failure to Warn, against Pfizer; Count Two, Strict Product Liability - Defective Design or Manufacture, against all defendants; Count Three, Fraud, against Pfizer; Count Four, Negligence, against Pfizer; Count Five, Gross Negligence; Count Six, Joint and Several Liability; Count Nine, Pre-Death Injury and Pain and Suffering;[4] Count Ten, Wrongful Death; and Count Eleven, Punitive Damages.

Pending before the Court are both Mylan's and Pfizer's motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

Discussion

A. Legal Standard

When reviewing a claim pursuant to a Rule 12(b)(6) motion, the Court accepts the allegations in the claim as true and construes them in the light most favorable to the party asserting the claim. See Jackson v. BellSouth Telecomms., 372 F.3d 1250, 1262 (11th Cir. 2004). "While a complaint

[4] Plaintiffs' complaint skips from Count Six to Count Nine, but there are no Counts Seven or Eight in the complaint. See Compl. at 25.

attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal quotations and citations omitted). Instead, the complaint must set forth factual allegations "plausibly suggesting (not merely consistent with)" a violation of the law. Id. at 557.

Accordingly, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Twombly, 550 U.S. at 570). The Iqbal Court explained as follows:

> A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. 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.

129 S. Ct. at 1949 (internal quotes and citations omitted).

"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." Id. at 1950 (citation omitted). "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.'" Id. (quoting Fed. R. Civ. P. 8(a)(2)).

B. Standing

Pfizer argues that all of the named plaintiffs do not have standing to bring this suit. Instead, Pfizer contends that only Johnnie May Frazier, decedent's surviving spouse, has standing to bring this suit individually and on behalf of the decedent's estate. In response, plaintiffs agree that Tanya Cephus, the decedent's sister, does not have standing. However, plaintiffs contend that all of the other named plaintiffs do have standing.

The Court agrees with Pfizer that only Johnnie May Frazier, as the surviving spouse of George L. Frazier, has standing to pursue the claims in this case individually and on behalf of the estate. Section 51-4-2(a) of the

Georgia Code provides that the surviving spouse may recover in a wrongful death action for the full value of the decedent. The statute provides further that if there is no surviving spouse, a child or children, may pursue the wrongful death action. O.C.G.A. § 51-4-2(a). Thus, here, the surviving spouse, Johnnie May Frazier, may rightfully pursue this action individually and on behalf of the decedent. See id.; see also Emory University v. Dorsey, 207 Ga. App. 808, 809 (1993) (a surviving spouse who brings an action for wrongful death acts both as an individual and as a representative of any children of the deceased and the cause of action vests in the surviving spouse, not the children of the deceased). It is where the children are left without an adequate remedy at law, such as the surviving spouse abandoning the decedent's children and not pursuing the wrongful death action, that the decedent's children might pursue the action. See O.C.G.A. § 51-4-2(a); see also Emory University, 207 Ga. App. at 809. Thus, because decedent's surviving spouse, Johnnie May Frazier, is pursuing this action, the decedent's children, George L. Frazier, Jr. and Jonathan A. Frazier, have no standing to do so. Moreover, Octavia L. Moore, either individually or as the guardian for George L. Frazier, Jr., has no standing. See Rommelman v. Hoyt, 295 Ga. App. 19, 21 (2008) (finding that neither the decedent's first spouse and

biological mother of decedent's children, nor the decedent's children, were authorized to pursue an action for wrongful death, as that right belonged to the surviving spouse). As previously stated, the parties agree that the decedent's sister, Tanya Cephus, also has no standing.

Accordingly, the only proper plaintiff in this action is Johnnie May Frazier, as the surviving spouse of the decedent. She may pursue this action individually and on behalf of the estate of George L. Frazier.[5]

C. Count One - Strict Product Liability - Failure to Warn, against Pfizer

In Count One, Strict Product Liability - Failure to Warn, against Pfizer, plaintiff alleges that defendants knew of the defective nature of the phenytoin products and had a duty to warn the public, including the decedent and his prescribing physicians, of the health risks associated with using defendants' phenytoin products. Instead, plaintiff contends that defendants failed to

[5] Accordingly, the Court will refer to only one (1) plaintiff in the remainder of this order.

warn the public, the decedent, or his prescribing physicians of the dangerous propensities of defendants' phenytoin products.

Pfizer argues, and plaintiff agrees, that Pfizer's duty to warn of the potential side effects of phenytoin is limited to physicians under the learned intermediary doctrine. Pursuant to this doctrine, the manufacturer of a prescription drug is not normally required to directly warn the patient of dangers in its use. Presto v. Sandoz Pharms. Corp., 226 Ga. App. 547, 548 (1997). Instead, in the case of prescription drugs, a warning to the prescribing physician as to the possible danger in the drug's use is sufficient. Id. To the extent the plaintiff attempts to allege claims for a failure to warn the decedent or the public at large, those claims are barred. Accordingly, the Court dismisses plaintiff's claim for strict liability for failure to warn against Pfizer except as to the failure to warn the decedent's prescribing physician. The Court will grant plaintiff's request for leave to amend her complaint to allege her strict liability failure to warn claim against Mr. Frazier's prescribing physician and to remove any allegation that Pfizer had a duty to warn Mr. Frazier or the general public.

D. Count Two - Strict Product Liability - Defective in Design or Manufacture, against all defendants

1. Insufficiently Pled Claim

In Count Two, Strict Product Liability - Defective Design or Manufacture, against all defendants, plaintiff alleges that the phenytoin products were defective in design or formulation and that the foreseeable risks exceeded the benefits associated with the products' design or formulation. Plaintiff maintains that the defendants knew of the defective nature of defendants' phenytoin products but continued to design, manufacture, market, and sell them so as to maximize sales and profits. Plaintiff contends that there were safer and alternative methods and designs for the phenytoin products.

Pfizer and Mylan argue that plaintiff has failed to sufficiently plead her design or manufacturing defect claim, as she has not alleged any specific facts supporting the elements of a design or manufacturing defect claim, has not identified a specific design or manufacturing defect, and has not pled

sufficient facts to show that the product the decedent consumed had a defect which proximately caused his injuries.[6]

In response to both Pfizer and Mylan, plaintiff requests leave to amend her complaint to allege facts sufficient to state a claim for defective design or manufacture. Plaintiff states that if she is allowed to amend her complaint, she will allege that there are feasible alternative designs to phenytoin which are safer, and she will cite the specific designs available in an amended complaint.

Pursuant to O.C.G.A. § 51-1-11(b), "strict liability is imposed for injuries suffered because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended and its condition when sold is the proximate cause of the injury sustained. Thus the injury must be the proximate result of a defect in the product which existed at the time sold." Hall v. Scott United States, 198 Ga. App. 197, 200 (1990) (quotation omitted). Moreover, the plaintiff needs to establish that the

[6] Pfizer filed a motion to join in Mylan's arguments for dismissal with respect to plaintiff's failure to properly plead the design and manufacturing defect claim. The Court grants Pfizer's motion for joinder [#13].

product that allegedly caused the injury was in fact manufactured or supplied by the defendant. Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351, 1355 (N.D. Ga. 2008) (quoting Hoffman v. AC&S, Inc., 248 Ga. App. 608, 610-11 (2001)).

Plaintiff's allegations in her complaint fail to state a claim for strict liability under Georgia law and meet the pleading standard required by Twombly, 550 U.S. at 570, and Iqbal, 129 S. Ct. at 1949-50. First, plaintiff has not alleged any specific design or manufacturing defect in either Pfizer's or Mylan's products. See Compl. ¶ 46 (phenytoin products were defective in design or formulation in that when they left the hands of the manufacturers and/or sellers and were unreasonably dangerous, the foreseeable risks exceeded the benefits associated with their design or formulation).

Second, because the complaint is silent as to a design or manufacturing defect, the Court cannot draw the reasonable inference that a design or manufacturing defect caused the decedent's injuries. See Hall, 198 Ga. App. at 200 (requiring a causal link between the defect in the product at the time sold and the injuries sustained). Plaintiff has not provided a specific list of

injuries suffered by the decedent as a result of a specific design or manufacturing defect by Pfizer or Mylan in the phenytoin product.

Third, setting aside the lack of specific factual information regarding a design or manufacturing defect, plaintiff has not even alleged that a phenytoin product designed or manufactured by Pfizer or Mylan proximately caused plaintiff's injuries. It is unclear from plaintiff's complaint whether Pfizer or Mylan manufactured, distributed, supplied, or sold the product that the decedent ingested and whether this product proximately caused his injuries and eventual death. Plaintiff has not provided any facts about who plaintiff's physicians may have been, when these physicians may have prescribed plaintiff medication, that plaintiff's physicians prescribed one of defendants' medications, and when plaintiff ingested this product.[7] See Compl. ¶ 15. (stating only that "Mr. Frazier, upon information and belief, was prescribed and ingested Defendants' Phenytoin products in the State of Georgia."). Without such information, plaintiff has failed to plead a causal link between a specific Pfizer or Mylan phenytoin product, containing a

[7] In response to Mylan's motion to dismiss, plaintiff has alleged that Mr. Frazier took 100-mg phenytoin. This is not enough factual information to save plaintiff's design or manufacturing defect claims.

design or manufacturing defect, and the decedent's injuries. See Swicegood, 543 F. Supp. 2d at 1355. Thus, plaintiff's vague allegations do not allow the Court to draw the reasonable inference that Mylan or Pfizer is liable for the injuries sustained by the decedent based on a design or manufacturing defect. See Iqbal, 129 S. Ct. at 1949; see also Henderson v. Sun Pharmaceuticals Industries, Ltd., No. 4:11-CV-00060-HLM, 2011 U.S. Dist. LEXIS 104989, at *15-16 (N.D. Ga. June 9, 2011).[8]

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[8] Henderson was a products liability case arising out of the plaintiff's personal injuries allegedly resulting from his use of phenytoin and fosphenytoin. 2011 U.S. Dist. LEXIS 104989, at *6-7. The plaintiff sued several pharmaceutical companies, including Mylan. Id. at *5. One of the plaintiff's attorneys in Henderson is also an attorney for plaintiff in this case. In the complaint, the plaintiff in Henderson alleged claims for, inter alia, strict product liability - failure to warn; strict product liability - defective in design or manufacture; fraud; negligence and gross negligence; joint and several liability; and punitive damages. 2011 U.S. Dist. LEXIS 104989, at *9-10. These claims are almost identical to the claims plaintiff alleges in her complaint in this case. Judge Murphy denied the defendant's motion to dismiss the plaintiff's failure to warn and joint and several liability claims. Id. at *13, 25. Judge Murphy granted the defendant's motion to dismiss the plaintiff's strict liability defective design and manufacture, negligence, gross negligence, and punitive damages claims for failing to plead sufficiently under Iqbal and granted the defendant's motion to dismiss the plaintiff's fraud claim for failing to state a claim with particularity. Id. at *16-19; 23-26. Judge Murphy dismissed these claims without prejudice and granted the plaintiff's request to amend his complaint. Id. at *26-27. Judge Murphy eventually dismissed plaintiff's amended complaint finding that it failed to state a claim against any defendant and terminated the case. Henderson v. Sun Pharms. Indus., 2011 U.S. Dist. LEXIS 104999 (N.D. Ga. Aug. 22, 2011). The Court finds Judge Murphy's Orders in Henderson to be persuasive precedent, especially considering that the complaints in both cases are practically identical.

2. Plaintiff's Claim that Mylan's Phenytoin Product Was Defective by and through its Inadequate Labeling/Warnings Is Preempted

Plaintiff has alleged that the phenytoin was defective by and through its inadequate labeling. Mylan argues that this is merely a failure to warn claim and that such a claim is preempted, as stated in Pliva, Inc. v. Mensing, 131 S. Ct. 2567, 2573 (2011). For the reasons set forth below, this Court agrees, and finds that any failure to warn claim against Mylan, cloaked in a design defect claim or otherwise, is preempted based on the U.S. Supreme Court's ruling in Mensing.

In Mensing, the plaintiffs sued the generic drug manufacturers that produced metoclopramide pursuant to state law for failing to provide adequate warning labels. 131 S. Ct. at 2573. The drug manufacturers urged that federal law preempted the state tort claims because federal statutes and the Food and Drug Administration ("FDA") regulations required them to use the same safety and efficacy labeling as their brand-name counterparts, and therefore, it was impossible for the drug manufacturers to comply with federal law and any state law or tort duty that required them to use a different label. Id. The U.S. Supreme Court held that the plaintiffs' state law

claims for failing to produce adequate warning labels were preempted by federal law. Id. at 2581.

In reaching this conclusion, the Court explained that generic drugs can gain FDA approval by showing that the generic is an equivalent to a reference listed drug that has already been approved by the FDA. Id. at 2574. The Court explained that the generic drug application must show that the proposed labeling is the same as the labeling approved for the brand name drug, i.e., that the label for the generic drug matches the label for the brand name drug. Id. at 2574. The parties disputed how and to what extent generic manufacturers could change the labels for generic drugs after these drugs received initial FDA approval. Id.

Relevant to plaintiff's arguments here, the Mensing plaintiffs argued that the generic drug manufacturers could use the FDA's "changes-being-effected" ("CBE") process to change the labels of their generic drugs. 131 S. Ct. at 2575. Under the CBE process, drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label, and instead they may simultaneously file a supplemental application with the

FDA. Id. The Court deferred to the FDA's interpretations of its CBE and generic labeling regulations to find that generic drug manufactures could not have used the CBE process, and instead, that generic drug manufacturers could only change the labels of generic drugs in order to match an updated brand name label or to follow the FDA's instructions. Id. at 2575. Thus, the CBE process was not open to the generic drug manufacturers for the sort of changes required by state law. Id. at 2575-76. Because state law imposed a duty upon the generic manufacturers to take a certain action, and federal law barred them from taking this action, the plaintiffs' claims were preempted. Id. at 2581.

Here, relying on Mensing, Mylan argues that any failure to warn claim, based on a design defect or otherwise, is preempted. Plaintiff argues in response that her claim of a defect based on an inadequate label or warning is not preempted because Mylan is not the type of generic drug manufacturer contemplated in Mensing. Instead, plaintiff asserts that Mylan is a manufacturer of a reference listed drug ("RLD"), and therefore, Mylan could have used the CBE process to change the label of phenytoin to conform to state law.

In order to understand plaintiff's argument, the following background information is necessary. The FDA approved Mylan's abbreviated new drug application ("ANDA") to market 100-mg generic phenytoin, which is the bioequivalent to the brand name drug, Dilantin Kapsules 100-mg extended phenytoin sodium capsules. Thus, the brand name drug upon which Mylan's generic 100-mg phenytoin was based was Dilantin. Plaintiff alleges in her response brief that Mr. Frazier ingested Mylan's 100-mg phenytoin.

Mylan then sought FDA approval to market 200-mg and 300-mg phenytoin, which were higher strengths of phenytoin than 100-mg. In Mylan's ANDA petition for 200-mg and 300-mg phenytoin, Mylan stated that both 200-mg and 300-mg phenytoin were based on the drug Dilantin. Mylan also stated that the proposed label for 200-mg and 300-mg phenytoin would be the same as that of the Dilantin label.[9] The FDA approved Mylan's ANDA petition for the 200-mg and 300-mg phenytoin. Therefore, all doses of Mylan's phenytoin were generic drugs based on Dilantin.

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[9] The only exceptions were changes allowed because the manufacturer of the generic product differed from that of the innovator and the listing of additional strengths.

Mylan has explained that at the time 300-mg was approved as a generic drug based on Dliantin, there was no other 300-mg phenytoin on the market. The FDA considers each strength of a drug to represent a different drug product. See 57 Fed. Reg. at 17,954. Therefore, 300-mg phenytoin is a different drug product than 100-mg, even though Mylan relied on Dilantin when it sought approval for the 300-mg phenytoin. According to Mylan, since there was no other 300-mg strength phenytoin on the market, the FDA designated Mylan's 300-mg phenytoin as the RLD. See id. at 17,958 (if there are multiple source drug products without a new drug application, the RLD generally will be the market leader as determined by the FDA). An RLD is defined as the listed drug identified by the FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application. 21 C.F.R. § 314.3(b). As an RLD, Mylan's 300-mg phenytoin would serve as the bioequivalent standard against which additional generic versions of 300-mg phenytion could be measured.

Regarding changing a drug label, the CBE process permits drug manufacturers to make changes to a drug label without having to wait for preapproval by the FDA. Mensing, 131 S. Ct. at 2575. As noted in Mensing,

the FDA has interpreted the CBE regulations to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand name label or to follow the FDA's instructions. 131 S. Ct. at 2575. Plaintiff asserts that the FDA's designation of Mylan's 300-mg phenytoin as an RLD gave Mylan the authority to use the CBE process to change its 300-mg phenytoin label. Under plaintiff's theory, Mylan would have had two avenues for changing the label on the generic100-mg phenytoin: (1) after Mylan changed the 300-mg label, Mylan would have been required to change the generic 100-mg phenytoin label to match the label of the 300-mg label because the generic 100-mg must match the RLD; or (2) because Mylan was an RLD holder of 300-mg phenytoin, Mylan had the same rights as a brand name drug manufacturer, and therefore, could have used the CBE process to change the 100-mg phenytoin label.

There are several problems with plaintiff's arguments. First, because the FDA considers each strength of a drug to represent a different drug product, 300-mg phenytoin is a different drug product than 100-mg. See 57 Fed. Reg. at 17,954. Thus, because 100-mg and 300-mg are two different

products, plaintiff has not shown any authority that would have required Mylan to change the label of 100-mg to conform to the 300-mg label.

Second, the RLD for 100-mg is Dilantin. The FDA designated 300-mg as the RLD for the 300-mg strength dosage of pheyntoin, not for 100-mg phenytoin. Thus, the RLD for 100-mg phenytoin – Dilantin – has not changed, and plaintiff has not shown otherwise. Accordingly, changing the 300-mg label would have not triggered a change in the 100-mg phenytoin label because the 100-mg phenytoin label must conform to Dilantin's label. Plaintiff has not shown that changing the 300-mg label would have changed the Dliantin label.

Third, plaintiff assumes without authority that because Mylan's 300-mg phenytoin was designated as the RLD, Mylan is "considered as having the same rights and obligations as a 'brand-name' manufacturer of phenytoin," including the right to use the CBE process to change labels. Pl.'s Resp. to Mylan's Mot. to Dismiss at 11. However, plaintiff has not shown how Mylan acquired all of the same rights as a brand name drug manufacturer simply by manufacturing one drug that was an RLD. Plaintiff has not shown that

Mylan's manufacture of one RLD converted Mylan into brand name drug manufacturer with the right to use the CBE process to change the label of any of its drugs or how listing 300-mg as an RLD converted the generic 300-mg phenytoin into a brand name drug.[10]

Accordingly, the Court finds that the FDA's designation of Mylan's 300-mg phenytoin as an RLD would not have permitted Mylan to use the CBE process to change the label of 100-mg phenytoin to conform to state law. Plaintiff has not shown any other federal statute or regulation that would have allowed Mylan to change the 100-mg phenytoin label. Thus, pursuant to federal drug regulations, Mylan, as the generic drug manufacturer of 100-mg phenytoin, was prevented from independently changing the 100-mg label to conform with state law. Because Mylan was prevented by federal law from

[10] To illustrate plaintiff's theory, the Court assumes, by way of example only, that Mylan did change the label of its 300-mg phenytoin through the CBE process. Pursuant to plaintiff's theory, Mylan was then either required or permitted to change the 100-mg phenytoin label to conform to the 300-mg label. Assume that Mylan did change the 100-mg phenytoin label to match the 300-mg phenytoin label. Under this example, now 100-mg phenytoin has a label that no longer matches Dilantin; instead 100-mg's label matches a different dosage and strength of phenytoin than Dilantin. Even plaintiff does not dispute that Dilantin is the brand name phenytoin drug on which Mylan's 100-mg phenytoin is based. However, under plaintiff's theory, Dilantin and 100-mg phenytoin would no longer have the same label. This result shows that plaintiff's theory is flawed, and plaintiff has not provided authority to show otherwise.

changing its label to conform with a state law duty, the Court finds that any failure to warn claim is preempted. See Mensing 131 S. Ct. at 2575-82.[11] Therefore, the Court dismisses plaintiff's claim that Mylan's phenytoin product was defective by and through its inadequate labeling and warnings.[12]

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[11] Plaintiff also argues that Mensing is silent as to the duty and ability of generic manufacturers to communicate existing warnings to the medical community, or to alert individuals to important safety related labeling changes made by the brand name labels. Plaintiff requests leave to amend her complaint to allege such a claim. Plaintiff's request is denied because plaintiff's proposed claim is preempted. See Mensing, 131 S. Ct. at 2576 (concluding that generic drug manufacturers were not permitted to issue additional warnings to prescribing physicians and other healthcare professionals because (1) additional warnings would have qualified as "labeling" and these new warnings would not have been consistent with the drug's approved labeling; and (2) new warnings from generic drug manufacturers would inaccurately imply a therapeutic difference between the brand name and generic drugs, which could be impermissibly misleading); see also 21 C.F.R. § 201.100(d)(1) (warnings distributed by or on behalf of the manufacturer, must be consistent with and not contrary to the drug's approved labeling); see 21 C.F.R. § 202.1(l)(2) (defining "labeling" broadly).

[12] As an additional ground for dismissal of plaintiff's manufacturing and design defect claims, Mylan argues inter alia that plaintiff has failed to plead a feasible alternative design. Plaintiff responds that if she is permitted to amend her complaint, she will allege a feasible alternative design. The Court will not address Mylan's additional dismissal arguments regarding design and manufacturing defects at this time because the parties' arguments appear to turn on a possible alternative design. Because plaintiff's current complaint fails to allege even a specific defect, arguments regarding an alternative design would be better addressed if, and when, plaintiff files an amended complaint.

E. Count Three - Fraud, against Pfizer

In Count Three, Fraud, against Pfizer, plaintiff alleges that defendants deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from the decedent and his prescribing physician in the advertising, marketing, distribution, and sale of defendants' phenytoin's products. Plaintiff maintains that defendants failed to ascertain the accuracy of the information regarding the safe use of defendants' phenytoin's products and failed to disclose that these products caused serious skin reactions.

Pfizer argues that plaintiff has failed to plead her fraud claim with particularity pursuant to Fed. R. Civ. P. 9(b) and that plaintiff has not provided which specific statements Pfizer allegedly made that Dilantin was safe or risk-free, or what specific information Pfizer withheld. Plaintiff argues in response that her fraud claim meets the particularity requirements of Fed. R. Civ. 9(b). Relying on Gainer v. Mylan Bertek Pharmaceuticals, Inc., Civil No. 09-690 (JNE/JSM), 2010 U.S. Dist. LEXIS 58966 (D. Minn. 2010), plaintiff argues that her fraud claim is almost identical to the plaintiff's fraud claim in Gainer, which the court found to be sufficient.

Therefore, plaintiff contends that this Court should also find that her fraud claim meet 9(b)'s standards.

Pursuant to Georgia law, a plaintiff asserting a fraud claim must establish the following elements: (1) a false representation made by the defendant; (2) scienter; (3) an intention to induce plaintiff to act or refrain from acting; (4) justifiable reliance by the plaintiff; and (5) damage to the plaintiff. Johnson v. GAPTV Motors, Inc., 292 Ga. App. 79, 82 (2008). Additionally, in order to survive a motion to dismiss in federal court, a plaintiff is required to plead fraud with particularity in accordance with Fed. R. Civ. P. 9(b).

Rule 9(b) is satisfied when the complaint sets forth the following elements:

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001). Thus, the particularity rule serves the important purpose of "alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral or fraudulent behavior." Id. (quotations omitted).

In the complaint, plaintiff provides a "non-exhaustive list" of what Pfizer knew or should have known regarding phenytoin, including that phenytoin causes SJS and TEN; phenytoin carries the highest risk of TEN; Depakote and Neurontin are safer SJS/TEN alternatives; for 16 years phenytoin has been reported in medical literature to be the most pharmacogenetically hazardous drug; etc. Compl. at ¶ 33. Plaintiff alleges that Pfizer "made misrepresentations of material facts to, and omitted and/or concealed material facts from Mr. Frazier and his prescribing physician in the advertising, marketing, distribution, and sale" of phenytoin regarding its safety and use. Id. at ¶ 58. Plaintiff then lists Pfizer's omissions, which include failing to disclose or intentionally concealing the results of tests showing the potential risk of serious skin reactions. Id. at ¶ 59. Plaintiff continues that Pfizer's representations that phenytoin was safe were false

and that Pfizer knew that their statements were false. Id. at ¶ 61. Plaintiff states that Mr. Frazier relied on Pfizer's misrepresentations and ingested Pfizer's phenytoin products. Id. at ¶ 63. Plaintiff maintains that Mr. Frazier and his prescribing physician's reliance on Pfizer's misrepresentations and omissions was justified because these "misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning" Pfizer's phenytoin's products. Id. at ¶ 64.

The Court finds that plaintiff has not pled her fraud claim with particularity sufficient to meet the standard of Rule 9(b). First, plaintiff has provided a list of facts that Pfizer allegedly concealed and omitted. See Compl. at ¶ 59. However, she has not explained specifically which of these facts, if any, were the omissions that misled plaintiff and how they misled plaintiff. Second, although this list contains omissions, plaintiff has not identified the misrepresentations or misstatements she alleges Pfizer made and upon which Mr. Frazier relied.

With regard to both omissions and misrepresentations, plaintiff has not explained the time, place, or context in which Pfizer made misrepresentations

or omissions or the person responsible for doing so. Importantly, plaintiff has not provided any facts about when and how Pfizer made misrepresentations or omissions to Mr. Frazier, including whether these misrepresentations or omissions were made to him through a label or brochure and at what times. Instead, plaintiff states vaguely that Pfizer materially misrepresented and concealed from Mr. Frazier and his physician through the "advertising, marketing, distribution and sale" of phenytoin. Compl. at ¶ 58. Plaintiff asserts that Mr. Frazier relied on Pfizer's misrepresentations and ingested Pfizer's phenytoin products, but plaintiff provides no facts about Mr. Frazier's reliance. This lack of factual information about Pfizer's misrepresentations and Mr. Frazier's reliance coupled with the lack of factual information about how and when Mr. Frazier obtained and ingested Pfizer's phenytion product, leads to a vague and conclusory complaint. Thus, the Court finds that because plaintiff's complaint does not set forth the time, location, substance, and method of communication for Pfizer's allegedly fraudulent statements or omissions, it does not satisfy Rule 9(b).[13] See Cooper v. Blue Cross & Blue

[13] The Court does not find plaintiff's reliance on Gainer to be persuasive. Plaintiff is correct that the complaint in Gainer alleged almost the same claim with regard to fraud against Mylan as does plaintiff's complaint in this case. 2010 U.S. Dist. LEXIS 58966, at *6. In denying Mylan's motion to dismiss, the Gainer court (continued...)

Shield of Fla., 19 F.3d 562, 567 (11th Cir. 1994) ("[P]leading must include facts as to time, place, and substance of the defendant's alleged fraud."); see also Henderson, 2011 U.S. Dist. LEXIS 104989, at *16-19.

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[13](...continued)
explained that the plaintiff alleged that Mylan knew or should have known of the connection between phenytoin and SJS and TEN and that plaintiff listed facts that Mylan should have known. 2010 U.S. Dist. LEXIS 58966, at *6. The Gainer court continued that the plaintiff maintained that despite this knowledge, Mylan represented that phenytoin was safe and effective and failed to disclose the connection between phenytoin and SJS and TEN. 2010 U.S. Dist. LEXIS 58966, at *6-7. The plaintiff then explained that due to these misrepresentations and omissions, the plaintiff's physician was deprived of the ability to fully assess the risks when making the decision to prescribe phenytoin that the plaintiff took in March 2003 and June 2004, and that she would not have taken the medication if she had been warned about it. Id. at *7. The Gainer court found that "[t]hese allegations sufficiently identify the who, what, where, when, and how of the alleged fraud and permit a meaningful response by Mylan." 2010 U.S. Dist. LEXIS 58966, at *7.

This Court respectfully disagrees. The Gainer court does not state where, when, or how Mylan made its representations or omissions. Additionally, the Gainer court required minimal factual information about the substance of Mylan's representations, and instead accepted merely that Mylan represented that phenytoin was safe and effective. 2010 U.S. Dist. LEXIS 58966, at *6. Gainer does not state where or in what context the plaintiff relied upon these misrepresentations or omissions. Thus, the complaint in Gainer fails to meet the requirements of this circuit that the complaint allege the time, place, and substance of defendant's fraud and the who, what, when, where, and how of the allegedly false statements. See Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1237 (11th Cir. 2008); Henderson, 2011 U.S. Dist. LEXIS 104989, at *19-20 (rejecting the analysis in Gainer).

F. Counts Four and Five - Negligence and Gross Negligence

Pursuant to Georgia law, to state a cause of action for negligence, a plaintiff must establish the following elements:

> (1) a legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm; (2) a breach of this standard; (3) a legally attributable causal connection between the conduct and the resulting injury; and (4) some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the legal duty.

Dixie Group, Inc. v. Shaw Indus. Group, 303 Ga. App. 459, 467 (2010).

In her claim for negligence, plaintiff alleges that Pfizer owed a duty to consumers, including Mr. Frazier, to use reasonable care in designing, testing, labeling, manufacturing, marketing, supplying, distributing, and selling defendants' phenytoin products. With regard to gross negligence, plaintiff alleges that defendants had a duty to exercise reasonable care in warning about, design, testing, manufacture, marketing, labeling, selling, and/or distributing defendants' phenytoin products. Plaintiff contends that defendants knew or recklessly disregarded the fact that their phenytoin products caused potentially lethal side effects and continued to market, design, manufacture, and sell the phenytoin products. Plaintiff maintains

that defendants' conduct was committed with knowing, conscious, and/or deliberate disregard for the rights and safety of consumers, including the decedent.

First, it appears that plaintiff intends to bring a claim for gross negligence against both Mylan and Pfizer because plaintiff has not specified that her claim is against only one defendant. However, plaintiff does not allege which defendant breached what duty to plaintiff. Moreover, with regard to plaintiff's claim for negligence against only Pfizer, although plaintiff provides a list of duties Pfizer allegedly breached, plaintiff has not specified how Pfizer breached a specific duty to plaintiff.

Second, for both negligence and gross negligence, it is unclear which of Mylan's or Pfizer's phenytoin products caused Mr. Frazier's injuries. As noted above, the complaint is void of any factual information regarding when Mr. Frazier's physicians prescribed him medications and what they prescribed. Without any factual information about when Mr. Frazier ingested phenytoin and when he suffered injuries from phenytoin, it is also unclear what specific injury Mr. Frazier suffered as a proximate result of

each defendants' negligence. In her negligence claim, plaintiff alleges that Mr. Frazier suffered from serious bodily injury "including, but not limited to," a list of possible injuries, including death. Compl. ¶ 75. In her gross negligence claim, plaintiff has not specified any injury but instead states that Mr. Frazier "suffered harm as previously alleged herein" and that Mr. Frazier was "sick, blistered and scarred." Id. at ¶ 85.

Third, it is unclear to the Court whether plaintiff intends to bring a negligent failure to warn claim and a negligent design claim against Pfizer in addition to, and separate from, her claims of strict liability for failure to warn and strict liability for a design or manufacturing defect. The Court's confusion is due to plaintiff generally alleging failure to warn claims throughout her entire complaint and alleging design and manufacturing defect claims in her negligence claims. To the extent plaintiff intended to bring a failure to warn claim against Mylan based on gross negligence, that claim is preempted. See Mensing 131 S. Ct. at 2575-82; see also discussion supra at D.2.[14]

[14] Plaintiff did not allege any negligence claims against Mylan. See Compl. at 19 ("Count IV Negligence (Against The Pfizer Defendants)"). If plaintiff intended (continued...)

Accordingly, the Court finds that plaintiff's formulaic recitations of a claim for negligence and gross negligence are insufficient because plaintiff's claims do not permit the Court to infer more than the mere possibility of misconduct. See Iqbal, 129 S. Ct. at 1949-50; Twombly, 550 U.S. at 570; Henderson, 2011 U.S. Dist. LEXIS 104989, at *23-25.

(...continued)
to bring a negligent failure to warn claim against Mylan, that claim would be preempted. See Mensing 131 S. Ct. at 2575-82.

Plaintiff argues in her Response Brief that she has other viable negligence claims against Mylan separate from any failure to warn claims. First, plaintiff has not pled any negligence claims against Mylan, only gross negligence claims. Second, the negligence claim that plaintiff asserts in her response against Mylan is for failing "to stop selling their dangerous drug phenytoin despite knowledge that their product was causing deadly allergic reactions." Pl.'s Resp. to Mylan's Mot. to Dismiss at 5. This claim is preempted because (1) plaintiff has not shown that there is a state law duty to compel generic drug manufacturers to stop production of a drug, when the manufacturer has authority to produce this drug under federal law, and (2) any such state law duty would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce. See Mensing, 131 S. Ct. at 2575-82 (in finding preemption, noting that "[w]here state and federal law directly conflict, state law must give way." (quotation omitted)); Gross v. Pfizer, Inc., 2011 U.S. Dist. LEXIS 134895, at *7-*10 (D. Md. Nov. 22, 2011) (finding that plaintiff's negligence claims based on the manufacturer's continued sale of a generic drug failed under Mensing). Therefore, even if plaintiff intended to bring a claim of negligence against Mylan for failing to stop selling phenytoin despite knowledge that the product was causing deadly allergic reactions, this claim is preempted.

G. Count Eleven - Punitive Damages

Plaintiff alleges in her compliant that defendants' conduct was intentional, willful, wanton, oppressive, malicious, and reckless. Additionally, plaintiff alleges that defendants acted only out of self interest and for personal gain. Defendants move to dismiss plaintiff's claim for punitive damages because plaintiff has listed the elements for punitive damages without actually stating any facts. Plaintiff argues in response that she has sufficiently pled her complaint, but that she requests leave to amend if the Court finds that her complaint is insufficient.

The Court agrees with defendants that plaintiff's conclusory pleading without stating any facts to support her claim fails to state a claim for punitive damages. See Henderson, 2011 U.S. Dist. LEXIS 104989, at *25-26.

H. Count Six, Joint and Several Liability; Count Nine, Pre-Death Injury and Pain and Suffering; and Count Ten, Wrongful Death

Pfizer has moved to dismiss plaintiff's complaint in its entirety. As to plaintiff's claims for Joint and Several Liability, Pre-Death Injury and Pain and Suffering, and Wrongful Death, Pfizer argues that the claims should be

dismissed because plaintiff has failed to associate these counts with a specific cause of action. The Court finds Pfizer's arguments to be without merit. Plaintiff may maintain a claim for joint and several liability against the Pfizer defendants because if plaintiff prevails on her failure to warn claim against the Pfizer defendants, then plaintiff's allegations in her complaint are sufficient to find the Pfizer defendants jointly and severally liable. Additionally, plaintiff may maintain separate claims for wrongful death and pain and suffering; the wrongful death claim is brought on behalf of plaintiff individually and the pain and suffering claim is brought on behalf of the estate. See Smith v. Memorial Med. Ctr., Inc., 208 Ga. App. 26, 27 (1993). Accordingly, the Court will deny Pfizer's motion to dismiss with regard to these claims.

I. Plaintiff's Request for Leave to Amend the Complaint

Throughout her responses to defendants' motions to dismiss, plaintiff has requested permission for leave to amend her complaint, if the Court finds that she has not pled her claims sufficiently. She notes that although she believes her complaint is sufficient, she filed this complaint originally in state court and was therefore not bound by federal rules or standards.

"Where a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice." Bank v. Pitt, 928 F.2d 1108, 1112 (11th Cir. 1991) (overruled in part by Wagner v. Daewoo Heavy Indus. Am. Corp., 314 F.3d 541, 542 (11th Cir. 2002) (en banc)). Accordingly, because plaintiff may be able to state a claim with a more carefully drafted complaint and plaintiff has requested leave to amend, the Court grants plaintiff's request. The amended complaint should address the concerns in this order.

In sum, the Court limits plaintiff's failure to warn claim against Pfizer to a failure to warn the decedent's prescribing physician. Plaintiff's claims for joint and several liability, pre-death injury and pain and suffering, and wrongful death are sufficiently pled and will proceed. The Court dismisses without prejudice plaintiff's claims for strict products liability based on a design or manufacturing defect against Pfizer and Mylan; for fraud and negligence against Pfizer; for gross negligence against Pfizer and Mylan; and for punitive damages against Pfizer and Mylan. The Court dismisses with

prejudice plaintiff's claims against Mylan that Mylan's phenytoin was defective by and through its inadequate labeling and warnings and any failure to warn claim against Mylan, including a claim for failure to warn based on gross negligence, because these claims are preempted.

Conclusion

For the foregoing reasons, the Court GRANTS Mylan's motion to dismiss [#11]; GRANTS IN PART AND DENIES IN PART Pfizer's motion to dismiss [#12]; GRANTS Pfizer's motion for joinder in Mylan's motion to dismiss [#13]; GRANTS Mylan's motion for leave to file excess pages [#18];[15] and DISMISSES WITH PREJUDICE plaintiff's claims against Mylan for failure to warn and DISMISSES WITHOUT PREJUDICE plaintiff's claims for strict products liability based on a design or manufacturing defect, fraud, negligence, gross negligence, and punitive damages. If plaintiff intends to file

[15] Extensions of page limits for briefs are not generally necessary or granted, and counsel should seek prior approval before filing the extended brief. However, because of the complex arguments raised by plaintiff in her response related to the FDA and the regulations of prescription drugs, the Court grants Mylan's request for leave to file excess pages and has considered Mylan's extended reply.

an amended complaint, she must do so within thirty (30) days from the date of entry of this order.

IT IS SO ORDERED, this 5th day of January, 2012.

Marvin H. Shoob, Senior Judge
United States District Court
Northern District of Georgia